

# EUROPEAN COMMUNITY LAW

(FIRST YEAR ELECTIVE)

**THREE HOURS.**

**This is a closed-book exam.**

**DO** read the questions carefully and think about your answers before beginning to write.

**DO** refer to treaty provisions, cases and other materials where appropriate. If you make general statements, try to back them up with specific references.

**DO NOT** use abbreviations unless you explain what you are using them to stand for.

**DO NOT** make assumptions in answering the hypothetical.

**DO** explain what further information you might need in order to answer the question properly.

**DO** write legibly and clearly.

**You will get credit for following these instructions, and may be penalized for failing to do so.**

The Food Supplements Directive of 10 June 2002 regulates vitamins and minerals which may be used in the manufacture of food supplements through a “positive list”. Vitamins and minerals included on the list may be used in food supplements. Vitamins and minerals not included in the list may not be used in food supplements. The date for implementation of the directive was 31 July 2003. Member States are required to prohibit trade in non-compliant products from 1 August 2005 at the latest. Member States should not as a general rule restrict trade in compliant products and Member States have been required to permit trade in compliant products since 1 August 2003.

Under Art. 4(6) of the directive, until 31 December, 2009, Member States may allow vitamins and minerals not on the positive list to be used in food supplements if they were used in one or more food supplements on sale when the directive entered into force (on the date of publication: 12 July, 2002) and if the European Food Safety Authority has not given an unfavourable opinion in respect of their use. Even where a Member State has relied on the Art. 4(6) derogation other Member States may continue to apply their existing restrictions and bans on trade in the substances concerned.

Food supplement ingredients other than vitamins and minerals are not regulated under the directive.

Article 6(2) of the directive provides that:

The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.

The directive does not specify any details about how products may be added to the positive list, or who may apply to have products added, although Recital number 10 states:

There is a wide range of vitamin preparations and mineral substances used in the manufacture of food supplements currently marketed in some Member states that have not been evaluated by the Scientific Committee on Food and consequently are not included in the positive lists. These should be submitted to the European Food Safety Authority for urgent evaluation, as soon as appropriate files are presented by the interested

parties.

The Directive is based on Art. 95 of the Treaty, an excerpt from which is set out at the end of this question.

Manufacturers of food supplements and trade associations have objected to the directive, arguing that the positive list is too restrictive.

A copy of the directive is attached to this examination for your reference although you will not need to have a detailed knowledge of the directive in order to answer the questions set out below.

### **Answer the following four questions:**

There are a total of 100 points for this exam. I have indicated points for each question to help you to allocate your time, but the points marked total 80. I will apply the additional 20 points across all of the questions to give credit for particularly good answers.

1. (15 points) Why does the EU need to regulate food supplements at all? If the EU did not regulate food supplements would the Member States be able to do so?

2. (25 points) When the UK adopted regulations to implement the Food Supplements Directive, a group called the Alliance for Natural Health (among others) challenged the UK regulations in the English High Court on a number of different grounds. The English High Court referred a number of questions to the ECJ under the preliminary rulings procedure of Art. 234. One of the questions related to the principle of proportionality. Advocate General Geelhoed delivered his opinion on the questions referred by the English Court in April 2005. In assessing the compatibility of the directive with the principle of proportionality the Advocate General expressed reservations about the directive's procedures for the inclusion of new substances in the positive list. His opinion includes the following paragraphs:

68. In its present form, Directive 2002/46 is seriously deficient in three respects...

– ...The Directive...contains no standard for assessing whether the Commission has, in taking decisions concerning modifications of the positive list, remained within the limits of its legal powers;

- It is not clear whether the Directive allows private parties to submit substances for evaluation with a view to having them included in the positive lists. Recital 10 in the preamble to the Directive refers unambiguously to this possibility, yet Article 4(6)(b) of the Directive would seem to suggest the contrary;
- On the supposition that private parties are indeed able to submit substances for an evaluation with a view to inclusion in the positive lists, there is no clear procedure for this purpose which provides minimum guarantees for protecting those parties' interests...

85. In short, this procedure, in so far as it may exist and in so far as it may deserve this title, has the transparency of a black box: no provision is made for parties to be heard, no time-limits apply in respect of decision-making; nor, indeed, is there any certainty that a final decision will be taken. The procedure therefore lacks essential guarantees for the protection of the interests of private applicants.

86. At the hearing, the representative of the Council, responding to a question, remarked that the decisions on the composition of the positive lists are of general application and that it was not necessary, therefore, to accord procedural rights to individual interested parties at the preparatory stage. That position, it would appear to me, is based on a misunderstanding. Even though decisions relating to the extension or the shortening of the positive lists have effect erga omnes,<sup>1</sup> plainly they may also affect the vital interests of individual parties. In order to ensure that these interests are taken into account in the decision-making process in a manner which is open to judicial scrutiny, the basic legislative act ought for that purpose to provide for the minimal guarantee of an adequate procedure...

87. The claimants in the main proceedings in this case observed, in both their written and their oral submissions, that preparing an 'admissible' application...is a costly matter and that the final decision – or the lack of such a decision – may have the consequence that the company concerned will have to cease (part of) its economic activities. These observations were not contradicted...The Directive does not comply with essential requirements of legal protection, of legal certainty and of sound administration, which are basic principles of Community law. Thus, lacking appropriate and transparent procedures for its application, the Directive infringes the principle of proportionality. It is, therefore, invalid.

88. ...In a Community of law, such as the European Union...there are two aspects to a

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<sup>1</sup> Towards all.

legislative act as an expression of the legislature's will. On the one hand, it is an instrument for pursuing and, if possible, achieving justified objectives of public interest. On the other hand, it constitutes a guarantee of citizens' rights in their dealings with public authority. Qualitatively adequate legislation is characterised by a balance between both aspects. The wording and the structure of the legislative act must strike an acceptable balance between the powers granted to the implementing authorities and the guarantees granted to citizens. Directive 2002/46 does not comply with this essential quality requirement of proper legislation.

Are these paragraphs of the opinion consistent with the cases you have read in terms of the concern for "citizens' rights in their dealings with public authority" (para 88)? Would better procedures necessarily solve the problems associated with the positive list? Do you think that the ECJ should follow Advocate General Geelhoed's approach?

**3. (15 points)** The Alliance for Natural Health waited until the UK adopted implementing regulations before challenging the directive in the English Courts. Could they have challenged the directive before that point? *Should* they have been able to challenge the directive before that point?

**4. (25 points)** Arcadia, a Member State of the EU, has not taken any steps at all to implement the directive. In Arcadia, Teaforlife sells herbal teas fortified with vitamins and minerals and advertises its products widely on television and in newspapers and magazines. Teaforlife claims that its products make those who use them more energetic, and help them to resist and recover from various illnesses. Brenda has complained to the Arcadian Medical Foundation (AMF) about what she sees as Teaforlife's misleading claims. Arcadia has a general consumer protection statute which makes it a criminal offence to make fraudulent claims about products sold to consumers, but the Arcadian courts have not in the past been willing to interpret this statute to cover the sort of claims Teaforlife has been making in its advertisements. What can Brenda, and/or the Arcadian Medical Foundation do to stop Teaforlife making the same sort of claims in future?

## **Article 95 (ex Article 100a)**

1. ...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...
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.