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Committee on Legal Affairs
The Chairman

3.5.2007

Mr Miroslav Ouzký
Chairman
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on the legal basis of the Proposal for a Regulation of the European Parliament and of the Council on food enzymes (COM(2006)0425 – C6-0257/2006 – 2006/0144(COD))[1]

Dear Mr Chairman,

By letter of 28 March 2007 you asked the Committee on Legal Affairs pursuant to Rule 35(2), to consider whether the legal basis of the above Commission proposal was valid and appropriate.

The committee considered the above question at its meeting of 2 May 2007.

The committee noted that whereas the proposal has a dual legal basis, Article 37 and Article 95 of the EC Treaty, the rapporteur, Mrs Doyle, proposes to delete Article 37 as she considers that Article 95 provides an appropriate and sufficient legal base.

Furthermore, Mr Schlyter and Mr Staes, taking into consideration the regulation's aim of providing a high level of consumer protection, propose not only to delete the reference to Article 37 but also to add a reference to Article 153, so that the legal bases would be Articles 95 and 153.

The legal bases under consideration

[1] Not yet published in OJ.

Article 37

1. In order to evolve the broad lines of a common agricultural policy, the Commission shall, immediately this Treaty enters into force, convene a conference of the Member States with a view to making a comparison of their agricultural policies, in particular by producing a statement of their resources and needs.

2. Having taken into account the work of the Conference provided for in paragraph 1, after consulting the Economic and Social Committee and within two years of the entry into force of this Treaty, the Commission shall submit proposals for working out and implementing the common agricultural policy, including the replacement of the national organisations by one of the forms of common organisation provided for in Article 34(1), and for implementing the measures specified in this title.
These proposals shall take account of the interdependence of the agricultural matters mentioned in this title.

The Council shall, on a proposal from the Commission and after consulting the European Parliament, acting by a qualified majority, make regulations, issue directives, or take decisions, without prejudice to any recommendations it may also make.

3. The Council may, acting by a qualified majority and in accordance with paragraph 2, replace the national market organisations by the common organisation provided for in Article 34(1) if:

(a) the common organisation offers Member States which are opposed to this measure and which have an organisation of their own for the production in question equivalent safeguards for the employment and standard of living of the producers concerned, account being taken of the adjustments that will be possible and the specialisation that will be needed with the passage of time;

(b) such an organisation ensures conditions for trade within the Community similar to those existing in a national market.

4. If a common organisation for certain raw materials is established before a common 2organisation exists for the corresponding processed products, such raw materials as are used for processed products intended for export to third countries may be imported from outside the Community.

Article 95

1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.
When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 226 and 227, the Commission and any Member State may bring the matter directly before the Court of Justice

if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure.

Article 153

1. In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.

2. Consumer protection requirements shall be taken into account in defining and implementing other Community policies and activities.

3. The Community shall contribute to the attainment of the objectives referred to in paragraph 1 through:

(a) measures adopted pursuant to Article 95 in the context of the completion of the internal market;

(b) measures which support, supplement and monitor the policy pursued by the Member States.

4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, shall adopt the measures referred to in paragraph 3 (b).

5. Measures adopted pursuant to paragraph 4 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with this Treaty. The Commission shall be notified of them.

Content of the draft Regulation

According to the explanatory memorandum, the aim and purpose of the proposal for a regulation is as follows:

The legislation controlling the use of enzymes in food processing is not fully harmonised in the EU. The national regulatory context for enzymes used as processing aids in food production differs significantly among Member States. Only a few Member States have a mandatory or voluntary authorisation procedure, the majority have none at all. Moreover, there are divided opinions among Member States in relation to the categorisation of enzymes into food additives or processing aids according to their function in the food process or in the final food. This lack of harmonised rules in the Community created barriers to the trade of

food enzymes and has hindered growth in this field.

With respect to safety, there is neither safety evaluation nor authorisation of food enzymes at European level, except for those that are considered as food additives. Historically, food enzymes were considered to be non-toxic. However, the food enzyme industry is continually striving to develop improved technology resulting in the development of food enzymes which became through the years more complex and sophisticated. There could be some potential hazards arising from their chemical nature and source such as allergenicity, activity-related toxicity, residual microbiological activity, and chemical toxicity. Therefore safety evaluation of all food enzymes, including those produced by genetically modified micro-organisms (GMOs), is essential in order to ensure consumer safety.

The content of the regulation may be analysed as follows:

Chapter I - Subject matter, scope and definitions.
The proposed Regulation is to apply to enzymes used for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of food, including those used as processing aids. Food enzymes are to be subject to safety evaluation and approval by means of a Community list.

Chapter II - Community list of approved food enzymes
All food enzymes and their use in food will be evaluated for safety, technological need, benefit to the consumer and to ensure that the consumer is not misled by their use. In line with the decision to separate risk management and risk assessment, the European Food Safety Authority (EFSA) will carry out the safety evaluations. The inclusion of a food enzyme in the Community list will be considered by the Commission on the basis of the opinion from EFSA, taking into account the other general criteria (technological need, consumer aspects). For every food enzyme included in the positive list specifications, including the criteria relating to the purity and the origin of the food enzyme, are to be laid down.

Chapter III - Labelling
The proposed Regulation will introduce labelling requirements for food enzymes sold to the manufacturer or directly to the consumer. For the purpose of labelling, enzymes used in food should be considered as ingredients in a similar way to additives in accordance with Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs. In most cases food enzymes will be used as processing aids, *i.e.* they will be present in food in the form of a residue, if at all, and will have no technological effect on the finished product. Taking into account that all food enzymes will be assessed for their safety, it is proposed that food enzymes which are used as processing aids should be exempted from labelling. Food enzymes used to exert a technological function in the final food will be labelled with their function (*e.g.* stabiliser, etc) and specific name.

Chapter IV - Procedural provisions and implementation
Wherever necessary, producers or users of food enzymes will be obliged to inform the Commission of any new information which may affect the safety assessment of the food enzyme.

Implementation of the measures proposed in the Regulation will be effected by the Commission in accordance with the regulatory procedure laid down in Council Decision 1999/468/EC.

Chapter V -Transitional and final provisions
Since many food enzymes are already on the market in the Community, the transition to a Community positive list should be smooth and should not lead to unfair conditions for enzyme producers. Therefore, the proposal provides for an initial period of 24 months, after the date of application of the implementing measures foreseen in the common procedure Regulation, during which applications can be submitted. The establishment of the Community list will take place in a single-step procedure after the EFSA has expressed opinions on all products for which sufficient information has been submitted during the 24-month period. Until such time as the Community list has been established, food enzymes and food produced with food enzymes may be placed on the market and used in accordance with existing national rules. A transitional period is also laid down for the proposed labelling requirements.

Appraisal

All Community acts must be founded upon a legal basis laid down in the Treaty (or in another legal act which they are intended to implement). The legal basis defines the Community's competence *ratione materiae* and specifies how that competence is to be exercised, namely the legislative instrument(s) which may be used and the decision-making procedure.

It is clear from settled case-law of the Court of Justice that the choice of legal basis is not at the discretion of the Community legislator but must be determined by objective factors which can be subject to judicial review[2], such as the aim and content of the measure in question[3]. Furthermore, the decisive factor should be the main object of a measure[4].

According to the case-law of the Court of Justice, a general Treaty article constitutes a sufficient legal basis even though the measure in question also seeks, in a subordinate manner, to attain an aim sought by a specific Treaty article[5].

However, where a measure has several contemporaneous objectives which are indissolubly linked with each other without one being secondary and indirect in respect to the others, the measure must be based on the various relevant Treaty provisions[6], unless this is impossible on account of the mutual incompatibility of the decision-making procedures laid down by the

[2] Case 45/86, *Commission* v. *Council* [1987] ECR 1439, para. 5.
[3] Case C-300/89, *Commission* v. *Council* [1991] ECR I-287, para. 10, and Case C-42/97, *European Parliament* v. *Council* [1999] ECR I-869, para. 36.
[4] Case C-377/98, *Netherlands* v. *European Parliament and Council* [2001] ECR I-7079, para. 27.
[5] Case C-377/98 *Netherlands* v. *European Parliament and Council* [2001] ECR I-7079, paras 27-28; Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paras 93-94.
[6] Case C-165/87 *Commission* v. *Council* [1988] ECR 5545, para. 11.

provisions[7].

In the light of the above, it is to be established whether Article 37 together with Article 95, Article 95 alone or Article 95 together with Article 153 of the EC Treaty should constitute the proper legal basis of the proposed regulation.

As far as *Article 37*, is concerned, it is noted that, even though that article is mentioned in the first citation in the preamble to the proposed regulation, the explanatory memorandum mentions only Article 95 as the legal basis. When in addition, it is considered that the only positive mentions of agricultural products are very ancillary indeed, namely in recitals 7[8] and 16[9], and that recital 4 makes it clear that "Microbial cultures traditionally used in the production of food, such as cheese and, wine and which may contain enzymes but are not specifically used to produce them should not be considered food enzymes", it is hard to see how Article 37 could constitute the legal basis. Consequently, given the proposed regulation's emphasis on the internal market and the protection of health as evinced in recitals 1, 2 and 3[10], it is considered that Article 37 does not qualify as joint legal basis on the basis of the criteria laid down in the case-law.

It should also be observed that Article 37 and Article 95 do not seem to be compatible - the former provides for the mere consultation of Parliament whilst the latter provides for the codecision procedure.

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[7] See, *e.g.*, Case C-300/89 *Commission* v. *Council* [1991] ECR I-2867, paras 17-21 (*Titanium dioxide* case), Case C-388/01 *Commission* v. *Council* [2004] ECR I-4829, para. 58 and Case C-491/01 *British American Tobacco* [2002] ECR I-11453, paras 103-111.

[8] *Some food enzymes are permitted for specific uses, such as in fruit juices and certain similar products and certain lactoproteins intended for human consumption and for certain authorised oenological practices and processes. Those food enzymes should be used in accordance with this Regulation and with the specific provisions laid down in the relevant Community legislation. Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption, Council Directive 83/417/EEC of 25 July 1983 on the approximation of the laws of the Member states relating to certain lactoproteins (caseins and caseinates) intended for human consumption and Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine should therefore be amended accordingly.*

[9] *... Council Regulation (EC) No 1493/1999 authorises the use of urease, beta-glucanase and lysozyme in wine subject to the conditions laid down in Commission Regulation (EC) No 1622/2000 of 24 July 2000 laying down certain detailed rules for implementing Regulation (EC) No 1493/1999 on the common organisation of the market in wine and establishing a Community code of oenological practices and processes. Those substances are food enzymes and they should fall within the scope of this Regulation. They should therefore be also added to the Community list when it is drawn up for their use in wine in accordance with Regulation (EC) No 1493/1999 and Regulation (EC) No 1622/2000.*

[10] *(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.*
(2) A high level of protection of human life and health should be assured in the pursuit of Community policies.
(3) Enzymes other than those used as food additives are not currently regulated or are regulated as processing aids under the legislation of the Member States. Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of food enzymes may hinder their free movement, creating conditions for unequal and unfair competition. It is therefore necessary to adopt Community rules harmonising national provisions relating to the use of enzymes in foods.

When it comes to the question whether *Article 153* may be added to the legal basis of Article 95, it is undeniable that the proposed regulation is concerned with the protection of the health of consumers and with their social and economic interests, of which mention is made in Article 153. It is indeed possible to take the view that the two aims of achieving the internal market and consumer protection within the meaning of Article 153 are equally balanced and that therefore both legal bases may be used.

However, in view of the wording of paragraph 3(a) of Article 153, which provides that the Community shall contribute to the attainment of the objective of, i*nter alia*, protecting the health and economic interests of consumers through measures adopted pursuant to Article 95 in the context of the completion of the internal market, there is, strictly speaking, no need to consider whether the proposed measure has "several contemporaneous objectives which are indissolubly linked with each other without one being secondary and indirect in respect to the others", since Article 95 may be used as the legal basis by itself, either on the ground that paragraph 3 of that article provides that internal market measures concerning consumer protection are to take as a base a high level of protection or on the ground of the explicit reference made to Article 95 in Article 153.

Articles 95 and 153 are intrinsically compatible and the addition of the latter article has no procedural or substantive implications.

Accordingly, where, as in this case, a measure seeks to attain consumer protection objectives in equal measure and at the same time as objectives relating to the completion of the internal market, it may be safely based on both Article 95 and Article 153.

At its meeting of 2 May 2007 the Committee on Legal Affairs accordingly decided, unanimously[11], to recommend as follows:

(a) Article 37 of the EC Treaty does not constitute an appropriate legal basis for the proposal for a regulation;

(b) the appropriate legal basis is Article 95 and Article 153 of the EC Treaty.

Yours sincerely,

Giuseppe Gargani

[11] The following were present for the final vote: Giuseppe Gargani (chairman), Cristian Dumitrescu, Francesco Enrico Speroni (vice-chairmen), Manuel Medina Ortega (draftsman), Sharon Bowles, Mogens N.J. Camre, Carlo Casini, Bert Doorn, Monica Frassoni, Klaus-Heiner Lehne, Eva Lichtenberger, Antonio Masip Hidalgo, Aloyzas Sakalas, Gary Titley, Jaroslav Zvěřina.