

## Grouping of 46 substances

## Group 1

Substances under pre-consultation or analogs of substances  
under review at the committee

18 substances

## Polysorbates group

| Name          | Major purposes | JECFA evaluation (year) | JECFA ADI | USA              | EU      |
|---------------|----------------|-------------------------|-----------|------------------|---------|
| Polysorbate20 | Emulsifier     | O(1973)                 | 0-25mg/kg | O(21CFR172.515b) | O(E432) |
| Polysorbate60 | Emulsifier     | O(1973)                 | 0-25mg/kg | O(21CFR172.836c) | O(E435) |
| Polysorbate65 | Emulsifier     | O(1973)                 | 0-25mg/kg | O(21CFR172.838c) | O(E436) |
| Polysorbate80 | Emulsifier     | O(1973)                 | 0-25mg/kg | O(21CFR172.840c) | O(E433) |

## Stearates group

| Name             | Major purposes                  | JECFA evaluation (year) | JECFA ADI     | USA              | EU       |
|------------------|---------------------------------|-------------------------|---------------|------------------|----------|
| Calcium stearate | Anticaking agent,<br>emulsifier | O(1985)                 | Not Specified | O(21CFR172.863c) | O(E470a) |

## Magnesium Phosphate

| Name                  | Major purposes | JECFA evaluation (year) | JECFA ADI         | USA              | EU        |
|-----------------------|----------------|-------------------------|-------------------|------------------|-----------|
| Dimagnesium phosphate | Nutrient       | O(1982)                 | MTDI 70mg/kg(as P | O(21CFR184.1434) | O(E343ii) |

## Hydroxypropylcellulose

| Name                         | Major purposes                           | JECFA evaluation (year) | JECFA ADI     | USA             | EU      |
|------------------------------|------------------------------------------|-------------------------|---------------|-----------------|---------|
| HPC(Hydroxypropyl cellulose) | Tablet binder,<br>emulsifier, thickener, | O(1989)                 | Not Specified | O(21CFR172.870) | O(E463) |

## Modified starches\*

11 substances

| Name                             | Major purposes                            | JECFA evaluation (year) | JECFA ADI     | USA             | EU       |
|----------------------------------|-------------------------------------------|-------------------------|---------------|-----------------|----------|
| Acetylated distarch adipate      | Thickener, binder, stabilizer             | O(1982)                 | Not Specified | O(21CFR172.892) | O(E1422) |
| Acetylated distarch phosphate    | Emulsifier, thickener, binder             | O(1982)                 | Not Specified | O(21CFR172.892) | O(E1414) |
| Acetylated oxidized starch       | Emulsifier, thickener, binder, stabilizer | O(2001)                 | Not Specified | O(21CFR172.892) | O(E1451) |
| Starch sodium octenylsuccinate   | Stabilizer, thickener, binder             | O(1982)                 | Not Specified | O(21CFR172.892) | O(E1450) |
| Hydroxypropyl starch             | Emulsifier, thickener, binder             | O(1982)                 | Not Specified | O(21CFR172.892) | O(E1440) |
| Hydroxypropyl distarch phosphate | Emulsifier, thickener, binder             | O(1982)                 | Not Specified | O(21CFR172.892) | O(E1442) |
| Phosphated distarch phosphate    | Stabilizer, thickener, binder             | O(1982)                 | Not Specified | O(21CFR172.892) | O(E1413) |
| Monostarch phosphate             | Stabilizer, thickener, binder             | O(1982)                 | Not Specified | O(21CFR172.892) | O(E1410) |
| Distarch phosphate               | Emulsifier, thickener, binder             | O(1982)                 | Not Specified | O(21CFR172.892) | O(E1412) |
| Oxidized starch                  | Emulsifier, thickener, binder             | O(1982)                 | Not Specified | O(21CFR172.892) | O(E1404) |
| Starch acetate                   | Emulsifier, thickener, binder             | O(1982)                 | Not Specified | O(21CFR172.892) | O(E1420) |

\*These modified starches are categorized as food.

## Group 2

### Analogs of authorized additives

12 substances

#### Alginates group

3 substances

| Name               | Major purposes                                   | JECFA evaluation (year) | JECFA ADI     | USA              | EU      |
|--------------------|--------------------------------------------------|-------------------------|---------------|------------------|---------|
| Ammonium alginate  | Emulsifier, stabilizer, thickener, gelling agent | O(1992)                 | Not Specified | O(21CFR184.1133) | O(E403) |
| Potassium alginate | Emulsifier, stabilizer, thickener, gelling agent | O(1992)                 | Not Specified | O(21CFR184.1610) | O(E402) |
| Calcium alginate   | Emulsifier, stabilizer, thickener, gelling agent | O(1992)                 | Not Specified | O(21CFR184.1187) | O(E404) |

| Name                                | Major purposes                                                                | JECFA evaluation (year) | JECFA ADI     | USA                 | EU       |
|-------------------------------------|-------------------------------------------------------------------------------|-------------------------|---------------|---------------------|----------|
| β-carotene(from Blakeslea trispora) | Colour, nutrient                                                              | O(2001)                 | 0-5mg/kg      | O(21CFR73.95,184.1) | O(E160a) |
| Calcium ascorbate                   | Preservative                                                                  | O(1981)                 | Not Specified | O(21CFR182.3189)    | O(E302)  |
| Calcium saccharin                   | Sweetener                                                                     | O(1993)                 | 0-5mg/kg      | O21CFR(180.37)      | O(E954)  |
| Magnesium hydroxide                 | Acidity regulator                                                             | O(1965)                 | Not Limited   | O(21CFR184.1428(c)) | O(E528)  |
| Sodium Stearoyl-2-lactate           | Emulsifier, stabilizer                                                        | O(1973)                 | 0-20mg/kg     | O(21CFR172.849c9)   | O(E481)  |
| Potassium lactate                   | Flavor enhancer, acid, acidity regulator, preservative, antioxidant synergist | O(1974)                 | Not Limited   | O(21CFR184.1634)    | O(E326)  |
| PVP(Polyvinylpyrrolidone)           | Bodying agent, stabilizer, clarifying agent, tableting adjuvant,              | O(1986)                 | 0-50mg/kg     | O21CFR(173.55)      | O(E1201) |
| Calcium sorbate                     | Preservative                                                                  | O(1973)                 | 0-25mg/kg     | O(21CFR184.3640)    | O(E202)  |
| Monoammonium L-glutamate            | Flavour enhancer, salt substitute                                             | O(1987)                 | Not Specified | O(21CFR184.1847)    | O(E624)  |

### Group 3

Substances not listed in groups 1,2 and 4

14 substances

#### Silicates group

| Name                          | Major purposes   | JECFA evaluation(year) | JECFA ADI     | USA              | EU       |
|-------------------------------|------------------|------------------------|---------------|------------------|----------|
| Sodium alminum silicate       | Anticaking agent | O(1985)                | Not Specified | O(21CFR182.2727) | O(E554)  |
| Calcium sorbate               | Preservative     | O(1985)                | Not Specified | O21CFR(172.410)  | O(E553)  |
| Calcium aluminium             | Anticaking agent | O(1985)                | Not Specified | O(21CFR182.2122) | O(E556)  |
| Magnesium silicate(synthetic) | Anticaking agent | O(1982)                | Not Specified | O(21CFR184.1847) | O(E553a) |

| Name                               | Major purposes                              | JECFA evaluation(year) | JECFA ADI           | USA              | EU                |
|------------------------------------|---------------------------------------------|------------------------|---------------------|------------------|-------------------|
| β-apo-8'-carotenal                 | Colour                                      | O(1974)                | 0-5mg/kg            | O(21CFR73.90)    | O(E160e)          |
| Carmines                           | Colour                                      | O(1982)                | 0-5mg/kg            | O(21CFR73.100)   | O(E120)           |
| Canthaxanthin                      | Colour                                      | O(1995)                | 0-0.03mg/kg         | O21CFR(73.75)    | O(E161g)          |
| Sodium aluminium phosphate, acidic | Raising agent                               | O(1988)                | PTWI 7mg/kg (as Al) | O(21CFR182.1781) | O(E541)           |
| Nisin                              | Preservative                                | O(1968)                | 0-33000unit/kg      | O(GRN0064)       | O(E234)           |
| Calcium acetate                    | Preservative, stabilizer, acidity regulator | O(1973)                | Not Limited         | O(21CFR184.1185) | O(E263)           |
| Calcium oxide                      | Dough conditioner, alkali, yeast food       | O(1965)                | Not Limited         | O(21CRR184.1210) | O(E529)           |
| Potassium sulphate                 | Salt substitute                             | O(1985)                | Not Specified       | O(21CFR184.1643) | O(E515)           |
| Triethyl citrate                   | Carrier solvent, sequestrant                | O(1999)                | Acceptable          | O(21CFR184.1625) | O(E1505)          |
| Isopropanol                        | Extract solvent, carrier solvent            | O(1998)                | Acceptable          | O(21CFR172.515b) | O(processing aid) |

### Group 4

Substances for which an application was already made

2 substances

| Name          | Major purposes                    | JECFA evaluation(year) | JECFA ADI                | USA              | EU      |
|---------------|-----------------------------------|------------------------|--------------------------|------------------|---------|
| Nitrous oxide | Propellant, gaseous filling agent | O(1985)                | Acceptable as propellant | O(21CFR184.1545) | O(E942) |
| Natamycin     | Fungicidal preservative           | O(2001)                | 0-0.3mg/kg               | O(21CFR172.155c) | O(E235) |