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COMMISSION OF THE EUROPEAN COMMUNITIES

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2002/0201 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**amending Directive 95/2/EC as regards the conditions of use for a food additive E 425
konjac**

(presented by the Commission)

EXPLANATORY MEMORANDUM

On 27 March 2002, the Commission adopted a Decision (2002/247/EC)¹ to suspend the placing on the market and import of jelly confectionery containing the food additive E 425 konjac. Also the use of E 425 konjac in jelly confectionery was suspended. The measure was adopted under Article 53 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety².

The Commission took this measure after being informed by the several Member States and third countries of the risk involved in consuming jelly confectionery (so called jelly mini-cups) containing E 425 konjac. Several children and elderly persons had died in third countries through choking.

In addition to the shape and size of this confectionery, the chemical and physical properties of the food additive konjac are such that it causes jelly mini-cups to constitute a life-threatening risk to humans.

Some manufacturers of jelly mini-cups recognise the risk by affixing a warning on the food package, highlighting the risk for children and the elderly. In the present case, warning through labelling is not sufficient to protect human health, especially with regard to children.

The use of the food additive E 425 konjac is authorised in foodstuffs in the European Community under certain conditions by Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners³.

It is necessary to amend the current authorisation to withdraw the authorisation to use E 425 konjac in jelly mini-cups in order to protect human health. In addition, the use of konjac in any other jelly confectionery should also be withdrawn, as it may present the same risk as jelly mini-cups.

¹ OJ L 84, 28.3.2002, p. 69

² OJ L 31, 1.2.2002, p.1

³ OJ L 61, 18.3.1995, p.1

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**amending Directive 95/2/EC as regards the conditions of use for a food additive E 425
konjac**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission⁴,

Having regard to the opinion of the Economic and Social Committee⁵,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁶,

Whereas:

- (1) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners⁷ authorises the use of the food additive E 425 konjac in foodstuffs under certain conditions.
- (2) The Commission has taken measures to temporarily suspend the placing on the market of jelly mini-cups containing E 425 konjac because they have been found to be dangerous as they have caused the death of several children and elderly persons in third countries through choking.
- (3) Some manufacturers of jelly mini-cups recognise the risk to human health by affixing a warning on the food package, highlighting the risk for children and the elderly.
- (4) On the basis of the information provided by the Member States which adopted measures at national level, it can be concluded that jelly mini-cups containing E 425 konjac constitute a life-threatening risk. In addition to their shape and size, the chemical and physical properties of konjac are the cause for jelly mini-cups to constitute a serious risk to human health.
- (5) In the present case, warning through labelling is not sufficient to protect human health, especially with regard to children.

⁴ OJ C , , p. .

⁵ OJ C , , p. .

⁶ OJ C , , p. .

⁷ OJ L 61, 18.3.1995, p.1. Directive as last amended by Directive 2001/5/EC (OJ L 55, 24.2.2001, p.59)

- (6) It is necessary to modify the conditions of use for E 425 konjac as regards its use in jelly confectionery, including jelly-mini cups.
- (7) Directive 95/2/EC should therefore be amended accordingly.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

In Annex IV to Directive 95/2/EC in the row for E 425: Konjac: (i) Konjac gum (ii) Konjac glucomannane the text “Foodstuffs in general (except those referred to in Article 2(3))” is replaced by the text “Foodstuffs in general (except those referred to in Article 2(3) and jelly confectionery including jelly-mini-cups”.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [31 December 2003] at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES(SMEs)

TITLE OF PROPOSAL

Proposal for a Directive of the European Parliament and of the Council amending Annex IV of Directive 95/2/EC on food additives other than colours and sweeteners

DOCUMENT REFERENCE NUMBER

SANCO/2002/2051

THE PROPOSAL

1. Taking account of the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims?

The area of food additives is fully harmonised in the EU. An amendment is proposed to modify the conditions of use of the food additive E 425 konjac as laid down in Annex IV of Directive 95/2/EC. This Directive was developed according to the provisions of the framework Directive on food additives, Council Directive 89/107/EEC, which request the Commission to make a proposal on all food additives and the food categories in which the approved food additives may be used together with the conditions of use.

On 27 March 2002, the Commission adopted a Decision 2002/247/EC⁸ to suspend temporarily the placing on the market and import of jelly confectionery containing the food additive E 425 konjac due to a risk for health. In addition, the use of E 425 konjac was suspended in jelly confectionery. The measure was adopted under Article 53 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

The use of the food additive E 425 konjac is authorised in foodstuffs in the European Community under certain conditions by Directive 95/2/EC.

In the light of the above-mentioned Commission Decision, it is necessary to modify the conditions of use currently authorised for E 425 konjac. Therefore, it is necessary to introduce a proposal to amend the Annex IV of Directive 95/2/EC on food additives other than colours and sweeteners.

⁸ OJ L 84, 28.3.2002, p. 69

THE IMPACT ON BUSINESS

2. Who will be affected by the proposal?

- which sectors of business

Confectionery industry using E 425 konjac and the importers of this type of confectionery are affected.

- which sizes of business (what is the concentration of small and medium-sized firms)

All size of businesses.

- are there particular geographical areas of the Community where these businesses are found

There is a homogenous geographic distribution.

3. What will business have to do to comply with the proposal?

As E 425 konjac cannot be used for manufacturing jelly confectionery any longer, the production will have to be adapted accordingly. Alternative additives are authorised.

4. What economic effects is the proposal likely to have?

- on employment
- on investment and the creation of new businesses
- on the competitiveness of businesses

The European manufacturers use very little of this food additive in jelly confectionery. Therefore, the effect on employment would be minimal. Importers of these type of products from third countries would also be affected.

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms (reduced or different requirements etc)?

The proposal does not provide special measures for SME. All enterprises are treated equally.

CONSULTATION

6. List the organisations which have been consulted about the proposal and outline their main views.

Associated Commission services have been formally consulted.

Association of the Chocolate, Biscuit and Confectionery Industries of the EU (CAOBISCO), Marinalg International and the European Consumers' Organisation

(BEUC) have been consulted. No comments were received from BEUC. CAOBISCO and Marinalg International do not oppose the proposal.