

ANNEX

EU list of additives for approval in Japan

It should be noted that the scope of what is covered by the term “food additives” is much larger in Japan than in the EU. In the EU, food additives cover substances that have certain technological functions in the final food (e.g. antioxidants, preservatives). In Japan, food additives cover also flavourings, processing aids and nutrients. Furthermore, sometimes a substance classified as a food ingredient in the EU is considered as a food additive in Japan (e.g. maltodextrins).

In the EU, the list of authorised food additives is harmonised. Flavouring substances are to be harmonised within the next five years. Processing aids are not harmonised (except for extraction solvents) at EU level. Nutrients are not harmonised (except use of vitamins and minerals in food supplements) yet.

The following list of substances for authorisation by Japan has been developed on the basis of the information submitted by the Member States of the European Union, the Confederation of the Food and Drink Industries of the EU (CIAA) and the Federation of European Food Additives and Food Enzymes Industries (ELC) and classified according to their status in the Community. Some food additives of the list are already authorised in Japan but not for the same uses as in the EU.

All these food additives have been evaluated for safety by the EU’s Scientific Committee on Food. Furthermore, for approval in the EU, their use must not mislead the consumer, there must be a technological need for their use and the use must be restricted to the lowest amount necessary to achieve the technological effect (Annex II of Directive 89/107/EEC).

1. Food additives not currently authorised in Japan

Colours:

Carmine (E 120)

Beta-apo-8’ carotenal (E 160e)

Betacarotene from *Blakeslea trispora* (E 160 a(ii))

Azorubine (E 122)

Other additives:

Nisin (E 234)

Natamycin (E 235)

Dimagnesium phosphate (E 343(ii))

Potassium, ammonium and calcium alginate (E 402, E 403 and E 404)

Glycerol (E 422)

Polysorbate 20, 60, 65, 80 (E 432, 435, 436, 433)
Trisodium Diphosphate (E 450ii)
Hydroxypropyl cellulose (E 463)
Hydroxypropyl methyl cellulose (E 464)
Ammonium phosphatides (E 442)
Polyglycerol esters of fatty acids (E 475)
Polyglycerol polyricinolate (E 476)
Sodium steroyl-2-lactylate (E 481)
Calcium silicate (E 552)
Sodium aluminium phosphate, acidic (SALP) (E 541)

2. Food additives authorised in Japan but with conditions of use preventing importation from the EU

Conditions of use laid down in Directive 95/2/EC:

Calcium carbonate (E 170)
Sorbic acid (E 200)
Potassium sorbate (E 202)
Benzoic acid (E 210)
Calcium propionate (E 282)
Butylated hydroxytoluene (BHT)(E 321)
Lecithin (E 322)
Sodium, potassium and calcium lactate (E 325, 326, 327)
Citric acid (E 330)
Sodium citrates (E 331)
Pectin (E 440)
Carboxymethylcellulose (E 466)
Calcium stearyl-2-lactylate (E 482)
Sodium carbonate, bicarbonate (E 500 ii)
Potassium carbonate, bicarbonate (E 501 ii)
Calcium sulphate (E 516)
Magnesium oxide (E530)

Conditions of use laid down in Directive 94/35/EC:

Acesulfame K (E 950)

3. Substances considered as flavouring substances in the EU

These substances are authorised for use in foodstuffs at national level and have been listed by the Commission in a Register of about 2700 substances, adopted as Commission Decision [1999/217/EC](#) , last amended by Commission Decision [2002/113/EC](#).

Acetaldehyde

Propionaldehyde

2-Methyl butyl aldehyde

n-Butyl alcohol (1-butanol)

4. Processing aids

The following substance is authorised in the EU as an extraction solvent under Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

Isopropanol

EU guidelines for handling food additives, including the definition of food additive

- (1) Food additives are defined in Directive 89/107/EC, Article 1(2) as follows:
- ‘food additive’ means any substance not normally consumed as a food by itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result in it or its by-products becoming directly or indirectly a component of such foods. The definition is in line with the definition used by Codex Alimentarius, to which Japan has adhered.

- (2) Food additives have to fulfil certain criteria for purity laid down in three specific Directives (Commission Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs, Commission Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs, as amended by Directives 99/75/EC and 2001/50/EC; Commission Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners). These directives define the substances, how to identify them and set the levels of impurities they may contain (e.g. lead, arsenic).
- (3) There are no specific rules for handling food additives. Food additives are considered to be food, therefore, general rules on hygiene of foodstuffs apply. These are laid down in [Council Directive 93/43/EEC](#) on the hygiene of foodstuffs and are currently being revised (Proposal for a Regulation of the European Parliament and of the Council on the hygiene of foodstuffs (COM (2002) 438 final).

Information on the use of iodine in salt in the EU

In the EU, the addition of iodine to salt is considered as fortification with a nutrient. Food fortification falls under national competence. The White Paper on Food Safety announced a Commission proposal on fortified foods laying down provisions on marketing foods to which nutrients such as vitamins and minerals have been added. It is expected that the Commission will adopt a proposal in 2003. The availability and promotion of the use of iodised salt in the Member States depends on their national public health policies.