

ANNEX

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

- (1) in Table 1 the following lines are inserted in numerical order of the FCM substance numbers:

| FCM substance No | Ref. No | CAS No | Substance name   | Use as additive or polymer production aid (yes/no) | Use as monomer or other starting substance or macro-molecule obtained from microbial fermentation (yes/no) | FRF applicable (yes/no) | SML (mg/kg) (yes/no) | SML (Group restriction) (mg/kg) (yes/no) | Restrictions and specifications  | Notes on compliance |
|------------------|---------|--------|--|--|--|-------------------------|----------------------|--|--|---------------------|
| (1)              | (2)     | (3)    | (4)  | (5)  | (6)  | (7)                     | (8)                  | (9)                                      | (10)   | (11)                |
| 855              | 40560   |        | (butadiene, styrene, methyl methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate  | yes  | no   | no                      |                      |  | Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below. |                     |
| 856              | 40563   |        | (butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene | yes  | no   | no                      |                      |  | Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level                                       |                     |

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|     |       |        |  |    |     |    |      |   |
|-----|-------|--------|--|----|-----|----|------|---|
|     |       |        | or<br>1,3-<br>butanediol<br>dimethacrylate   |    |     |    |      | of<br>12 %<br>at<br>room<br>temperature<br>or<br>below.   |
| 857 | 66765 | 003795 | vinyl<br>methacrylate,<br>butyl<br>acrylate,<br>styrene,<br>glycidyl<br>methacrylate)<br>copolymer | no | no  |    |      | Only<br>to be<br>used<br>in<br>rigid<br>poly(vinyl<br>chloride)<br>(PVC)<br>at a<br>maximum<br>level<br>of<br>2 %<br>at<br>room<br>temperature<br>or<br>below.  |
| 863 | 15260 | 000064 | 1,6-<br>decanediamine  | no | yes | no | 0,05 | Only<br>to be<br>used<br>as a<br>co-<br>monomer<br>for<br>manufacturing<br>polyamide<br>articles<br>for<br>repeated<br>use in<br>contact<br>with<br>aqueous,<br>acidic<br>and<br>dairy<br>foodstuffs<br>at<br>room<br>temperature<br>or for<br>short<br>term<br>contact |

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|     |       |        |  |     |    |    |      |  |   |
|-----|-------|--------|--|-----|----|----|------|--|---|
|     |       |        |  |     |    |    |      |  | up to 150 °C.   |
| 873 | 93460 |        | titanium dioxide reacted with octyltriethoxysilane   | yes | no | no |      |  | Reaction product of titanium dioxide with up to 2 % w/w surface treatment substance octyltriethoxysilane, processed at high temperatures. |
| 894 | 93360 | 001654 | 5-14-13 propionic acid, ditetradecyl ester   | no  | no |    | (14) |  |   |
| 895 | 47060 | 017109 | 0-93-0 (3,5-di-tert-butyl-4-hydroxyphenyl)propanoic acid, esters with C13-C15 branched and linear alcohols | yes | no | no | 0,05 |  | Only to be used in polyolefins in contact with foods other than fatty/high-alcoholic and dairy products.                                  |
| 896 | 71958 | 095844 | 3-14-8 perfluoro-3-[(3-methoxypropoxy)propanoic acid], ammonium salt                                       | yes | no | no |      |  | Only to be used in the polymerisation of fluoropolymers when:<br>— processed at temperatures  |

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|     |       |           |                                     |     |    |    |   |  |   |  |
|-----|-------|-----------|-------------------------------------|-----|----|----|---|--|---|--|
|     |       |           |                                     |     |    |    |   |  | — | higher than 280 °C for at least 10 minutes, processed at temperatures higher than 190 °C up to 30 % w/w for use in blends with polyoxymethylene polymers and intended for repeated use articles. |
| 923 | 39150 | 000012040 | N,N-bis(2-hydroxyethyl)dodecanamide | yes | no | no | 5 |  |   | (18) The residual amount of diethanolamine in plastics, as an impurity and decomposition product of the substance, should not result in a migration of   |

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|     |       |         |   |     |    |      |  |  |
|-----|-------|---------|---|-----|----|------|--|--|
|     |       |         |   |     |    |      |  | diethanolamine higher than 0,3 mg/kg food.   |
| 924 | 94987 |         | trimethylpropane, mixed triesters and diesters with n-octanoic and n-decanoic acids | no  | no | 0,05 |  | Only for use in PET in contact with all types of foods other than fatty, high-alcoholic and dairy products.                            |
| 926 | 71955 | 0908020 | perfluoro(2-ethoxyethoxy)acetic acid], ammonium salt                                | no  | no |      |  | Only to be used in the polymerisation of fluoropolymers that are processed at temperatures higher than 300 °C for at least 10 minutes. |
| 971 | 25885 | 0002459 | trimellitic anhydride   | yes | no |      |  | Only to be used as a co-monomer up to (17)   |

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|     |       |         |   |     |     |     |   |  |   |
|-----|-------|---------|---|-----|-----|-----|---|--|---|
|     |       |         |   |     |     |     |   |  | 0,35 %<br>w/<br>w to<br>produce<br>modified<br>polyesters<br>intended<br>to be<br>used<br>in<br>contact<br>with<br>aqueous<br>and<br>dry<br>foodstuffs<br>containing<br>no<br>free<br>fat at<br>the<br>surface. |
| 972 | 45197 | 0012158 | zinc<br>hydroxide<br>phosphate  | yes | no  | no  |   |  |   |
| 973 | 22931 | 0019430 | perfluorobutylacrylate  | no  | yes | no  |   |  | Only<br>to be<br>used<br>as a<br>co-<br>monomer<br>up to<br>0,1 %<br>w/w<br>in the<br>polymerisation<br>of<br>fluoropolymers,<br>sintered<br>at<br>high<br>temperatures.  |
| 974 | 74050 | 939402  | phosphoric<br>acid,<br>mixed<br>2,4-<br>bis(1,1-<br>dimethylpropyl)phenyl<br>and<br>4-<br>(1,1- | yes | no  | yes | 5 |  | SML<br>expressed<br>as the<br>sum<br>of<br>phosphite<br>and<br>phosphate<br>form  |

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|  |  |  |                                 |  |  |  |  |  |  |   |
|--|--|--|---------------------------------|--|--|--|--|--|--|---|
|  |  |  | dimethylpropyl)phenyl triesters |  |  |  |  |  |  | of the substance and the hydrolysis product 4-t-amyphenol. The migration of the hydrolysis product 2,4-di-t-amyphenol should not exceed 0,05 mg/kg. |
|--|--|--|---------------------------------|--|--|--|--|--|--|---|

(2) in Table 1 for the following substance, the content of the columns (2), (5), (6) and (10) is replaced by the following:

| FCM substance No | Ref. No | CAS No    | Substance name                         | Use as additive or polymer production aid (yes/no) | Use as monomer or starting substance or macro-molecule obtained from microbial fermentation (yes/no) | FRF applicable (no) | SML (mg/kg) (yes/no) | SML (mg/kg) (Group restriction No) | Restrictions and specificities  | Notes on certification of compliance |
|------------------|---------|-----------|--|--|--|---------------------|----------------------|------------------------------------|---|--------------------------------------|
| (1)              | (2)     | (3)       | (4)                                    | (5)  | (6)  | (7)                 | (8)                  | (9)                                | (10)  | (11)                                 |
| 438              | 13303   | 0002162-3 | bis(2,6-diisopropylphenyl)carbodiimide | no   | yes  | no                  | 0,05                 |                                    | Expressed as the sum of bis(2,6-diisopropylphenyl)carbodiimide and its hydrolysis product |                                      |

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|  |  |  |  |  |  |  |  |  |  |                        |
|--|--|--|--|--|--|--|--|--|--|------------------------|
|  |  |  |  |  |  |  |  |  |  | 2,6-diisopropylaniline |
|--|--|--|--|--|--|--|--|--|--|------------------------|

- (3) in Table 1 for the following substance, the content of the column (3) is replaced by the following:

| FCM substance No | Ref. No | CAS No | Substance name   | Use as additive or polymer production aid (yes/no) | Use as monomer or starting substance or macro-molecule obtained from microbial fermentation (yes/no) | FRF applicable (yes/no) | SML (mg/kg) (yes/no) | SML (mg/kg) (Group restriction No) | Restrictions and specificities | Notes on certification of compliance |
|------------------|---------|--------|--|--|--|-------------------------|----------------------|------------------------------------|--------------------------------|--------------------------------------|
| (1)              | (2)     | (3)    | (4)  | (5)  | (6)  | (7)                     | (8)                  | (9)                                | (10)                           | (11)                                 |
| 797              | 76807   | 007301 | polyesters of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol | no   | no   | yes                     |                      | (31)<br>(32)                       |                                |                                      |

- (4) in Table 1 for the following substances, the content of the column (8) is replaced by the following:

| FCM substance No | Ref. No | CAS No | Substance name | Use as additive or polymer production aid (yes/no) | Use as monomer or starting substance or macro-molecule obtained from microbial fermentation (yes/no) | FRF applicable (yes/no) | SML (mg/kg) (yes/no) | SML (mg/kg) (Group restriction No) | Restrictions and specificities | Notes on certification of compliance |
|------------------|---------|--------|----------------|--|--|-------------------------|----------------------|------------------------------------|--------------------------------|--------------------------------------|
|------------------|---------|--------|----------------|--|--|-------------------------|----------------------|------------------------------------|--------------------------------|--------------------------------------|



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| (1) | (2)   | (3)          | (4)                           | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|--------------|-------------------------------|-----|-----|-----|-----|-----|------|------|
| 239 | 19975 | 0000102-48-1 | 2,4,6-triamino-1,3,5-triazine | yes | yes | no  | 2,5 |     |      |      |
|     | 25420 |              |                               |     |     |     |     |     |      |      |
|     | 93720 |              |                               |     |     |     |     |     |      |      |
| 376 | 66905 | 0000872-50-4 | 2-methylpyrrolidone           | yes | no  | no  | 60  |     |      |      |

(5) in Table 1 for the following substance, the content of the columns (8) and (10) is replaced by the following:

| FCM substance No | Ref. No | CAS No       | Substance name  | Use as additive or polymer production aid (yes/no) | Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no) | FRF applicable (yes/no) | SML (mg/kg) (yes/no) | SML (Group restriction No) | Restrictions and specificities | Notes on compliance |
|------------------|---------|--------------|---|--|---|-------------------------|----------------------|----------------------------|--------------------------------|---------------------|
| (1)              | (2)     | (3)          | (4)   | (5)  | (6)   | (7)                     | (8)                  | (9)                        | (10)                           | (11)                |
| 452              | 38885   | 0002722-42-6 | bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine | yes  | no  | no                      | 5                    |                            |                                |                     |

(6) in Table 1 for the following substances, the content of the column (10) is replaced by the following:

| FCM substance No | Ref. No | CAS No | Substance name | Use as additive or polymer production aid (yes/no) | Use as monomer or other starting substance or macromolecule | FRF applicable (yes/no) | SML (mg/kg) (yes/no) | SML (Group restriction No) | Restrictions and specificities | Notes on compliance |
|------------------|---------|--------|----------------|--|---|-------------------------|----------------------|----------------------------|--------------------------------|---------------------|
|------------------|---------|--------|----------------|--|---|-------------------------|----------------------|----------------------------|--------------------------------|---------------------|

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| (1) | (2)   | (3)       | (4)  | (5) | obtained<br>from<br>microbial<br>fermentation<br>(yes/<br>no) | (7) | (8) | (9) | (10)  | (11) |
|-----|-------|-----------|--|-----|---|-----|-----|-----|---|------|
| 794 | 18117 | 000007914 | glycolic<br>acid   | no  | yes   | no  |     |     | Only<br>to be<br>used<br>for<br>manufacture<br>of<br>polyglycolic<br>acid<br>(PGA)<br>for (i)<br>indirect<br>food<br>contact<br>behind<br>polyesters<br>such<br>as<br>polyethylene<br>terephthalate<br>(PET)<br>or<br>polylactic<br>acid<br>(PLA);<br>and<br>(ii)<br>direct<br>food<br>contact<br>of a<br>blend<br>of<br>PGA<br>up to<br>3 %<br>w/<br>w in<br>PET<br>or<br>PLA. |      |
| 812 | 80350 | 012457812 | poly(12-<br>hydroxystearic<br>acid)-<br>polyethyleneimine<br>copolymer | yes | no  | no  |     |     | Only<br>to be<br>used<br>in<br>plastics<br>up to  |      |

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|  |  |  |  |  |  |  |  |  |  |   |
|--|--|--|--|--|--|--|--|--|--|---|
|  |  |  |  |  |  |  |  |  |  | 0,1 % w/w. Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine. |
|--|--|--|--|--|--|--|--|--|--|---|

(7) in Table 1 for the following substance, the content of the columns (10) and (11) is replaced by the following:

| FCM substance No | Ref. No | CAS No       | Substance name     | Use as additive or polymer production aid (yes/no) | Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no) | FRF applicable (yes/no) | SML (mg/kg) (yes/no) | SML (Group restriction No) | Restrictions and specificities   | Notes on certification of compliance |
|------------------|---------|--------------|--------------------|--|---|-------------------------|----------------------|----------------------------|--|--------------------------------------|
| (1)              | (2)     | (3)          | (4)                | (5)  | (6)   | (7)                     | (8)                  | (9)                        | (10)   | (11)                                 |
| 862              | 15180   | 0018083-02-4 | diacetoxy-1-butene | no   | yes   | no                      | 0,05                 |                            | SML (17) including the hydrolysis product 3,4-dihydroxy-1-butene. Only to be used as a co-monomer for ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers. | (17) (19)                            |

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- (8) in Table 2 for the following group restriction, the content of the columns (2) and (4) is replaced by the following:

| <b>Group restriction No</b> | <b>FCM substance No</b> | <b>SML (T)[mg/kg]</b> | <b>Group restriction specification</b>                              |
|-----------------------------|-------------------------|-----------------------|---|
| <b>(1)</b>                  | <b>(2)</b>              | <b>(3)</b>            | <b>(4)</b>  |
| 14                          | 294                     | 5                     | Expressed as the sum of the substances and their oxidation products |
|                             | 368                     |                       |   |
|                             | 894                     |                       |   |

- (9) in Table 3 the following notes on verification of compliance are inserted in numerical order:

| <b>Note No</b> | <b>Notes on verification of compliance</b>   |
|----------------|--|
| <b>(1)</b>     | <b>(2)</b>   |
| (18)           | There is a risk that the SML could be exceeded from low-density polyethylene (LDPE)  |
| (19)           | There is a risk that the OML could be exceeded in direct contact with aqueous foods from ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers |

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