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*****I** **REPORT**

on the proposal for a European Parliament and Council directive amending Directive 95/2/EC on food additives other than colours and sweeteners (COM(1999) 329 – C5-0068/1999 – 1999/0158(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Paul Lannoye

<i>Symbols for procedures</i>	<i>Abbreviations for committees</i>
* Consultation procedure <i>majority of the votes cast</i>	I. AFET Committee on Foreign Affairs, Human Rights, Common Security and Defence Policy
**I Cooperation procedure (first reading) <i>majority of the votes cast</i>	II. BUDG Committee on Budgets
**II Cooperation procedure (second reading) <i>majority of the votes cast, to approve the common position majority of Parliament's component Members, to reject or amend the common position</i>	III. CONT Committee on Budgetary Control
*** Assent procedure <i>majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty</i>	IV. LIBE Committee on Citizens' Freedoms and Rights, Justice and Home Affairs
***I Codecision procedure (first reading) <i>majority of the votes cast</i>	V. ECON Committee on Economic and Monetary Affairs
***II Codecision procedure (second reading) <i>majority of the votes cast, to approve the common position majority of Parliament's component Members, to reject or amend the common position</i>	VI. JURI Committee on Legal Affairs and the Internal Market
***III Codecision procedure (third reading) <i>majority of the votes cast, to approve the joint text</i>	VII. INDU Committee on Industry, External Trade, Research and Energy
(The type of procedure depends on the legal basis proposed by the Commission)	VIII. EMPL Committee on Employment and Social Affairs
	IX. ENVI Committee on the Environment, Public Health and Consumer Policy
	X. AGRI Committee on Agriculture and Rural Development
	XI. PECH Committee on Fisheries
	XII. REGI Committee on Regional Policy, Transport and Tourism
	XIII. CULT Committee on Culture, Youth, Education, the Media and Sport
	XIV. DEVE Committee on Development and Cooperation
	XV. AFCO Committee on Constitutional Affairs
	XVI. FEMM Committee on Women's Rights and Equal Opportunities
	XVII. PETI Committee on Petitions

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PROCEDURAL PAGE

By letter of 22 July 1999 the Commission submitted to Parliament, pursuant to Articles 251(2) and 95 of the EC Treaty, the proposal for a European Parliament and Council directive amending Directive 95/2/EC on food additives other than colours and sweeteners (COM(1999) 329 - C5-0068/1999 - 1999/0158(COD)).

At the sitting of 13 September 1999 the President of Parliament announced that she had referred this proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Industry, External Trade, Research and Energy for its opinion (C5-0068/1999).

The Committee on the Environment, Public Health and Consumer Policy had appointed Paul Lannoye rapporteur at its meeting of 22 September 1999.

It considered the Commission proposal and the draft report at its meetings of 24 February 2000 and 23 March 2000.

At the latter meeting it adopted the draft decision unanimously.

The following were present for the vote: Carlos Lage, acting chairman; Alexander de Roo and Ria G.H.C. Oomen-Ruijten, vice-chairmen; Paul A.A.J.G. Lannoye, rapporteur; Per-Arne Arvidsson, Maria del Pilar Ayuso González, Hans Blokland, David Robert Bowe, Hiltrud Breyer, Philip Rodway Bushill-Matthews (for Marialiese Flemming), Dorette Corbey, Chris Davies, Avril Doyle, Carlo Fatuzzo, Francesco Fiori (for Roger Helmer), Karl-Heinz Florenz, Robert Goodwill, Françoise D. Grossetête, Cristina Gutiérrez Cortines, Marie Anne Isler Béguin, Bernd Lange, Werner Langen (for Horst Schnellhardt, pursuant to Rule 162(6)), Torben Lund, Jules Maaten, Maria Martens, Rosemarie Müller, Giuseppe Nisticò, Karl Erik Olsson, Marit Paulsen, Encarnación Redondo Jiménez, Frédérique Ries, Guido Sacconi, Ulla Margrethe Sandbæk (for Jean Saint-Josse), Renate Sommer, María Sornosa Martínez, Robert William Sturdy, Marianne L.P. Thyssen, Joaquim Vairinhos (for Anneli Hulthén) and Phillip Whitehead.

The opinion of the Committee on Industry, External Trade, Research and Energy is attached.

The report was tabled on 24 March 2000.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

LEGISLATIVE PROPOSAL

Proposal for a European Parliament and Council directive amending Directive 95/2/EC on food additives other than colours and sweeteners (COM(1999) 329 – C5-0068/1999 – 1999/0158(COD))

This proposal is amended as follows:

Text proposed by the Commission¹

Amendments by Parliament

(Amendment 1)

Recital 5

(5) In accordance with requests from Member States, the following nationally authorised additives should be approved at Community level: ethyl hydroxyethyl cellulose, propane, butane and isobutane.

In view of the pressing need to guarantee food safety through the application of the precautionary principle, additives whose harmless nature is in any doubt must not be authorised.

Justification:

The precautionary principle must be strictly applied where food additives are concerned. This amendment is essential for the coherence of the text.

(Amendment 2)

Recital 7 (a)(new)

Whereas the specific benefit to the consumer must be clearly stated in each approval of fresh additives during the co-decision procedure.

Justification

Any new additive to be potentially added to the positive list must also be accompanied by a full statement on what benefits it offers to the consumer.

(Amendment 3)

Annex, point 1

In Annex I:

a) The following additives are inserted in the table:

“ E 467 Ethyl hydroxyethyl cellulose

In Annex I:

a) The following additive is inserted in the table:

Deleted

¹ OJ C 21, 25.1.2000, p. 42.

E 949 Hydrogen*"

E 949 Hydrogen*"

Justification:

Ethyl hydroxyethyl cellulose may contain dangerous impurities which are harmful to health, such as ethylene oxide, etc. (see Explanatory Statement point 3.1)

(Amendment 4)
Annex, point 2

Text proposed by the Commission

In Annex II:

The following row is added:

"Peeled and cut ready-to-eat
carrots

E 401 Sodium alginate

quantum satis"

Amendments by Parliament

Deleted

Justification:

The presence of additives in a non-transformed foodstuff risks misleading the consumer. The authorising of this additive would result in an increase in substances with a laxative effect and this is problematic since the synergistic effects have not been examined (see Explanatory Statement point 3.2).

(Amendment 5)
Annex, point 3(b)

Text proposed by the Commission

In Annex IV:

(b) The following rows are added:

<u>"E 650</u>	<u>Zinc acetate</u>	<u>Chewing gum</u>	<u>1 000 mg/kg</u>
<u>E 943a</u>	<u>Butane</u>	<u>Vegetable oil pan spray (for professional use only)</u>	<u>"quantum satis"</u>
<u>E 943b</u>	<u>Isobutane</u>		
<u>E 944</u>	<u>Propane</u>	<u>Water-based emulsion sprays</u>	

Amendment by Parliament

Deleted

Justification:

The information provided by the Commission on these gases is insufficient (see Explanatory Statement point 3.3).

DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the proposal for a European Parliament and Council directive amending Directive 95/2/EC on food additives other than colours and sweeteners (COM(1999) 329 – C5-0068/1999 – 1999/0158(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(1999) 329¹),
 - having regard to Articles 251(2) and 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0068/1999),
 - having regard to Rule 67 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Consumer Policy (and the opinion of the Committee on Industry, External Trade, Research and Energy) (A5-0072/1999),
1. Approves the Commission proposal as amended;
 2. Asks to be consulted again should the Commission intend to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council and Commission.

¹ OJ C 21, 25.1.2000, p. 42.
PE 232.063/fin.

EXPLANATORY STATEMENT

I. Introduction

In the space of a few decades our food consumption habits have undergone profound changes as a result of changing lifestyles and new technologies. The time spent preparing food has been considerably reduced, opening the way to ready meals, fast food and ever more sophisticated processed foods.

The practice of eating in restaurants and canteens, which has also greatly increased, has only served to reinforce in consumers a relationship to food in which the dictates of taste, freshness and variety are constantly gaining ground.

The mass-produced foods that arrive on our plates have often been highly processed, with a resulting loss of taste, texture and colour. To rectify these shortcomings, the chemists in the food industry add flavouring, flavour enhancers, firming agents, colouring agents, etc.

Since food distribution chains are growing ever longer, the use of preservatives and antioxidants has become unavoidable, so that even basic foodstuffs such as bread often contain a considerable number of additives.

Finally, since the aim of industry is always to produce faster and more cheaply, many additives geared to greater profitability find their way onto our plates.

This invasion of food by chemicals flies in the face of an ever more pronounced tendency for consumers, who are aware of the risks to their health and that of their children, to look for healthy, natural foods.

II. Food additives: the current situation

Faced with these developments, the European Union has equipped itself with a particularly complex legislative arsenal which is supposed to prevent any risk to the consumer.

In reality, while the desire to protect health is one factor in any decision to include an additive in the list of authorisations or to widen its field of application to include new foodstuffs, this concern is not a priority in reaching this decision.

Three criteria are in fact taken into consideration: the technological need for the additive to be authorised, its usefulness to the consumer and its harmlessness. One can see that the margin of interpretation is very wide and the weight given to each criterion of decisive importance.

The technological need is of course determined by industry, which thinks primarily in terms of reducing production costs and conquering markets. This criterion currently weighs very heavily in the equation.

Usefulness to the consumer is a particularly vague concept. Is it useful for a foodstuff to be able to be preserved for months on end? For the manufacturer and the distributor, without doubt; for the consumer the advantage is very much more debatable. Can one speak of usefulness when the main purpose of an additive is to deceive the consumer? A fruit coating agent intended to give the fruit a 'fresher' appearance can hardly be described as useful to the consumer.

Finally, harmlessness, which never has to be proved by the applicant. Before any substance is authorised as a food additive it is, in principle, subjected to toxicological examination. Usually a number of experiments are carried out on laboratory animals to determine whether the substance is harmless and in what dose it can be consumed without danger.

This way of proceeding has major shortcomings, however. For one thing, human beings do not always react in the same way as animals, so that it is never a simple matter to transfer animal results to human beings. Also, in these experiments the effect of each substance is evaluated in isolation, whereas in reality our food often contains a cocktail of different substances which can, as is now known, develop synergetic effects.

Also, when a substance is suspect it is not simply banned, as the precautionary principle would dictate. Instead, the Scientific Committee on Human Food sets an admissible daily dose, beneath which it hopes that there will be no harmful effects, and usually decides to reevaluate the substance a few years later in the light of new studies. Often, under pressure from the agri-foodstuffs sector, a great deal of evidence that a substance is harmful is needed before it is finally withdrawn from the market. In the same way, new substances on which very few independent studies exist are regularly authorised at the request of the industry.

The recent food safety crises (BSE, dioxins, etc.) show how important it is to apply the precautionary principle rigorously to the manufacture of foodstuffs. If we really want to learn the lessons of these crises it is imperative that the criteria of 'usefulness to the consumer' and 'harmlessness' are given their true importance.

This will involve, on the one hand, reevaluation of certain additives (see below) authorised by Directive 95/2/EC (and its amendments) in the light of new scientific knowledge and on the basis of the 'usefulness to the consumer' criterion. Secondly, there can no longer be any question of authorising new additives which are under suspicion or about which too little is known.

(*) Authorised additives to be reevaluated on the basis of the precautionary principle and in the light of new scientific knowledge:

- benzoic acid (E 210) and the benzoates (E 211 – E 213)
- the parabens (E 214 – E 219)
- biphenyl (E 230)
- orthophenylphenol (E 231) and sodium orthophenylphenate (E 232)
- nisin (E 234) and natamycin (E 235)
- hexamethylenetetramine (E 239)
- dimethyl dicarbonate (E 242)
- the gallates (E 310 – E 312)
- BHA (E 320) and BHT (E 321)
- EDTA (E 385)
- polyoxyethylene stearate (E 431)
- the polysorbates (E 432 – E 436)
- thermally oxidised soya bean oil (E 479b)
- the aluminium sulphates (E 520 – E 523)
- sodium aluminium phosphate, basic (E 541)
- glutamic acid and the glutamates (E 620 – E 625)
- dimethylpolysiloxane (E 900)
- the quillaia extracts (E 999)
- the polyvinylpyrrolidones (E 1201 – E 1202)

(P.S. Similar reevaluation should also be carried out in the case of certain colouring agents and sweeteners.)

III. The new proposal amending Directive 95/2/CE presented by the Commission:

III.1. E 467: Ethyl hydroxyethyl cellulose (EHEC)

*** Technological need**

According to the information obtained from the Commission, EHEC has been used in Sweden for 20 years as a stabiliser in gluten-free bread, since this cellulose has surfactant properties. The use of other hydrocolloids would not produce gluten-free bread of the same quality.

It is worth mentioning that in the other Member States gluten-free bread is also made – without the use of EHEC.

According to the Commission, EHEC can also be used as a binding agent in batter coating for deep-frozen fish (the additive reduces absorption of fat by the fish), pastries, cake mixes and confectionery.

EHEC is not essential in these applications either.

*** Usefulness to the consumer**

The Commission does not state whether there is any advantage to the consumer as far as the quality of the food is concerned in using this cellulose rather than another.

*** Harmlessness**

No source reports greater toxicity of this cellulose as compared with the other five modified celluloses that are currently authorised. Its laxative effect should not come into play in the quantities in which it is ingested. The overall quantity of celluloses incorporated in food should not change in the event of EHEC being authorised, since this cellulose will take the place of another.

However, the impurities that may be present in this cellulose pose a problem. The purity criteria for EHEC laid down by the FAO/WHO Joint Expert Committee on Food Additives (JECFA) at its 49th meeting are as follows:

- ethylene oxide, 1,4-dioxan and ethylene chlorhydrine:

no more than 0.5 mg/kg, taken individually

- mono- and diethylene glycol:

no more than 1%, individually or in combination.

Ethylene oxide is classified as a ‘proven carcinogen’ (Group 1) by the WHO’s International Agency for Research on Cancer (IARC), and 1,4 dioxan is classified as a ‘possible carcinogen’ (Group 2B).

To authorise an additive which may contain such dangerous impurities would be totally at odds with the EU’s stated intention to protect public health; the presence of ethylene glycols further exacerbates the situation.

Commission Directive 98/86/EC laying down specific purity criteria on food additives other than colours and sweeteners does not mention maximum residue limits for ethylene oxide and 1,4 dioxan in the case of the five other modified celluloses authorised. So the problem would indeed seem to be linked to EHEC.

III.2. E 401: Sodium alginate

*** Technological need**

Sodium alginate is used as a firming agent for peeled, cut, ready-to-eat packaged carrots. The carrots are plunged into a water bath containing 10 mg of alginate per litre of water. This treatment prevents the whitening of the carrots’ surface that results from drying out and internal metabolism. It also prevents softening of the carrot pieces and helps maintain the organoleptic qualities of the carrots.

*** Usefulness to the consumer**

In view of the preceding paragraph, the use of alginate might seem to be of positive value to the consumer. However, treatment with alginate may mislead the consumer, since the food may appear fresher than it really is.

Also, what is being done here is to authorise the use of E 401 for peeled, cut, ready-to-eat carrots. This additive is currently contained in Annex I to Directive 95/2/EC and cannot, therefore, be used for the carrots in question. Article 2(3) of that Directive stipulates that the additives listed in Annex I cannot be used for non-transformed foodstuffs, i.e. food which has not undergone treatment involving a significant change to its original state. However, these foodstuffs are allowed to be [...], peeled, [...], cut, [...], packaged or unpackaged.

By authorising the use of sodium alginate in the case of peeled carrots one would thus be introducing an additive into an unprocessed item of food; food in which the consumer does not expect to find any additives. Here again there is a risk of the consumer being misled.

*** Harmlessness**

Sodium alginate is a substance which is generally regarded as harmless. It has a laxative effect which is considered negligible in the quantities in which alginate is ingested.

However, sodium alginate is not the only additive with a laxative effect present in human food. The celluloses, polyols, etc. also have this effect. On the subject of the various components of human food having a laxative effect, the Scientific Committee on Human Food concluded its opinion of 13 March 1992 on reevaluation of five cellulose derivatives as follows (see: “Reports of the Scientific Committee on Human Food”, 32nd series, 1994):

In accordance with its evaluation of thickening agents with similar biological properties, the Committee has set an 'unspecified' acceptable daily intake (ADI) for the five cellulose derivatives listed in Directive 74/329/EEC.

This evaluation applies only to the current uses of food additives, for which the addition levels are usually in the region of 0.2 to 3.0%. Provided utilisations remain at their current level and that addition levels are kept within the limits necessary for purely technological purposes, real clinical laxative effects should not occur. However, the contribution of other food components with potential laxative effects to the overall dietetic burden of substances with this biological property should be the subject of a study.

The study recommended by the Scientific Committee was not carried out, although consumption of foods containing such substances is on the increase (polyols in 'light' sugar-free foods, thickening agents, many ready-to-eat desserts, yoghurts, etc.).

By authorising the use of sodium alginate in ready-to-eat carrots we would be adding still further to the sources of additives with a laxative potential without having studied the synergy between such substances.

III. 3. E 943a: Butane; E 943b: Isobutane and E 944: Propane

*** Technological need**

These gases are used as propellants for the vegetable oil or water-vegetable oil emulsions used to grease containers for oven cooking or to apply a mixture of spices or other flavourings to a food item (oven-ready pizzas, for example).

According to information obtained from the Commission, the other propellant gases authorised for this purpose (CO₂ and nitrogen oxide) are less soluble in oil than the three new gases and are thus less effective in producing the pressure needed for even distribution of the product.

*** Usefulness to the consumer**

Of no direct use.

*** Harmlessness**

The SCF takes the view that food, after cooking, should not contain more than 1 mg of residual propellant gas per kg. The data show that there is usually a residue of about 0.1 mg of residues per kg of food. The SCF does not consider this level of residue to present any risk.

The Joint Expert Committee on Food Additives (JECFA) has not established any purity criteria for this gas; the Commission says it will determine them after the additives have been authorised. Neither has it been possible to obtain from the Commission the 'Specifications on iso-butane, propane, butane, provided by MAFF, Joint Food Safety and Standards Group, Additives and Novel Foods Division, London, UK'.

It is therefore impossible to judge as to the real harmlessness of the three additives in question.

The Commission has not replied to the question: 'What other additives have to be added to vegetable oils in order to vaporise them using the three gases?'

Finally, one wonders whether it is useful to authorise use of a propellant gas which, firstly, carries a high explosion risk and, secondly, comes from a fossil source.

In the absence of precise answers to the questions put to the Commission, use of the three additives should not therefore be authorised.

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27 January 2000

OPINION

(Rule 162)

for the Committee on the Environment, Public Health and Consumer Policy

on the proposal for a European Parliament and Council Directive amending Directive 95/2/EC on food additives other than colours and sweeteners (COM(1999) 329 - C5-0068/1999 - 1999/0158(COD)) (report by Mr Lannoye)

Committee on Industry, External Trade, Research and Energy

Draftsman: Samuli Pohjamo

PROCEDURE

At its meeting of 4 October 1999 the Committee on Industry, External Trade, Research and Energy appointed Samuli Pohjamo draftsman.

It considered the draft opinion at its meetings of 23 November 1999 and 27 January 2000.

At the latter meeting it adopted the following conclusions unanimously.

The following were present for the vote: Carlos Westendorp y Cabeza, chairman; Renato Brunetta, vice-chairman; Samuli Pohjamo, draftsman; Konstantinos Alyssandrakis, Maria del Pilar Ayuso González (for Marjo Tuulevi Matikainen-Kallström), Alexandros Baltas, Eduard Beysen (for Willy C.E.H. De Clercq), David Robert Bowe (for Glyn Ford), Massimo Carraro, Giles Bryan Chichester, Nicholas Clegg, Dorette Corbey (for Mechtild Rothe), Claude J.-M.J. Desama, Harlem Désir, Concepció Ferrer, Francesco Fiori (for Anders Wijkman), Christos Folias, Norbert Glante, Michel Hansenne, Malcolm Harbour, Wolfgang Kreissl-Dörfler (for Nuala Ahern), Helmut Kuhne (for Erika Mann), Bernd Lange (for François Zimeray), Werner Langen, Peter Liese (for Konrad K. Schwaiger), Rolf Linkohr, Caroline Lucas, Linda McAvan, Eryl Margaret McNally, Albert Jan Maat (substitute), Nelly Maes, Bill Miller (for Simon Francis Murphy), Elizabeth Montfort, Luisa Morgantini, Angelika Niebler, Reino Kalervo Paasilinna, Elly Plooij-van Gorsel, John Purvis, Godelieve Quisthoudt-Rowohl, Alexander Radwan (for Peter Michael Mombaur), Imelda Mary Read, Christian Foldberg Røvsing, Paul Rübig, Jacques Santer (for Guido Bodrato), Umberto Scapagnini, Ilka Schröder, Esko Olavi Seppänen, Antonios Trakatellis (for Alain Lamassoure), Claude Turmes (for Yves Piétrasanta), Jaime Valdivielso de Cué and W.G. van Velzen.

1. INTRODUCTION

On 22 July 1999 the Commission submitted its proposal for a European Parliament and Council Directive amending Directive 95/2/EC on food additives other than colours and sweeteners (COM(1999) 329 final - 99/0158(COD)).

Pursuant to Directive 89/107/EEC, Member States have the power temporarily to authorise the use of a new additive in their territory for a maximum of two years. A Member State may extend a provisional authorisation for 18 months if the Commission proposes that the additive be authorised at Community level. Such a proposal may only be made if the Scientific Committee on Food has delivered a favourable opinion.

In addition, it is proposed that the use of certain additives be adapted in the light of technical developments. Member States do not have the power to extend provisionally the use of additives which are already authorised in the same way as they can for new additives. This makes it impossible for the food industry in Europe to introduce the latest innovations rapidly if the innovation comprises a new use for an authorised additive.

2. APPRAISAL OF THE PROPOSAL

The rules on the use of food additives are detailed and become outdated rapidly on account of technical progress. There is therefore a constant need for amendment. It is important that the European food industry should be able to apply new innovations flexibly and rapidly, but in such a way as to guarantee that a new additive or the extended use of an existing additive is safe to consumers. The proposal for amendments which has now been submitted accords with the procedure laid down in the basic directive on additives. The amendments in the Commission proposal are based on a need expressed by a Member State, and the Scientific Committee on Food has delivered a favourable opinion on them.

3. CONCLUSIONS

1. The Committee endorses the Commission's amendments 1, 3 and 4 as they stand in the proposal.
2. The Committee draws attention to amendment 2 concerning 'peeled and cut ready-to-eat carrots'. A product containing additives should be offered for sale to the consumer only ready-packed so that the consumer is informed about the use of the additive in the peeled carrots and is given any other information required, for example concerning the use of the food product.
3. The Committee calls on the Committee on the Environment to adopt its opinion rapidly so that the change in the rules can be adopted within the time limit and the Member States can continue to permit the use of additives whose use has been shown to be safe.