Executive Order on food additives

Pursuant to Section 15, subsections 2 and 3, Section 16 and Section 78, subsections 3, of the Danish Foodstuffs Act, Act No. 471 of 1 July 1998), as amended by Act No. 279 of 25 April 2001, the following shall be laid down:

Scope and definitions

Section 1. This Executive Order shall apply to:
1) additives to foodstuffs,
2) additives to additives,
3) colours for health markings and other obligatory labelling of meat,
4) colours for decoration or stamping of eggs and
5) extraction solvents.

Subsection 2. The Executive Order does not concern the use of flavourings in foodstuffs and flavourings, but cf. Appendix 1.

Section 2. For the purposes of this Executive Order, a food additive is any substance which, without itself being a food or a usual ingredient of compound foods, is intended to be added to foods in order to modify their nutritional value, their shelf-life, colour, flavour, taste or for technical or other purposes.

Subsection 2. Definitions of additive groups are given in Appendix 2.

Section 3. For the purposes of this Executive Order, 'flavouring' is flavouring substances, flavouring preparations, reaction flavourings, smoke flavouring, smoke flavouring substances or mixtures of these or with other additives or foodstuffs.

Section 4. For the purposes of this Executive Order, 'processing aids' is such substances that cannot be consumed as foodstuffs in their own right, but which are intentionally used in the preparation of ingredients, foodstuffs or their ingredients in order to accomplish a particular technological aim in the course of treatment of processing, this potentially resulting in the finished product's containing an unintended but unavoidable residue of this substance or derivatives thereof, on condition that such residues do not constitute a health risk and do not have any technological influence on the finished product.

Section 5. For the purposes of this Executive Order, 'unprepared foodstuffs' is foodstuffs that are not treated in such a way that significant alteration has been made to their original condition. Foodstuffs that are, for example, trimmed, shelled, deep-frozen, diced, skinned, ground, frozen, chopped, chilled, carved, peeled, cleaned, pared, cut, boned or filleted, whether packaged or unpackaged, are considered to be 'unprepared'.

Section 6. For the purposes of this Executive Order, an 'extraction solvent' is a solvent that is used in an extraction process during the preparation of ingredients, foodstuffs or components or ingredients in such products, and which is removed, but which may potentially result in the foodstuff's or foodstuff ingredient's containing an unintended but unavoidable residue of this substance or its intermediates in the foodstuff or foodstuff ingredient.

Subsection 2. 'Solvent' is any substance capable of dissolving foodstuffs or any component in a foodstuff, including any contaminant substance occurring within or on the foodstuff concerned.

Section 7. For the purposes of this Executive Order, 'quantum satis' ('QS') is that no maximum value is given for the use of an additive. The substance may be used in accordance with good preparation practice in a quantity not exceeding that which is necessary to accomplish the intended purpose, and such that the consumer is not misled.

Section 8. In connection with the use of sweeteners in this Executive Order, 1) 'low-energy' is an energy reduction of at least 30 % in relation to the original foodstuff or a similar product, and 2) 'without added sugar' is without the addition of monosaccharides or disaccharides or of other foodstuffs used by reason of their sweetening effects.

Section 9. For the purposes of this Executive Order, 'nitrite salt' is a mixture of potassium nitrite or sodium nitrite with sodium chloride with a content not exceeding 1.2 % nitrite calculated as sodium nitrite. A mixture of nitrite salt with potassium nitrate or sodium nitrate is also acceptable.

Subsection 2. Notwithstanding subsection 1, sodium chloride with added iodine, i.e. potassium iodate, potassium iodide and sodium iodide, cf. Positive List, may have nitrite salt added in the quantities stipulated by the Danish Veterinary and Food Administration.
Positive List

Section 10. The Danish Veterinary and Food Administration completes a list, the Positive List (Positivlisten), of additives that may be used in foodstuffs.

Subsection 2. The Positive List is not included in the Danish Legal Gazette (Lovtidende).

Subsection 3. The Danish Veterinary and Food Administration will publish notification in the Danish Official Gazette (Statsbladene) regarding the issuance of the Positive List, the date of its entry into force and details of where it may be purchased.

Section 11. The Positive List shall contain the following information:
1) Which additives may be used in particular foodstuffs or groups of foodstuffs.
2) Which additives may be used in flavourings.
3) Which additives may be used in other additives.
4) Which additives may be sold directly to consumers.
5) Specifications of the identity and purity of the individual substances.

Subsection 2. Subsection 1 does not include the additives specified in Section 21, subsection 1, Nos 1-3, or processing aids.

Subsection 3. The Danish Veterinary and Food Administration may rule that the additives specified in subsection 2 may (individually or all) be included in the Positive List.

Section 12. An additive is included in the Positive List giving the specific nomenclature that shall be used in labelling. However, the Danish Veterinary and Food Administration may rule that additives must be listed under a different nomenclature or, in special cases, that they are not included in the list.

Use of additives

Section 13. Only additives contained in the Positive List in sections A 1, A 2 and A 3 under the individual food groups may be used for those foodstuffs on the conditions given and with the stipulated purposes and limitations.

Subsection 2. Only additives contained in the Positive List in section B under carriers etc. may be used for additives. The Danish Veterinary and Food Administration may permit use of additives as carriers for foodstuffs.

Subsection 3. Additives contained in subsections 1 and 2 may only be used for the purposes given in Appendix 2. However, this does not apply to:
1) additives contained in Section 21, subsection 1, Nos 1-4, or
2) processing aids.

Subsection 4. The following additives, which are not covered by subsections 1 and 2, may nonetheless be used in foodstuffs:
1) processing aids not regulated in section A 3 in the Positive List,
2) bacteria cultures, mould and yeast fungi permitted under Section 21,
3) enzymes used as processing aids and permitted under Section 21,
4) additives permitted under Section 23.

Section 14. Only additives contained in section A 4 in the Positive List may be used in the preparation of flavourings.

Section 15. Only additives contained in section F in the Positive List may be sold directly to consumers.

Section 16. Only colours contained in Appendix 3 may be used for health marking and other obligatory labelling made directly on meat and products containing meat and for the decoration and stamping of eggs.

Section 17. Substances specified in section A 1 of the positive list may be used as processing aids.

Section 18. Additives are also permitted in:
1) foodstuffs solely intended for the preparation of compounds of foodstuffs, if the substances are permitted in the compound foodstuff,
2) compound foodstuffs, if the substances are permitted in one of the ingredients in the compound foodstuff. Sweeteners, however, are only permitted in such foodstuffs insofar as compound foodstuffs are low-energy or without added sugar, compound diet products and compound foodstuffs with long shelf-life, and
3) foodstuffs to which a flavouring has been added, and in which the additive has been transferred to the foodstuff via the flavouring, if the additive does not have a technological function in the finished product. If an additive is present in a foodstuff due to the use of a flavouring, and if the additive has a technological function in the foodstuff, it is regarded as an additive in the foodstuff and not as an additive in the flavouring.

Subsection 2. Subsection 1 is not applicable to infant formulae, supplement blends and follow-up food for infants and small children, as treated in Directive 89/398/EØF, unless otherwise stated.

Subsection 3. Subsection 1, No. 2, is not applicable to the compound foodstuffs contained in Appendix 4.

Section 19. Additives may only be used in accordance with good manufacturing practice.
Subsection 2. Additives shall comply with the requirements on identity and purity that are laid down in the specifications in section B in the Positive List.

Section 20. Maximum values in the notes column in section A 1 of the Positive List refer to the maximum quantity of the additive that may be present in a foodstuff in the form in which it is sold, unless otherwise stated.

Subsection 2. Maximum values for colours and sweeteners, however, refer to the maximum quantity of the additive that may be present in a foodstuff as prepared in accordance with any preparation instructions.

Subsection 3. Maximum values for colours further refer to the quantity of active colouring agent in the colouring.

Section 21. The following additives may be used six months after they have been submitted to the Danish Veterinary and Food Administration:
1) Bacteria cultures.
2) Mould and yeast fungi.
3) Enzymes.
4) Nutrients.

Subsection 2. Where data has already been supplied and subsequently evaluated and approved in another EU Member State, and where this evaluation has been submitted to the Danish Veterinary and Food Administration, however, the additives mentioned in subsection 1 may be used three months after they have been submitted to the Danish Veterinary and Food Administration, though cf. subsection 3.

Subsection 3. Where a sound need for doing so exists, the Danish Veterinary and Food Administration may extend the period specified in subsection 2 to six months.

Subsection 4. However, it is a precondition for use in accordance with subsections 1, 2 and 3 that the Danish Veterinary and Food Administration has not meanwhile issued a ban on the proposed use of the substance.

Subsection 5. A submitted substance may only be used in accordance with the information in the application.

Subsection 6. The Danish Veterinary and Food Administration may set conditions for the use of the substance, including limiting its use to a particular period of time.

Subsection 7. In case of a report in respect of subsection 1, the method shall be followed and documentation be submitted that are given in
1) Appendix 5, for bacteria cultures, mould and yeast fungi,
2) Appendix 6, for enzymes, and
3) the Positive List, for nutrients.

Section 22. Even if the Danish Veterinary and Food Administration in connection with the report has not issued a ban on an additive covered by Section 21, subsection 1, the Danish Veterinary and Food Administration may later issue a ban against its use should conditions so dictate.

Section 23. The Danish Veterinary and Food Administration may allow for an additive not listed in the Positive List to be used and sold in Denmark.

Subsection 2. In connection with such authorisation, the Danish Veterinary and Food Administration may set requirements on
1) use for particular foodstuffs or foodstuff groups,
2) particular purposes for use,
3) quantity limitations,
4) identity and purity and
5) special labelling.

Subsection 3. Authorisation under subsection 1 may be given for a maximum of two years for additives covered by EU regulations on additives.

Section 24. The Danish Veterinary and Food Administration may set rules or impose rulings on requirements for processing aids concerning
1) use for particular foodstuffs or food groups,
2) particular purposes for use,
3) permissible residue content in foodstuffs,
4) identity and purity and
5) application under Section 21.

Use of extraction solvents

Section 25. Only those substances specified in Appendix 1 may be used as extraction solvents in the preparation of foodstuffs and foodstuff ingredients.

Subsection 2. Notwithstanding subsection 1, water, any added acidity regulator and foodstuff or foodstuff ingredient may be used as extraction solvent.

Section 26. Extraction solvents shall not contain an amount of any element or substance dangerous to health.
Subsection 2. Extraction solvents shall not contain more than 1 mg/kg of arsenic or more than 1 mg/kg of lead, unless otherwise specified in the specific purity criteria.

Subsection 3. Extraction solvents shall otherwise satisfy any other purity criteria.

Administration and penalty provisions

Section 27. The regional veterinary and food administration centres may impose upon enterprises processing or selling foodstuffs the requirement that they prepare written documentation on the use of additives in the whole or part of the enterprise’s product range.

Subsection 2. For additives that may be added to foodstuffs according to the principle of quantum satis, the regional veterinary and food administration centres may impose upon enterprises in writing the requirement to document their need for the quantity of particular additives used.

Section 28. A fine is imposed on those who
1) do not comply with Sections 13-16, Sections 18-20 and Sections 25-26,
2) disregard agreements made in respect of this Executive Order or
3) neglect to observe injunctions or bans under this Executive Order.

Subsection 2. This fine may increase to imprisonment for up to two years if the violation has been deliberate or with gross negligence and if the violation has
1) caused damage to health or given rise to the risk of such damage or
2) brought or been intended to bring financial advantage to the perpetrator himself or to others, including through savings.

Subsection 3. Enterprises etc. (legal entities) are subject to criminal liability in accordance with Chapter 5 of the Danish Penal Code (Straffeloven).

Entry into force

Section 29. This Executive Order enters into force on 29 January 2005. At the same time, Executive Order No 282 of 19 April 2000 on foodstuff additives is repealed.

Subsection 2. Products put on the market or labelled prior to 3 November 2000 and fulfilling the requirements of Executive Order No. 942 of 11 December 1997 on foodstuffs and Executive Order No 817 of 23 November 1998 on extraction solvents for the production of foodstuffs or foodstuff ingredients, may be sold until stocks are used up.

Subsection 3. Products put on the market or labelled prior to 1 November 2004 and not fulfilling the requirements of Commission Directive 2003/95/EC of 27 October 2003 amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners may be sold until stocks are used up.

Subsection 4. Products put on the market or labelled prior to 1 April 2005 and not fulfilling the requirements of Commission Directive 2004/45/EC of 16 April 2004 amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners may be sold until stocks are used up.

Subsection 5. Products put on the market or labelled prior to 27 January 2006 and not fulfilling the Directive of the European Parliament and Council 2003/114/EC of 22 December 2003 amending Directive 95/2/EC laying down specific purity criteria on food additives other than colours and sweeteners may be marketed until stocks are used up.


Danish Veterinary and Food Administration, 11 January 2005

Anders Munk Jensen

/Malene Piepgrass
Appendix 1

Extraction solvents which may be used during the processing of raw materials ingredients, of foodstuffs, of food components or of food ingredients

Part I
All-purpose extraction solvents used in compliance with good manufacturing practice\(^1\)

<table>
<thead>
<tr>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetone(^2)</td>
</tr>
<tr>
<td>Butane</td>
</tr>
<tr>
<td>Carbon dioxide</td>
</tr>
<tr>
<td>Dinitrogen oxide</td>
</tr>
<tr>
<td>Ethanol</td>
</tr>
<tr>
<td>Ethyl acetate</td>
</tr>
<tr>
<td>Propane</td>
</tr>
</tbody>
</table>

1) An extraction solvent is considered as being used in compliance with good manufacturing practice if its use results only in the presence of residues or derivatives in technically unavoidable quantities presenting no danger to human health.
2) The use of Acetone in the refining of olive-pomace oil is forbidden.
### Part II
Extraction solvents for which conditions of use are specified

<table>
<thead>
<tr>
<th>Name</th>
<th>Conditions of use (summary description of extraction)</th>
<th>Maximum residue limits in the extracted foodstuff or food ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dichloromethane</td>
<td>Decaffeination of, or removal of irritants and bitters from coffee and tea&lt;br&gt;Production or fractionation of fats and oils and production of cocoa butter</td>
<td>2 mg/kg in the roasted coffee and 5 mg/kg in the tea&lt;br&gt;1 mg/kg in the fat or oil or cocoa butter</td>
</tr>
<tr>
<td>Hexane(^1)</td>
<td>Preparation of defatted protein products and defatted flours</td>
<td>10 mg/kg in the food containing the defatted protein products and the defatted flours&lt;br&gt;30 mg/kg in the defatted soya products as sold to the final consumer&lt;br&gt;5 mg/kg in the defatted cereal germ&lt;br&gt;10 mg/kg&lt;br&gt;20 mg/kg in the coffee or tea&lt;br&gt;1 mg/kg in the sugar&lt;br&gt;5 mg/kg in the fat or oil&lt;br&gt;20 mg/kg in the coffee and tea</td>
</tr>
<tr>
<td>Methanol</td>
<td>Preparatoin of defatted cereal germs&lt;br&gt;Not specified</td>
<td>10 mg/kg</td>
</tr>
<tr>
<td>Methyl acetate</td>
<td>Decaffeination of, or removal of irritants and bitters from coffee and tea&lt;br&gt;Production of sugar from molasses</td>
<td>10 mg/kg</td>
</tr>
<tr>
<td>Ethylmethylketone(^2)</td>
<td>Fractioning of fats and oils&lt;br&gt;Decaffeination of, or removal of irritants and bitters from coffee and tea</td>
<td>10 mg/kg</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>Not specified</td>
<td>10 mg/kg</td>
</tr>
</tbody>
</table>

\(^1\) Hexane means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. The combined use of Hexane and Ethylmethylketone is forbidden.

\(^2\) The level of n-Hexane in this solvent should not exceed 50 mg/kg. The combined use of Hexane and Ethylmethylketone is forbidden.
### Part III

Extraction solvents for which conditions of use are specified

<table>
<thead>
<tr>
<th>Name</th>
<th>Maximum residue limits in the foodstuff due to the use of extraction solvents in the preparation of flavourings from natural flavouring materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butan-1-ol</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Butan-2-ol</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Cyclohexane</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Dichloromethane</td>
<td>0.02 mg/kg</td>
</tr>
<tr>
<td>Diethyl ether</td>
<td>2 mg/kg</td>
</tr>
<tr>
<td>Hexane (^1)</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Methyl acetate</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Ethylmethylketone (^1)</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Propan-1-ol</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>1, 1, 1, 2-tetrafluorethane</td>
<td>0.02 mg/kg</td>
</tr>
</tbody>
</table>

\(^1\) The combined use of these two extraction solvents is forbidden.
Appendix 2

Definitions of food additive groups

Anti-caking agents: Substances which reduce the tendency of individual particles of a foodstuff to adhere to one another.

Antioxidants: Substances which prolong the shelf-life of foods by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes.

Carriers (including solvents used as carriers): Substances used to dissolve, dilute, disperse or otherwise physically modify a food additive without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use.

Propellants: Gases other than air which expel a foodstuff from a container.

Packaging gases: Gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container.

Emulsifiers: Substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff.

Colours: Substances which add or restore colour in a food, and include natural constituents of foods and natural sources which are normally not consumed as foods as such and not normally used as characteristic ingredients of food. Preparations obtained from foods and other edible natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours within the meaning of this Regulation.

Thickeners: Substances which increase the viscosity of a foodstuff.

Humectants: Substances which prevent foods from drying out by counteracting the effect of an atmosphere having a low degree of humidity, or promote the dissolution of a powder in an aqueous medium.

Bulking agents: Substances which contribute to the volume of a foodstuff without contributing significantly to its available energy value.

Gelling agents: Substances which give a foodstuff texture through formation of a gel.

Raising agents: Substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter.

Sequestrants: Substances which form chemical complexes with metallic ions.

Preservatives: Substances which prolong the shelf-life of foods by protecting them against deterioration caused by micro-organisms.

Firming agents: Substances which make or keep tissues of fruit or vegetables firm or crisp, or interact with gelling agents to produce or strengthen a gel.

Flour treatment agents: Substances, other than emulsifiers, which are added to flour or dough to improve its baking quality.
Modified starches: Substances obtained by one or more chemical treatments of edible starches, which may have undergone a physical or enzymatic treatment, and may be acid or alkali thinned or bleached.

Glazing agents (including lubricants): Substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating.

Foaming agents: Substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff.

Anti-foaming agents: Substances which prevent or reduce foaming.

Flavour enhancers: Substances which enhance the existing taste and/or odour of a foodstuff.

Emulsifying salts: Substances which convert proteins contained in cheese into a dispersed form and thereby bring about homogenous distribution of fat and other components.

Stabilisers: Substances which make it possible to maintain the physico-chemical state of a foodstuff; stabilisers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff, substances which stabilise, retain or intensify an existing colour of a foodstuff and substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into re-constituted food.

Acidity regulators: Substances which alter or control the acidity or alkalinity of a foodstuff.

Acids: Substances which increase the acidity of a foodstuff and/or impart a sour taste to it.

Sweeteners: Substances used to impart a sweet taste to foods or in table-top sweeteners.
Appendix 3

Colours for health markings and other obligatory labelling of meat and meat products

Allura Red AC ................................................................. E 129
Brilliant Blue FCF ; .......................................................... E 133
Brown HT .......................................................... E 155

Colours for decoration or stamping of eggs

Curcumin ; ................................................................. E 100
Riboflavins ; ................................................................. E 101
Tartrazine ; ................................................................. E 102
Quinoline yellow ; .......................................................... E 104
Sunset Yellow FCF .......................................................... E 110
Carmines ; ................................................................. E 120
Azorubine ; ................................................................. E 122
Amaranth ; ................................................................. E 123
Ponceau 4R ; ................................................................. E 124
Erythrosine ; ............................................................... E 127
Red 2G ; ................................................................. E 128
Allura Red AC ; .......................................................... E 129
Patent Blue V ; ............................................................. E 131
Indigotine ; ................................................................. E 132
Brilliant Blue FCF ; .......................................................... E 133
Chlorophylls and chlorophyllins ........................................ E 140
Copper complexes of chlorophyll and chlorophyllins .......... E 141
Green S ; ................................................................. E 142
Caramels ; ................................................................. E 150a-d
Black PN ; ................................................................. E 151
Vegetable carbon ; .......................................................... E 153
Brown FK ; ................................................................. E 154
Brown HT ; ................................................................. E 155
Carotenoids ; .............................................................. E 160a
Annatto extracts ; .......................................................... E 160b
Paprika extract ; ............................................................. E 160c
Lycopene ; ................................................................. E 160d
Beta-apo-8'-carotenal (C 30) .................................................. E 160e
Ethyl ester of beta-apo-8'-carotenoid acid (C30) ................. E 160f
Lutein ; ................................................................. E 161b
Canthaxanthin ; ............................................................ E 161g
Beetroot red ; ............................................................... E 162
Anthocyanins ; ............................................................. E 163
Calcium carbonate ; ....................................................... E 170
Titanium dioxide ; .......................................................... E 171
Iron oxides and hydroxides .............................................. E 172
Aluminium ; ................................................................. E 173
Silver ; ................................................................. E 174
Gold ; ................................................................. E 175
Litholrubine BK ; .......................................................... E 180
Appendix 4

Foodstuffs not covered by Section 18, subsection 1, No 2

1. For the purposes of transfer of colours

(The designations do not prejudice the 'carry over' principle in cases where products contain ingredients with legitimate colouring in their own right.)

1. Unprocessed foodstuffs
2. All bottled or packed water
3. Milk, semi-skimmed and skimmed milk, pasteurized or sterilized (including UHT sterilization) (unflavoured)
4. Chocolate milk
5. Fermented milk (unflavoured)
6. Preserved milk as mentioned in Directive 2001/114/EC
7. Buttermilk (unflavoured)
8. Cream and cream powder (unflavoured)
9. Oils and fats of animal or vegetable origin
10. Eggs and egg products as defined in Directive 89/437/EEC article 2, subsection 1
11. Flour and other milled products and starches
12. Bread and similar products
13. Pasta and gnocchi
14. Sugar, including monosaccharides and disaccharides
15. Tomato paste and canned and bottled tomatoes
16. Tomato-based sauces
17. Fruit juice and fruit nectar as mentioned in Directive 2001/112/EC, and vegetable juice
18. Fruit, vegetables (including potatoes) and mushrooms – canned, bottled or dried; processed fruits, vegetables (including potatoes) and mushrooms
19. Extra jam, extra jelly, and chestnut purée as mentioned in Directive 2001/113/EC; Crème de pruneaux
20. Fish, molluscs and crustaceans, meat, poultry and game as well as their preparations, but not including prepared meals containing these ingredients and colours in respect of Section 16.
21. Cocoa products and chocolate components in chocolate products as mentioned in Directive 2000/36/EC
22. Roasted coffee, tea, chicory; tea and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products
23. Salt, salt substitutes, spices and mixtures of spices
24. Wine and other products as defined by Regulation (EEC) No 1493/1999
25. Korn, Kornbrand, fruit spirit drinks, fruit spirits, Ouzo, Grappa, Tsikoudia from Crete, Tsipouro from Macedonia, Tsipouro from Thessaly, Tsipouro from Tynnavos, Eau de vie de marc Marque nationale luxembourgeoise, Eau de vie
26. Sambuca, Maraschino and Mistra as defined in Regulation (EEC) No 1180/91
27. Sangria, Clarea and Zurra as mentioned in Regulation (EEC) No 1601/91
28. Wine vinegar
29. Honey
30. Malt and malt products
31. Ripened and unripened cheese (unflavoured)
32. Butter from sheep and goats’ milk

2. For the purposes of transfer of additives other than colours and sweeteners

1. Unprocessed foodstuffs
2. Honey as defined in Directive 2001/110/EC
3. Non-emulsified oils and fats of animal or vegetable origin
4. Butter
5. Pasteurised and sterilised (including UHT sterilised) milk (skimmed, plain and semi-skimmed) and cream
6. Unflavoured, live fermented milk products
7. Natural mineral water as defined in Directive 80/777/EEC, and spring water
8. Coffee (excluding flavoured instant coffee) and coffee extracts
9. Unflavoured leaf tea
10. Sugars as defined in Directive 2001/111/EC
12. Naturally unflavoured buttermilk (excluding sterilised buttermilk)
13. Cocoa and chocolate products as defined in Directive 2000/36/EC
14. Fruit juice, fruit nectar, grape juice and pineapple juice as defined in Directive 2001/112/EC
15. Extra jam and fruit jelly as defined in Directive 2001/113/EC and other similar fruit spreads, including low-calorie products
16. Wholly or partly dehydrated preserved milk as defined in Directive 2001/114/EC
17. Sterilised, pasteurised and UHT cream, low-calorie cream and pasteurised low-fat cream
18. Frozen and deep-frozen unprocessed fruit and vegetables
19. Fruit compote
20. Unprocessed fish, crustaceans and molluscs, including frozen and deep-frozen
21. Easy-cook rice
22. Non-emulsified oils and fats of animal or vegetable origin (excluding virgin and olive oil)
23. Refined olive oil, including oil from pressed olive residues
24. Ripened cheese
25. Mozzarella and whey cheese
26. Canned and bottled fruit and vegetables
27. Gehakt
28. Packaged preparations of fresh minced meat
29. Bread solely made of the ingredients wheat flour, water, yeast or sourdough and salt
30. Pain courant français
31. Fresh pasta
32. Wine and sparkling wine and partly-fermented grape must
33. Beer
34. Foie gras, foie gras entier and blocs de fois gras
Appendix 5

Information to be submitted in connection with evaluation of a bacteria culture and mould or yeast

Administrative information

Name of applicant, producer(s) and the person responsible for the application.

Technical data

1 Name of the culture (trading name).

2 Application. Information shall be given on:

2.1 The technological function of the culture. The purpose of the composition of the culture shall be explained. If the purpose is bioconservation, the action of the culture and its active principle in bioconservation shall be explained.

2.2 Argument for the need for the culture. According to the Executive Order, the actual application of the culture shall be reported – not its importation or sale. For instance, an importer wishing to sell on cultures shall therefore be able to document a business interest in the Danish foodstuffs market for each individual culture.

2.3 The foodstuffs for which the culture is to be used.

2.4 Form of storage for the culture, including specification of any carriers/processing aids.

General requirements

3 Instructions for the foodstuffs producer on the technological use of the culture should be available.

4 Any other information, including countries in which the culture concerned is authorised.

5 Reported cultures may only be used in accordance with the information in the application, and only in accordance with good manufacturing practice for foodstuffs.

6 The Danish Veterinary and Food Administration approves the individual pure cultures with associated area of application. New applications must be submitted in case of changes to the information given in the application, including

– use in other foodstuff group(s), and
– use of other pure culture (change of brand).
No new application need to be submitted for new mixed cultures, if the enterprise has already had the individual constituent pure cultures in the mix approved and if the area of application is the same.

7 The requirement for application also applies to cultures which have been killed during production of a foodstuff, e.g. during heat treatment, such that the culture is no longer present as a living organism in the foodstuff.

Documentation for culture

8 Information must be given on:

8.1 Characterisation of the culture, i.e. indication of a number of criteria permitting characterisation of each individual microbiological strain with reference to the literature according to which characterisation has been done. Possible reference to standard cultures in recognised type culture collections.

8.2 The purity of the culture in the form of test results of the presence of other germs.

8.3 On request, documentation must be given to show if the culture is capable of forming toxic or antibiotic connections.

8.4 Information on microbiological/toxicological studies enabling evaluation of whether the culture in question safely can be used as proposed.

8.5 All results under 8.1-8.4 shall be reported for each culture as signed certificates of analysis.
Appendix 6

Information to be submitted in connection with evaluation of an enzyme

Administrative information

Name of applicant, producer(s) and the person responsible for the application.

Technical data

1 Active components

1.1 The essential activities of the enzyme shall be described using their systematic names and their Enzyme Commission numbers 1)

1.2 Activity of the enzyme products should be measured in relation to the reaction catalysed by the individual enzymes, and should normally be expressed in activity units per weight or volume unit of the product. In trading, the activity of a product is sometimes also given as the quantity of enzyme product that must be added to a given quantity of foodstuff in order to achieve the desired effect.

1.3 A list of secondary enzymatic activities, whether they constitute a useful function or not.

2 Basic materials

If there is a possibility that specific basic materials may contain substances that can be harmful to health, absence of such substances from the enzyme product shall be documented (see point 8.5).

2.1 Animal basic products. Species and part of animal used for production shall be given. Animal tissue used for enzyme production shall comply with the requirements of meat control and be treated in accordance with good hygiene practice.

2.2 Vegetable basic materials. Species of plant and part of plant used for production shall be given.

2.3 Microbial source organisms used in the production of enzyme products may be original strains or variants of micro-organisms or may be derived from original strains or variants using selective propagation or genetic modification. These shall be independent, stable strains or variants sufficiently well-described in relation to generally accepted identification criteria, such that they are described without ambiguity as the source organisms for the particular enzyme products described in the specifications. The microbial culture used in production shall be stored under conditions that ensure the absence of phenotypic drift, and when it is made ready for use in
the production of enzyme products, the methods used and propagation conditions provided shall ensure uniformity and reproducibility from batch to batch. These procedures shall ensure that the source organism does not produce toxins, and shall prevent the development of alien micro-organisms that may be sources of toxic materials and other undesired substances in the final enzyme products.

2.4 Genetically modified organisms. Specifications shall include characteristics of host organism, vector (sc. plasmid) and DNA sequence introduced into the vector or chromosome. The donor organism shall also be identified, whether it is a plant, animal or micro-organism. It is important for detailed information to be provided on the implicit genetic structures, in order for every conceivable undesired interaction between the original genetic material of the host organism and the new genetic material that must be incorporated to be foreseen. Data regarding the structure of the genetic material, e.g. information on the presence of extra DNA (plasmids or alien DNA introduced into the host chromosome), specific genetic characteristics ('markers'), presence of recessive genes (which may be expressed in mutations), genetic stability (mutation rates, intermolecular and intramolecular recombinations, restriction barriers), gene transfer (mobilisation/conjugation capacity), and resistance (antibiotics, heavy metals) may help predict health risks for humans, animals and plants, and ecological impacts. Exact information on the identity and biology of the vectors forms the basis of the evaluation on whether incorporation of the vector would increase or reduce the risk posed by the host micro-organism. Vectors should be described on a DNA level (size, restriction maps and, if possible, full DNA sequence) as well as genetically in respect of the genes occurring in the vector and which it would be possible to use as marker genes. Vectors shall be free of harmful sequences, and shall be non-conjugative and non-mobilisable. The DNA sequence(s) to be incorporated in the host organism shall be fully described both on a molecular level and in respect of the number of incorporated genes, regulation method (promoter-activity) and actual gene products. Whether the DNA sequence is of microbial, vegetable or animal origin, the precise origin and species characteristics of the genetic construction shall be used in order for a correct health evaluation to be made. Each individual recombinant product must be evaluated on a case by case basis in the light of host, vector and introduced genetic material, consideration being given to the possibility that potential risk in the final construction may be greater than the mere sum of the individual elements.

3 Production method
3.1 Satisfactory information on production method. For microbial source organisms, information on culture medium and conditions are regarded as essential. All components used shall be of food quality.

3.2 Satisfactory information shall be given on the cleaning method. If there are changes to the production method or to the cleaning of the enzyme product, this will be regarded as new, unless it is confirmed that the final product can be regarded as identical to that produced using the old methods.

4 Carriers and other additives and ingredients

4.1 Information shall be given on carriers, solvents, aids and other additives and ingredients (including processing aids) used in production, distribution and use of the enzyme products. Substances shall be used that are acceptable in relation to the relevant foodstuff use of the enzyme products concerned, otherwise substances shall be used that are insoluble in foodstuffs and are removed from the foodstuff after processing or prior to ingestion.

4.2 For immobilised enzyme products, carriers and immobilisation agents used shall be acceptable in respect of the relevant applications. When considering new materials, these must be tested to show that they do not produce harmful residual materials in the foodstuff. Tests should be done to show that all releases of immobilisation agents or enzymes are kept within the acceptable limits described in the individual specifications.

4.3 In order to be able to distinguish the part of the enzyme product that comes from the source material from the part that is made up of solvents and other additives and ingredients, it may be required that total organic solids (T.O.S) be stated. T.O.S. is defined as follows:

\[
\% \text{T.O.S.} = 100 - (A + W + D)
\]

where A = % ash, W = % water and D = solvents and/or other additives and ingredients.

T.O.S. can also be expressed in relation to the pure active ingredient (i.e. enzyme content). Depending on the product in question, the ratio can be very close to 1.

5 Application

Information should be given on:

5.1 Technological function of the enzyme.

5.2 Types of foodstuffs for use in which enzyme is intended.

5.3 Maximum quantity of enzyme product to be used in individual foodstuffs.
6 Stability and behaviour in foodstuffs

Information on:

6.1 Quantity of enzyme product (i.e. active enzyme and other components) in the finished foodstuff.

6.2 Primary reaction products and possible secondary reaction products not regarded as normal food components which are formed during production and storage of enzyme-treated foodstuffs.

6.3 Possible effect on nutrient substances.

General requirements and specifications

7 Hygiene

7.1 Enzyme products shall be produced in accordance with good manufacturing practice for foodstuffs. The strains of micro-organisms used as source materials for enzyme products should be tested regularly to ensure their purity (see point 2.3).

7.2 Adding an enzyme product to a foodstuff must not result in an increase in the total plate count for the foodstuff.

8 Contamination

8.1 Heavy metals

Products should not contain toxicologically significant quantities of heavy metals such as lead, cadmium, arsenic or mercury. Actual heavy metal quantities should be given for each product.

8.2 Microbiological contamination

Using suitable methods, it must not be possible to demonstrate the presence of pathogenic micro-organisms (e.g. Campylobacter, Clostridium perfringens, Escherichia coli, Listeria, Salmonella, Shigella) \( \text{?1} \). Coliform must not exceed \( \text{30/g, determined by a suitable method \( \text{?1} \).} \)

Total plate count must not exceed \( \text{10}^2 - \text{10}^6/g, \text{determined by a suitable method \( \text{?1} \).} \)

8.3 It shall be proved by testing that no viable cells from the microbial source organism occur in the final product.

8.4 Using a suitable method, it may not be possible to show antibiotic activity in the enzyme products \( \text{?1} \).
8.5 Enzyme products may not contain toxins in demonstrable quantities. Where it is known that a given source material is capable of producing toxins, absence of the toxins concerned shall be proved using a suitable method.

Documentation of safety in use

9 Basic toxicological requirements

9.1 No toxicological tests are ordinarily required for enzymes obtained from edible parts of animals or plants. If parts that are not generally regarded as common food material are used, requirements for some toxicological testing may be imposed, unless other satisfactory documentation is submitted showing that the product is safe to use.

9.2 For enzyme products made using micro-organisms, the following tests are ordinarily required:
   a) 90-day oral toxicity test in a rodent.
   b) 2 short-term tests
      – one test for genetic mutations in bacteria, and
      – one test for chromosomal deviations (preferably in vitro).

The toxicological testing shall, where possible, be on a batch of the final, cleaned culture product prior to addition of carriers, solvents etc. They should as a rule be done in accordance with set guidelines (EU/OECD), although it may be necessary to make certain changes to standard testing protocols, especially in connection with in vitro tests due to the impact of the protein-like character and/or enzymatic activity of some enzyme products on the cellular level. Such deviations can be accepted if accompanied by a satisfactory argument in support thereof.

The testing system is organised with the aim of disclosing unspecified toxic reactions and revealing genotoxic effects. The combination of information from the general specifications and this set of tests makes it possible to evaluate the presence in a product both of specific, well-known toxins and unknown toxic substances.

The toxicological report shall contain satisfactory documentation showing that the tests carried out have been done on the material which is the source of the product being marketed, as described in the technical part of the application.

10 Exceptions from basic toxicological requirements

From a toxicological viewpoint, it is important to complete a toxicological test procedure on each individual enzyme product that is produced based on a microbiological source organism.

10.1 If, however, one enzyme product from a particular strain has been thoroughly tested, and the manufacturing process is not significantly different
for other enzymes from the same strain, the full set of tests could be excluded for these enzymes. Decisions on this issue are made on a case by case basis.

10.2 If the micro-organism used for production,
- has been used in foodstuffs without causing health problems for a long time,
- belongs to a species documented not to produce toxins, and
- the actual strain used is of well-documented origin, there may be grounds for accepting an enzyme product from this organism without specific toxicological tests. If so, the correct and confirmed identification of the organism is particularly important.

Currently, only one example of such an organism can be given, viz. *Saccharomyces cerevisiae*.

Nonetheless, enzyme products from such source organisms shall still conform to the general specifications.

10.3 If the original strain of a micro-organism being used for the production of an already tested and approved enzyme product is replaced by a mutant strain, an amended and less comprehensive testing procedure may perhaps be appropriate. Such a reduced procedure must be justified on a case by case basis.

10.4 For immobilised enzyme products, where the immobilisation methods are evaluated and approved on the basis of satisfactory toxicity testing, these immobilisation methods may be combined with existing evaluated and approved enzyme products without the need for further toxicity testing of the finished product, provided that analytical data are submitted to show that the release of the components of the combined product falls within acceptable limits (see point 4.2).

10.5 With the introduction of well-specified, non-toxin-producing genetically-modified source organisms for the production of foodstuff enzyme products, it may become possible to produce enzymes of very high purity and specificity in the future. For products in which such a high purity and specificity can be demonstrated, there may possibly be no need for the entire toxicity testing procedure.

Apart from situations in which reduced testing procedures may be acceptable, cf. above, situations are also conceivable in which there is a need for further testing beyond the basic requirements in order to answer questions raised during some of the basic testing.


