

II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive on the approximation of the laws of the Member States relating to modified starches intended for human consumption*COM(84) 726 final**(Submitted by the Commission to the Council on 3 January 1985)**(85/C 31/09)*

THE COUNCIL OF THE EUROPEAN
COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas any laws concerning modified starches which may be used in foodstuffs intended for human consumption must take account firstly of the need to protect human health, secondly of the need to protect the consumer from adulterated products and thirdly of the economic and technological necessities within the limits imposed by health protection considerations;

Whereas differences between national laws relating to these substances, in so far as they impede the free movement of foodstuffs intended for human consumption, can lead to unequal conditions of competition and thus directly affect the establishment or proper functioning of the common market;

Whereas the approximation of these laws is necessary to ensure the free movement of foodstuffs intended for human consumption;

Whereas for this purpose it is appropriate to draw up a single list of relevant substances, use of which in foodstuffs intended for human consumption does not, according to the present state of scientific knowledge, pose a threat to human health; whereas this list should be supplemented by the definition of purity criteria which these substances must satisfy;

Whereas, in the event of a subsequent threat to public health, the Member States should be able to take

protective measures without delay; whereas, however, such action should be followed by a Community Decision;

Whereas it is necessary to define labelling requirements in respect of modified starches in order to facilitate trade and to enable the manufacturers of such products to provide a more precise indication of their intended use, by adopting the designations listed in Annex 1;

Whereas, however, since foodstuffs intended specifically for infants and young children constitute the principal source of infant nutrition in many cases, the use of certain starches should be limited to 5 % and the use of propylene oxide-modified starches should be prohibited;

Whereas the list of authorized modified starches should be adapted in line with scientific and technical developments; whereas, however, it is advisable in such cases to entrust the Member States with the task of contributing, through the adoption of temporary national measures, to the search for a Community solution;

Whereas any changes, based on advances in scientific and technical knowledge, to the conditions of use and the upper residue limits set out in Annex 1 as well as the definition of sampling and analysis methods for the purpose of checking the listed substances and their purity constitute technical implementing measures; whereas, for the purpose of simplifying and accelerating their adoption and facilitating their implementation, steps should be taken to ensure close cooperation between the Member States and the Commission within the framework of the Standing Committee on Foodstuffs set up pursuant to Council Decision 69/414/EEC ⁽¹⁾,

⁽¹⁾ OJ No L 291, 19. 11. 1969, p. 9.

HAS ADOPTED THIS DIRECTIVE:

Article 1

For the purposes of this Directive, the term 'modified starches' means the products obtained by one or more chemical treatments of edible starches, which may have previously undergone a physical or enzymatic treatment.

Article 2

1. Subject to the provisions of Article 3, and notwithstanding Community or national requirements governing the composition of certain foodstuffs which are justified on grounds of the prevention of fraud, Member States shall authorize the marketing and use as foodstuffs ingredients of the modified starches listed in Annex 1 under the conditions laid down therein.

2. The Member States shall prohibit the marketing and use of all other modified starches.

Article 3

Without prejudice to Community provisions relating to infant formulae and follow-up milk, use as an ingredient of foodstuffs intended specifically for infants and young children:

- (a) shall be prohibited in the case of the modified starches listed in Annex 1 under the letters K and R;
- (b) shall be limited to 5 % m/m in the case of the modified starches listed in Annex 1 under the letters D, F, G, H, I, J and N.

Article 4

Modified starches shall satisfy the general purity criteria set out in Annex 2.

Article 5

1. In order to take account of scientific or technical developments which have occurred since the adoption of this Directive, a Member State may authorize the marketing and use within its territory of a modified starch not listed in Annex 1, provided that the following conditions are satisfied:

- (a) the authorization shall be limited to a maximum period of three years;
- (b) the Member States must ensure that foodstuffs containing any modified starch it has authorized are officially monitored;

(c) all foodstuffs manufactured therewith shall bear a special indication to be laid down in the authorization.

2. The Member States shall communicate to the other Member States and to the Commission the text of any authorization decision adopted pursuant to the provisions of paragraph 1, within two months after the date on which the decision takes effect.

3. Before the three-year period stipulated in paragraph 1 has expired the Member State may request the Commission to include in Annex 1 the modified starch which had been the subject of national authorization pursuant to the provisions of paragraph 1. At the same time, the Member State shall provide the evidence which, in its view, supports such inclusion and shall indicate how the modified starch is to be used.

Within 18 months from the date of submission of the request, a decision shall be taken, on the basis of data relating to public health and after consulting the Scientific Committee for Food in accordance with the procedure laid down in Article 9, as to whether the modified starch in question can be included in Annex 1 or whether the authorization given by the Member State should be revoked. If provisions additional to those set out in Annex 2 are found to be necessary, they shall be adopted using the same procedure. By way of derogation from paragraph 1 (a), an authorization granted by a Member State shall remain in force until a decision has been taken on the request for inclusion.

If, in accordance with the provisions of the second subparagraph, it is decided that the authorization granted by a Member State must be revoked, this decision shall apply simultaneously to any authorization of the same modified starch granted by any other Member State.

Article 6

1. If, as a result either of the submission of a detailed assessment based on new data or the re-evaluation of existing data since the adoption of this Directive, a Member State ascertains that the use as a foodstuffs ingredient of one of the modified starches listed in Annex 1 or its content in one or more of the substances referred to in Annexes 1 and 2 constitutes a hazard for public health, notwithstanding its compliance with the provisions of this Directive, that Member State may provisionally suspend or restrict the application of the relevant provisions within its territory. It shall immediately inform the other Member States and the Commission of such action and of the reasons therefor.

2. As soon as possible thereafter, the Commission shall examine the reasons cited by the Member State concerned and shall consult the Member States within the framework of the Standing Committee on Foodstuffs. It shall then deliver its opinion without delay and proceed to the adoption of the appropriate measures.

3. If the Commission is of the opinion that amendments to the Directive are necessary to mitigate the difficulties referred to in paragraph 1 and to ensure the protection of public health, it shall initiate the procedure laid down in Article 9 with a view to the adoption of those amendments; in that case, the Member State which originally adopted the protective measure shall be permitted to maintain them until those amendments enter into force.

Article 7

1. The labelling of modified starches shall consist solely of the following mandatory wording:

- (a) the denomination under which the product is sold, consisting
 - either of the term 'modified starch' followed by the reference letter of the product indicated in Annex 1,
 - or of the name of the modified starch as given in Annex 1,
 the constituents of a mixture being designated individually;
- (b) the words 'for human consumption' or an indication of the specific intended use of the modified starch;
- (c) the net quantity, except in the case of products put up in bulk;
- (d) the date of manufacture, or identification of the production batch;
- (e) the name or business name and address of the manufacturer or packer, or of a vendor established within the Community.

2. The information referred to in paragraph 1 (a) and (d) shall appear on the package or on a label attached thereto.

The information referred to in paragraph 1 (b) and (c) shall appear:

- either on the package or on a label attached thereto;
- or on the commercial documents relating to the modified starch in question.

3. The provisions of this Article shall be without prejudice to more specific or more comprehensive Community provisions relating to metrology.

Article 8

The rules relating to sampling and the methods of analysis necessary for checking the composition and

manufacturing characteristics of the modified starches shall be adopted in accordance with the procedure laid down in Article 9.

Article 9

1. If the procedure laid down in this Article is invoked, the matter shall be referred to the Standing Committee on Foodstuffs, hereinafter referred to as the 'Committee', by its chairman, acting either on his own initiative or at the request of a representative of a Member State.

2. The Commission representative shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit to be set by the chairman in the light of the urgency of the matter. Opinions shall be delivered by a qualified majority, the votes of the Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures in question if they accord with the opinion of the Committee.

(b) If the measures do not accord with the opinion of the Committee or if it is not able to deliver an opinion, the Commission shall immediately submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

(c) If the Council does not act within three months following the date on which the proposal is submitted, the proposed measures shall be adopted by the Commission.

Article 10

Member States shall take the measures necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

Those measures shall be applied in such a way as to:

- permit products complying with this Directive to be marketed as from 1 July 1986 at the latest ⁽¹⁾;
- prohibit products not complying with this Directive from being marketed with effect from 1 November 1987 ⁽²⁾.

Article 11

This Directive is addressed to the Member States.

⁽¹⁾ 18 months after notification.

⁽²⁾ Three years after notification.

ANNEX 1

LIST OF MODIFIED STARCHES

Notes

1. The raw materials used may be dry, moist or in an aqueous suspension.
2. The percentages given relate to the dry material (m/m).

Reference letter	Denomination	Treatment	Specification of the finished product
A	White or yellow dextrin, roasted or dextrinated starch	Dry heat treatment in the presence of not more than 0,15 % hydrochloric acid or not more than 0,17 % orthophosphoric acid (E 338)	Final pH of 2,5 to 7,0
B	Starch modified by acid treatment	Treatment with not more than 7 % hydrochloric acid or not more than 2 % sulphuric acid or not more than 7 % orthophosphoric acid (E 338)	Final pH of 4,8 to 7,0
C	Starch modified by alkali treatment	Treatment with not more than 1 % sodium hydroxide or potassium hydroxide	Final pH of 5,0 to 7,5
D	Oxidized starch	Treatment with not more than 5,5 % sodium hypochlorite, expressed as chlorine	Not more than 1 % of carboxyl groups and not more than 0,5 % of sodium chloride
E	Bleached starch	Treatment with peracetic acid and/or hydrogen peroxide containing not more than 0,45 % active oxygen, or with sodium hypochlorite containing not more than 0,82 % available chlorine, or with 0,5 % sodium chlorite; or with sulphur dioxide (E 220) or other permitted forms of sulphites (E 221-E 227) With not more than 0,2 % potassium permanganate, or with not more than 0,075 % ammonium persulphate	Not more than 0,1 % of added carboxyl groups No reagent residues Not more than 50 mg/kg of residual manganese
F	Monostarch phosphate	Esterification with orthophosphoric acid (E 338), sodium (E 339) or potassium (E 340) orthophosphate or sodium tripolyphosphate (E 450b)	Not more than 0,5 % residual phosphate, calculated as phosphorus in the case of potato starch or wheat starch, or not more than 0,4 % in the case of other starches
G	Acetylated starch	Esterification with not more than 10 % acetic anhydride Esterification with not more than 7,5 % vinyl acetate	Not more than 2,5 % acetyl groups Not more than 2,5 % acetyl groups
H	Acetylated distarch adipate	Esterification with not more than 0,10 % acetic anhydrides and not more than 0,12 % adipic anhydrides	Not more than 2,5 % acetyl groups
I	Distarch phosphate	Esterification with sodium trimetaphosphate Esterification with not more than 0,1 % phosphorus oxychloride	Not more than 0,14 % residual phosphate, calculated as phosphorus in the case of potato starch and wheat starch, or not more than 0,04 % in the case of other starches Not more than 0,14 % residual phosphate, calculated as phosphorus in the case of potato starch and wheat starch, or not more than 0,04 % in the case of other starches

Reference letter	Denomination	Treatment	Specification of the finished product
J	Distarch phosphate	Esterification with not more than 0,1 % sodium trimetaphosphate or phosphorus oxychloride combined with esterification with not more than 10 % acetic anhydride or not more than 7,5 % vinyl acetate	Not more than 2,5 % acetyl groups and not more than 0,14 % residual phosphate, calculated as phosphorus in the case of potato starch and wheat starch, or not more than 0,04 % in the case of other starches
K	Hydroxypropyl starch	Esterification with not more than 10 % propylene oxide	Not more than 0,1 mg/kg (0,1 ppm) propylene chlorhydrins
N	Phosphated distarch phosphate	Combination of the treatment under F and I	Not more than 0,5 % residual phosphate, calculated as phosphorus in the case of potato and wheat starch, or not more than 0,4 % in the case of other starches
R	Hydroxypropyl distarch phosphate	Esterification with sodium trimetaphosphate or phosphorus oxychloride, combined with etherification with not more than 10 % propylene oxide	Not more than 0,1 mg/kg (0,1 ppm) propylene chlorhydrin, and not more than 0,14 % residual phosphate, calculated as phosphorus in the case of potato starch and wheat starch, or not more than 0,04 % in the case of other starches

ANNEX 2

GENERAL PURITY CRITERIA APPLICABLE TO MODIFIED STARCHES

1. Modified starches shall not:

- contain any substances in quantities that are liable to endanger public health;
- contain moulds, insects, remains of insects or other impurities of an animal nature or origin;
- have an abnormal flavour or odour.

2. The maximum contents set out below shall not be exceeded:

NB: Where the amounts refer to one or more vegetable species, these amounts only refer to the products derived from a single species. In the case of mixtures, it is necessary to calculate the permissible amounts proportionately to the percentages of the various constituents.

Substance	Maximum content
— Arsenic	1 mg/kg
— Lead	1 mg/kg
— Cadmium	0,1 mg/kg
— Mercury	0,05 mg/kg
— Sulphur dioxide	50 mg/kg
<i>Moisture</i>	
— Modified starches made from cereals	15 % m/m
— Modified starches made from potatoes	21 % m/m
— Modified starches of other origins	18 % m/m
<i>Proteins</i>	
— Starches in general	0,5 %
— Amylase-rich starches	1,0 %