OPINION OF ADVOCATE GENERAL KOKOTT

delivered on 8 September 2005 [1]

I — Introduction

1. Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods ('the Regulation') [2] does not regulate directly which smoke flavourings may be used in the internal market. It essentially provides for a procedure in which the Commission authorises 'primary products' for the production of smoke flavourings. The substances authorised are entered in a positive list annexed to the Regulation.

2. The parties are in dispute as to whether Article 95(1) EC allows the introduction of such 'multi-step' legislative models or only permits measures which themselves directly approximate the laws of the Member States. It is also disputed whether the powers of the Commission in this procedure are sufficiently precisely regulated.

II — Legal background and context

3. The legal basis of the Regulation is Article 95 EC, which — in extract — reads as follows:

'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.

...

1 — Original language: German.

2 — OJ 2003 L 309, p. 1.

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.'

4. The delegation of implementing powers to the Commission is governed by the third indent of Article 202 EC:

'To ensure that the objectives set out in this Treaty are attained the Council shall, in accordance with the provisions of this Treaty:

...

— confer on the Commission, in the acts which the Council adopts, powers for the implementation of the rules which the Council lays down. The Council may impose certain requirements in respect of the exercise of these powers. The Council may also reserve the right, in specific cases, to exercise directly implementing powers itself. The procedures referred to above must be consonant with principles and rules to be laid down in advance by the Council, acting unanimously on a proposal from the Commission and after obtaining the opinion of the European Parliament.'

5. The production of smoke flavourings is described in recital 7 in the preamble to the Regulation:

'... The production of these smoke flavourings starts with the condensation of smoke. The condensed smoke is normally separated by physical processes into a water-based primary smoke condensate, a water-insoluble high-density tar phase and a water-insoluble oily phase. The water-insoluble oily phase is a by-product and unsuitable for the production of smoke flavourings. The primary smoke condensates and fractions of the water-insoluble high-density tar phase, the "primary tar fractions", are purified to remove components of smoke which are most harmful to human health. They may then be suitable for use as such in or on foods or for the production of derived smoke flavourings made by further appropriate

physical processing such as extraction procedures, distillation, concentration by evaporation, absorption or membrane separation and the addition of food ingredients, other flavourings, food additives or solvents, without prejudice to more specific Community legislation.'

6. On the risks of smoke flavourings, recital 6 in the preamble observes:

'The chemical composition of smoke is complex and depends among other things on the types of wood used, the method used for developing smoke, the water content of the wood and the temperature and oxygen concentration during smoke generation. Smoked foods in general give rise to health concerns, especially with respect to the possible presence of polycyclic aromatic hydrocarbons. Because smoke flavourings are produced from smoke which is subjected to fractionation and purification processes, the use of smoke flavourings is generally considered to be of less health concern than the traditional smoking process. However, the possibility of wider applications of smoke flavourings in comparison to conventional smoking has to be taken into account in safety assessments.'

7. Recital 8 in the preamble explains the difficulties of scientific evaluation of smoke flavourings:

'The Scientific Committee on Food concluded that because of the wide physical and chemical differences in smoke flavourings used for flavouring food, it is not possible to design a common approach to their safety assessment and, accordingly, toxicological evaluation should focus on the safety of individual smoke condensates.'

8. A smoke flavouring or a food with a smoke flavouring may, under Article 4(2) of the Regulation, be placed on the market only if the Commission, in accordance with the Regulation, has authorised the primary product from which it is derived.

9. Article 3 of the Regulation defines 'primary products' as primary smoke condensates and primary tar fractions. These primary products are the subject of the authorisation procedure laid down in the Regulation. Authorisation is decided on by the Commission on application by the

producer, with the participation of a regulatory committee [3] and the European Food Safety Authority ('the Food Safety Authority'). [4] It must evaluate a primary product on application and either add it, by an implementing regulation, to the list of authorised smoke flavourings ('the positive list') or refuse authorisation by means of a decision addressed to the applicant.

10. The conditions for authorisation are defined as follows in Article 4(1) of the Regulation:

'The use of smoke flavourings in or on foods shall only be authorised if it is sufficiently demonstrated that

— it does not present risks to human health,

— it does not mislead consumers.'

11. Under Article 9 of the Regulation, the Commission can take 'other legitimate factors relevant to the matter under consideration' into account when making its decision.

12. In addition, under Article 5 of the Regulation, the wood used for the production of primary products must not have been treated, whether intentionally or unintentionally, with chemical substances during the six months immediately prior to felling or subsequent thereto, unless it can be demonstrated that the substance used for the treatment does not give rise to potentially toxic substances during combustion. Annex I to the Regulation contains additional requirements for the production process and maximum values of benzo[a]pyrene and benz[a]anthracene.

3 — See Article 5 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (the comitology decision), OJ 1999 L 184, p. 23. The committee consists of representatives of the Member States. If the Commission's planned measure is not supported in that committee by a qualified majority, the Commission must refer it to the Council. The Council can reject the measure or adopt it. If the Council is silent, the Commission can adopt the implementing measure itself after the expiry of a period of three months.

4 — The Food Safety Authority was created by 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 (OJ 2002 L 31, p. 1).

III — Forms of order sought by the parties

13. The United Kingdom of Great Britain and Northern Ireland, by application of 11

February 2004, received at the Court on 16 February 2004, brought an action against the European Parliament and the Council of the European Union under Article 230 EC, asking the Court to:

1. declare that Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods is invalid;

2. order the European Parliament and the Council of the European Union to pay the United Kingdom's costs.

14. The European Parliament and the Council of the European Union contend that the Court should:

1. dismiss the application and

2. order the United Kingdom to pay the costs.

15. The Commission of the European Communities, by order of the President of the Court of 24 June 2004 pursuant to the first paragraph of Article 40 of the Statute of the Court and Article 93(1) of the Rules of Procedure, was given leave to intervene in support of the Parliament and the Council. It supports the forms of order sought by the Parliament and the Council.

IV — Legal assessment

16. The action primarily raises the question whether Article 95(1) EC is the correct legal basis for the Regulation. The United Kingdom also casts doubt, however, on the proportionality of its legislative model. Finally, the United Kingdom argues that the Regulation is in breach of the third indent of Article 202 EC, as it delegates core functions of the approximation of laws to the Commission: only 'implementation' may be delegated.

A — *Article 95(1) EC as legal basis of the Regulation*

17. Under Article 95(1) EC, the Council is to 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.

18. Article 95(1) EC is a possible legal basis only if it is actually apparent from the legal act, in a way which is objectively reviewable, [5] that its purpose is to improve the conditions for the establishment and functioning of the internal market. [6]

19. That is so in the present case. Under the Regulation, authorised primary products may be used throughout the Community. As the Commission submits, without being contradicted, previously there were authorisation procedures of the Member States, which could at least potentially have divergent results, which could affect the free movement of primary products, the flavourings produced from them and the foodstuffs treated with those flavourings, and distort free competition. In so far as primary products will in future have to be withdrawn from the market on the basis of the Regulation, this is justified by the protection of health, for which Article 95(3) EC prescribes a high level of protection.

20. However, Article 95(1) EC allows exclusively 'measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States'. This formulation is the subject of differing interpretations by the parties. The different points of view may be summarised as follows:

21. From the point of view of the United Kingdom, the 'measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States' must be directed to the laws of the Member States: Article 95(1) EC cannot be used for measures that would go beyond what is possible for the Member States. The decisive question is therefore whether or not a measure is aimed at a result which could have been achieved by the simultaneous enactment of identical legislation in the Member States.

22. According to the United Kingdom, the answer in the present case must be in the negative, since the Regulation does not introduce any material criteria for the approximation of legislation of the Member States and does not establish any harmonised standards in national law. Instead it creates a centralised authorisation procedure at Community level which confers on the Commission and the Food Safety Authority the task of drawing up a positive list of smoke flavourings. Such a measure could not be taken by the legislatures of the Member States, even by simultaneously adopting national laws with the same content as the Regulation. Article 95(1) EC is therefore the wrong legal basis for the Regulation. Article 308 EC should have been used as legal basis instead.

5 — Case C-300/89 *Commission* v *Council (Titanium dioxide)* [1991] ECR I-2867, paragraph 10, and Case C-110/03 *Belgium* v *Commission* [2005] ECR I-2801, paragraph 78.

6 — See Case C-376/98 *Germany* v *Parliament and Council (Tobacco advertising)* [2000] ECR I-8419, paragraphs 84 and 85

23. The United Kingdom's argument on the interpretation of Article 95(1) EC corresponds to a view that is widespread, especially in German legal writing, and is likewise based on the passage 'for the approximation of the provisions laid down by law, regulation or administrative action in Member States', but as a rule sees the main problem as a 'usurpation' by the Community of the administrative powers of the Member States. [7]

24. According to the institutions that are parties to the proceedings, on the other hand, Article 95(1) EC allows such multi-stage measures. A measure such as the present one must not be looked at in isolation, but taken together with the implementing measures adopted on its basis. The Regulation does indeed have the result of bringing about an approximation, in the form of the positive list of authorised primary products to be drawn up by the Commission on the basis of the Regulation. This interpretation too has its supporters in legal writing. [8]

25. Taking these arguments into account, it must be pointed out that the contested regulation itself does *not* bring about any direct approximation of the laws of the Member States. In so far as it contains material standards, they are directed to the Commission for drawing up a positive list. Only an implementing regulation of the *Commission* based on the Regulation could be an approximation measure in the form of a positive list. The Regulation therefore at most regulates an intermediate step on the way to an approximation of the laws of the Member States on the use of smoke flavourings.

26. It must therefore be examined whether Article 95(1) EC allows the establishment of such multi-stage legislative models, or permits only measures that themselves directly approximate the laws of the Member States.

7 — See Wyatt, D. and Dashwood, A., *European Union Law*, 4th ed., Sweet & Maxwell, London 2000, p. 521; Müller-Graff, P.-C., 'Die Rechtsangleichung zur Verwirklichung des Binnenmarktes', *Europarecht*, Beck, Munich 1989, p. 107, 129; von Borries, R., 'Verwaltungskompetenzen der Europäischen Gemeinschaft', *Festschrift für Ulrich Everling*, vol. 1, 1995, p. 127, 128 ff.; Ludwigs, M., *Rechtsangleichung nach Artikel 94, 95 EG-Vertrag*, Nomos, Baden-Baden 2004, pp. 236 ff.; Schreiber, S., *Verwaltungskompetenzen der Europäischen Gemeinschaft*, Nomos, Baden-Baden 1997, pp. 122 ff.; Biervert, B., *Der Missbrauch von Handlungsformen im Gemeinschaftsrecht*, Nomos, Baden-Baden 1999, pp. 146 ff.; Klepper, M., *Vollzugskompetenzen der Europäischen Gemeinschaft aus abgeleitetem Recht: Zulässigkeit, Modalitäten, Rechtsfolgen*, Nomos, Baden-Baden 2001, pp. 62 ff.; and Wahl, R. and Groß, D., 'Die Europäisierung des Genehmigungsrechts am Beispiel der Novel Food-Verordnung', *Deutsches Verwaltungsblatt*, Rechts- und staatswissenschaftlicher Verlag, Hamburg 1998, pp. 2 ff.

8 — See Pipkorn, J., Bardenhewer-Rating, A. and Taschner, H.-C., 'Artikel 95 EG — Angleichung von Vorschriften mit Bezug auf den Binnenmarkt', in von der Groeben, H. and Schwarze, J., *Kommentar zum Vertrag über die Europäische Union und zur Gründung der Europäischen Gemeinschaften*, vol. 2, 6th ed., Nomos, Baden-Baden 2003, paras 36 ff.; Herrnfeld, H.-H., 'Artikel 95 EGV — Angleichung der Rechtsvorschriften', in Schwarze J., *EU-Kommentar*, Nomos, Baden-Baden 2000, paras 23 and 37; Leible, S., 'Artikel 95 EGV', in Streinz, R., *EUV/EGV — Vertrag über die Europäische Union und Vertrag zur Gründung der Europäischen Gemeinschaft*, Beck, Munich 2003, paras 28 f.; and Streinz, R., 'Die EG-Verordnung über neuartige Lebensmittel und neuartige Lebensmittelzusätze — Eine Analyse der Novel Food-Verordnung', *Europäische Zeitschrift für Wirtschaftsrecht*, Beck, Munich 1997, p. 487, 490.

27. It is not disputed that the term 'measure' used in Article 95(1) covers at least all the forms of legal acts in Article 249 EC, in other words regulations, directives, decisions and opinions. The adoption of a regulation on the basis of Article 95(1) EC is therefore formally covered.

28. However, the United Kingdom concentrates on the individual components of the rest of the passage, focusing especially on the elements 'approximation' and 'in Member States':

29. It argues that Article 95(1) confers power to *approximate* the provisions laid down by law, regulation or administrative action in Member States. The concept of 'approximation' thus already refers to laws of the Member States, since Community law with its uniform validity does not need any approximation. A directive is precisely for that reason the classic approximating measure, as it requires the Member States to adapt their law to Community requirements. A regulation as a form of action goes beyond that, in that it displaces the laws of the Member States by directly applicable Community law, but its effect of making the law uniform may still be regarded as the 'most intensive form' of approximation. Decisions addressed to Member States can also bring about an approximation of laws of the Member States. A common feature of the measures is that they bring about the adaptation or substitution of potentially divergent laws of the Member States. The subject of measures for the approximation of laws can accordingly be only what the Member States could potentially regulate themselves under their own powers.

30. It further argues that Article 95(1) EC confers power to approximate the provisions laid down by law, regulation or administrative action *in Member States*. From the reference to the laws of the Member States it may likewise be concluded that the Community is empowered only to take measures that are also within the possibilities available to the laws of the Member States.

31. The United Kingdom's view is convincing to the extent that the wording, by mentioning 'approximation' of the provisions laid down by law, regulation or administrative action 'in Member States', calls for a reference by the (harmonisation) measures taken to national law. Such a reference exists if, by means of provisions of Community law that are to be transposed, approximated national laws come into being in all the Member States. But Community law with direct and superior effect, which displaces or prevents national law that diverges from it, also has that reference to national law. Purely Community measures which take effect *alongside* the law of a Member State without altering its normative content, on the other hand, do not in fact

effect any approximation of the laws of the Member States. This was decided by the Court with respect, for instance, to new intellectual property rights which took effect alongside the existing national rights. [9]

32. However, all that follows from this necessary reference to the laws of the Member States is that the measures must *approximate* the laws of the Member States. Conditions as to the manner of approximation — how it must be done and what it must relate to — cannot be derived solely from those two components of the passage.

33. The institutions are correct in so far as they deduce from the expression 'Maßnahmen *zur* Angleichung' ('measures *for the* approximation') that these measures need not themselves directly approximate the laws of the Member States. Unlike formulations such as 'Angleichungsmaßnahmen' ('approximation measures'), 'angleichende Maßnahmen' ('approximating measures') or 'Maßnahmen, die ... angleichen' ('measures which approximate'), that wording allows for intermediate steps. Other language versions, such as the French, English, Spanish, Italian and Portuguese versions, confirm that distinction. [10] Provided, then, that a measure merely serves as a whole for the approximation of the law of the Member States, it can provide for procedures which do not bring about approximation directly but only in a multi-stage model with intermediate steps.

34. This — contrary to the view of the United Kingdom — does not contradict the interpretation of the two elements of the *approximation* of the laws *of the Member States*. The institutions recognise the requirement for a reference to the laws of the Member States, but see more possibilities than the United Kingdom does of achieving that aim.

35. The positive list aimed at by the Regulation, to be established by means of implementing regulations, has the effect of displacing the relevant laws of the Member States or preventing them from coming into existence. It thus — as the United Kingdom recognises — as a whole displays an approximating reference to the laws of the Member States.

36. The connection with other provisions of the Treaty also confirms the permissibility of a multi-stage model of approximation of laws. The third indent of Article 202 EC contains the basic principle that measures of the Community legislature need not be conclusive and may instead provide for implementing measures on the part of the Commission. Neither Article 202 EC nor Article 95 EC contains particular restrictions

9 — See Case C-377/98 *Netherlands* v *Parliament and Council* [2001] ECR I-7079, paragraphs 24 and 25; Case C-350/92 *Spain* v *Council* [1995] ECR I-1985, paragraph 23; and Opinion 1/94 (Competence of the Community to conclude international agreements concerning services and the protection of intellectual property) [1994] ECR I-5267, paragraph 59.

10 — In French the passage is 'mesures relatives au rapprochement', in English 'measures for the approximation', in Spanish 'medidas relativas a la aproximación', in Italian 'misure relative al ravvicinamento', and in Portuguese 'medidas relativas à aproximação'.

of the power to delegate for provisions under Article 95(1) EC. Rather, as the Parliament correctly observes, paragraphs 4 and 5 of Article 95 EC presuppose the 'adoption ... by the Commission of a harmonisation measure'. Article 95 EC therefore ascribes to the Commission's implementing measures under Article 202 themselves the quality of harmonisation measures.

37. Contrary to the United Kingdom's submissions referring to the judgment on the customs information system, [11] the approximating effect of the procedure laid down for the drawing up of a positive list by the Commission is also not so remote that it may be regarded as a mere incidental effect of the measure. In fact, the approximation of laws is the sole purpose of the procedure laid down for drawing up a positive list.

38. The United Kingdom is also mistaken in asserting that the Regulation creates a Community body and that that is not possible on the basis of Article 95 EC. A procedure that is carried out by an institution set up by the Treaty cannot be equated with the creation of a new Community body. [12]

39. Nor can the finding of a multi-stage procedure for the approximation of laws be objected to on the ground that the Regulation confers on the Commission implementing powers which the Treaty reserves to the Member States. [13] Regardless of the question whether Community law — in common, for example, with German constitutional law — recognises such a division of legislative and implementing powers, [14] this objection fails in relation to the Regulation at issue in the present case. The procedure for the authorisation of primary products does contain administrative elements, but on the basis of the result to be aimed at — the general, Community-wide authorisation of certain primary products — it must be regarded as a whole as legislation. Implementing functions also, to a considerable extent, remain with the Member States: the inclusion of a primary product in the positive list does not entail marketing authorisations for the end products. This still remains within the Member States' competence. They are merely prevented from prohibiting the use of authorised primary products for smoke flavourings, and must prohibit the marketing of smoke flavourings based on non-authorised primary products.

40. In summary, then, the conclusion must be that Article 95(1) EC is the correct legal basis for the Regulation, since that provision allows the introduction of multi-stage nor-

11 — Case C-209/97 *Commission* v *Council* [1999] ECR I-8067, paragraph 35 et seq.

12 — Whether Article 95 EC makes it possible to create new Community bodies is to be clarified in the pending Case C-217/04 *United Kingdom* v *Parliament and Council* concerning the European Network and Information Security Agency.

13 — On this argument, see point 23 above.

14 — A negative answer is given by the judgment in Case C-359/92 *Germany* v *Council* [1994] ECR I-3681, paragraph 38.

mative procedures such as the Regulation that have the *result* of bringing about an approximation of the laws of the Member States.

B — *The United Kingdom's other arguments*

41. In the further course of the proceedings the United Kingdom developed arguments relating not to the legal basis of the Regulation but to its proportionality with reference to the powers of the Member States and the limits of delegation under Article 202 EC.

42. As the Commission and the Council submit with reference to delegation, however, those submissions are out of time in both respects, in accordance with Article 42 (2) of the Rules of Procedure. They are new pleas which were adduced only in the reply and the response to the Commission's statement in intervention. The application does not mention either proportionality or a possible infringement of the limits of possible delegation. If the United Kingdom had had such concerns, it would be incomprehensible how, in the application, it could have considered the adoption of the Regulation on the basis of Article 308 EC to be fully permissible. In so far as the United Kingdom has argued from the outset that a regulation based on Article 95 EC must prescribe material standards, that argument relates exclusively to the question whether the Regulation can be regarded as a measure for the approximation of laws.

43. I shall therefore consider the proportionality of the Regulation and the possibilities of delegation only in the alternative.

1. Proportionality of the Regulation

44. Article 5 EC, which lays down the principle of limited specific empowerment in its first paragraph and the principle of subsidiarity in its second paragraph, requires in its third paragraph that action by the Community must not go beyond what is necessary to achieve the objectives of that Treaty. This is an expression of the principle of proportionality in terms of the law of competence. In accordance with that principle, which is one of the general principles of Community law, the acts of the Community institutions must not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the legislation in question. Where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must

not be disproportionate to the aims pursued. [15]

45. Since what is involved is the relationship between Community measures and competences of the Member States, it must be considered whether the aims of the Regulation could not be pursued by other equally effective provisions leaving more responsibility to the Member States.

46. It must be taken into account, however, that the Community legislature has a broad discretion when political, economic and social decisions requiring complex evaluations are to be made. [16] That is the case with the subject of legislation at issue here. Marketing authorisation for smoke flavourings for use in foods requires complex assessments which, in relation to the production and marketing of flavourings of a commercial nature and to the protection of human health, are of a scientific and social nature.

47. There is no indication to be seen in the present case that the Community legislature overstepped the limits of that discretion. On the contrary, everything suggests that the solution chosen is, of the various conceivable regulatory models, the most appropriate for achieving its aim. A directive prescribing standards for the Member States for the authorisation of smoke flavourings and providing for the mutual recognition of authorisations could not be adopted, since, according to recital 8 in the preamble to the Regulation, a uniform procedure for assessing the safety of primary products for smoke flavourings is impossible for scientific and objective reasons, so that toxicological evaluation must focus on the safety of *individual* smoke condensates. A 'coordination solution' [17] under which the Member States issue authorisations which are automatically recognised in all the other Member States if no objection is made would precisely, in the absence of common standards, have led to conflicts between Member States, which

15 — See Joined Cases C-96/03 and C-97/03 *Tempelman and van Schaijk* [2005] ECR I-1895, paragraph 47; Case C-189/01 *Jippes and Others* [2001] ECR I-5689, paragraph 81; Joined Cases C-27/00 and C-122/00 *Omega Air and Others* [2002] ECR I-2569, paragraph 62; Case C-112/00 *Schmidberger* [2003] ECR I-5659, paragraph 79; and Case C-220/01 *Lennox* [2003] ECR I-7091, paragraph 76.

16 — See most recently Case C-210/03 *Swedish Match* [2004] ECR I-1189, paragraph 47 et seq.

17 — See Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs (OJ 1996 L 299, p. 1); 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 (OJ 2002 L 31, p. 1); Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ 1998 L 123, p. 1); Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ 2004 L 104, p. 1); Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1); Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67); and European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs (OJ 1994 L 237, p. 3).

would then have had to be settled by the Commission. The immediate determination of a positive list in the co-decision procedure, that is, by the Parliament and the Council on a proposal by the Commission, as the United Kingdom ultimately recommends, would restrict the competences of the Member States just as much as the solution chosen, and would at the same time make the procedure for the authorisation of smoke flavourings considerably clumsier and if anything reduce the rights of participation of manufacturers.

48. For the above reasons, the 'disadvantages' for the competences of the Member States are proportionate to the aims of Article 95(1) EC and of the Regulation.

49. The Regulation therefore complies with the requirements of proportionality.

2. The limits of delegation under Article 202 EC

50. In accordance with the third indent of Article 202 EC and the fourth indent of Article 211 EC, competence is normally to be conferred on the Commission to implement secondary law. [18] To assess the lawfulness of a delegation of powers to the Commission, the Court distinguishes between provisions that are essential for the matter to be regulated and must therefore be reserved to the basic instrument and provisions that are only of an implementing nature and can thus be left to the Commission to adopt. [19] Consequently, as the United Kingdom correctly assumes, the decisive point here is whether the delegated powers are to be reckoned to the 'essential elements of the matter to be regulated' or to the sphere of 'implementation'.

51. The United Kingdom doubts that the essential elements of the matter to be regulated are, in the present case, determined in the basic regulation. It says that the Council and the Parliament did not lay down material standards for the approximation of laws, but only conferred on the Commission the task of elaborating the material criteria for regulating the matter.

52. Against that argument, it must be countered that the Court interprets the concept of 'essential elements of the matter

18 — The Court has made it clear that the new version of the wording now provides for this normal delegation: see Case 16/88 *Commission* v *Council* [1989] ECR 3457, paragraph 10.

19 — See Case C-240/90 *Germany* v *Commission* [1992] ECR I-5383, paragraph 36; Joined Cases C-63/90 and C-67/90 *Portugal and Spain* v *Council* [1992] ECR I-5073, paragraph 14; Case 46/86 *Romkes* [1987] ECR 2671, paragraph 16; Case 230/78 *Eridania* [1979] ECR 2749, paragraph 7; and Case 25/70 *Köster* [1970] ECR 1161, paragraph 6.

to be regulated' very strictly, and regards as such only the provisions intended to give shape to the fundamental guidelines of Community policy. [20] Its settled case-law correspondingly interprets the concept of 'implementation' very widely [21] and thereby enables the Council to confer extensive powers on the Commission. [22]

53. In its wide interpretation of the concept of implementation, the Court relies firstly on the overall context of the EC Treaty and secondly on practical requirements, especially in the agricultural market and in connection with the law of foreign trade. It considers that only the Commission is in a position to track developments in agricultural or international markets, as the case may be, constantly and attentively and act with the swiftness called for by the situation. [23]

54. In accordance with that approach, the Court has so far as a rule required only very little as to the degree of definiteness of a delegation of powers to the Commission. Thus it has held that the Commission may be delegated a general power to regulate the detailed rules for the application of provisions. In particular, the essential elements of the delegated powers do not have to be specified precisely: provisions drafted in general terms have also provided a sufficient basis for authority to act in the particular case. [24] Such general conferments of power read, for example: 'Detailed rules for the application of this Regulation ... shall be adopted in accordance with the procedure ...'. [25]

55. Such an indefinite delegation would not be acceptable in the present case. This case does not concern fields such as the agricultural market, which are fast-moving and at the same time characterised by intensive interventions on the part of the Community. Rather, on the basis of scientific assessments, a balance is to be struck, once only, for each primary product between the commercial freedom of action of undertakings and the protection of health and consumers in the internal market. This balancing exercise does not require flexibility and rapidity but a careful investigation and evaluation of all the relevant information.

20 — See Case C-356/97 *Molkereigenossenschaft Wiedergeltingen* [2000] ECR I-5461, paragraph 21, and *Germany* v *Commission*, cited in footnote 19, paragraphs 36 and 37.

21 — See Case C-159/96 *Portugal* v *Commission* [1998] ECR I-7379, paragraph 40; Case 23/75 *Rey Soda* [1975] ECR 1279, paragraph 10; Joined Cases C-9/95, C-23/95 and C-156/95 *Belgium and Germany* v *Commission* [1997] ECR I-645, paragraph 36; Case 22/88 *Vreugdenhil* [1989] ECR 2049, paragraph 16; Case C-478/93 *Netherlands* v *Commission* [1995] ECR I-3081, paragraph 30; and Joined Cases 279/84, 280/84, 285/84 and 286/84 *Walter Rau* [1987] ECR 1069, paragraph 14.

22 — See *Belgium and Germany* v *Commission*, cited in footnote 21, paragraph 36; *Vreugdenhil*, cited in footnote 21, paragraph 16; *Netherlands* v *Commission*, cited in footnote 21, paragraph 30; and *Walter Rau*, cited in footnote 21, paragraph 14.

23 — See, on the agricultural market, *Belgium and Germany* v *Commission*, cited in footnote 21, paragraph 36, *Vreugdenhil*, cited in footnote 21, paragraph 16, and *Rey Soda*, cited in footnote 21, paragraphs 10 and 14; and, on the law of foreign trade, *Portugal* v *Commission*, cited in footnote 21, paragraph 40 et seq.

24 — See Case C-374/96 *Vorderbruggen* [1998] ECR I-8385, paragraph 36; *Germany* v *Commission*, cited in footnote 19, paragraph 41; Case C-48/98 *Sohl & Sohlke* [1999] ECR I-7877, paragraph 34; and *Molkereigenossenschaft Wiedergeltingen*, cited in footnote 20, paragraph 23.

25 — See, for instance, Article 12 of Council Regulation (EEC) No 768/89 of 21 March 1989 establishing a system of transitional aids to agricultural income (OJ 1989 L 84, p. 8), which was the basis of the judgment in *Germany* v *Commission*, cited in footnote 19.

56. Moreover, respect for the Parliament's rights of participation, which even the Parliament itself may not relinquish unduly, and the danger of circumventing the legislative procedure prescribed in the Treaty argue in favour of stricter requirements for delegation. By contrast with the committee procedure (comitology) provided for here, in which the Parliament can participate only theoretically and in exceptional cases, [26] the procedure under Article 95 EC is characterised by greater transparency and markedly increased democratic legitimacy.

57. Even applying the stricter standards in certain sectors for which there are indications in the case-law, [27] the delegation in the present case is lawful. Articles 4 and 5 of the Regulation in particular, in conjunction with Annex I, state adequately the aims and subject-matter of the matter to be regulated. They thereby serve at the same time, as the institutions rightly submit, to implement the fundamental guidelines of Community policy in this field, and consequently determine the essential features of the matter to be regulated. Furthermore, the Regulation contains precise provisions as to how the delegated powers are to be exercised.

58. Article 4(1) defines the three essential conditions under which smoke flavourings may be authorised and used in connection with foods. They must not present risks to human health, must not mislead consumers, and must if appropriate comply with specific conditions of use. Article 4(2) accordingly prohibits the marketing of smoke flavourings which are not authorised or which do not adhere to the conditions of use.

59. The institutions which are parties to the proceedings correctly observe that Article 3 of the Regulation and recitals 7, 11 and 17 in its preamble make reference to Directive 88/388/EEC [28] and Regulation (EC) No 178/2002, [29] which give the general concepts in the Regulation a context that provides them with a technical background and thereby makes them specific. Article 4 of Directive 88/388/EEC and Articles 3, 5, 14 and 16 of Regulation (EC) No 178/2002 in

26 — See Article 8 of the comitology decision, cited in footnote 3, according to which the Parliament can call on the Commission to re-examine draft implementing measures on the ground that the limits of delegation have been exceeded. In 2000 and 2001 the Parliament made use of this possibility only once, in 2000 (see the Reports from the Commission on the working of the committees during 2000 and 2001, COM (2001) 783 final of 20 December 2001, p. 6 et seq., and COM (2002) 733 final of 13 December 2002, p. 4 et seq.).

27 — See Case 291/86 *Central-Import* [1988] ECR 3679, paragraph 13; *Vreugdenhil*, cited in footnote 21, paragraph 17; and the reinforcement of the normative content of the comitology decision, cited in footnote 3, by the judgment in Case C-378/00 *Commission* v *Parliament and Council* [2003] ECR I-937, paragraph 40 et seq., Article 1(1) of which requires the basic instrument to stipulate the essential elements of the powers conferred.

28 — Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production, OJ 1988 L 184, p. 61.

29 — 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, OJ 2002 L 31, p. 1.

particular offer more precise indications as to when a foodstuff does not present a risk to human health and when consumers are not misled. Whether these may actually be recognised as technical terms, as the Parliament submits, may be left open; in any event the terms are adequately defined.

60. Furthermore, the Commission has emphasised, without being contradicted, that the method of production of the primary products has decisive influence on the potential toxic effect of smoke flavourings. For the production of primary products, Article 5 therefore prohibits the use of chemically treated wood, unless it can be demonstrated that it is not dangerous. Annex I further specifies the conditions for the production of primary products, with respect to additives, heat treatment and chemical and physical processes for obtaining condensates and phases and their further treatment. Maximum contents are also given for two substances. Annex II gives further substantive indications in its references to the information relevant for the assessment.

61. The Regulation thus lays down specific, in any case sufficiently definite criteria for the method of production of the primary products, and regulates noticeably more than just the essential features of the matter. Everything else, in particular the elaboration of specific criteria of protection of health and consumers in the sphere of Article 4 of the Regulation, may very well — contrary to the United Kingdom's view — be allocated to the broad area of 'implementation' as interpreted in the case-law of the Court. The implementing provisions and detailed rules of application which the Commission can adopt under delegated powers include precisely the determination of the preconditions, extent, and the other conditions for the application of general rules to individual cases. [30]

62. Moreover, the Commission has convincingly shown that practical and legal necessities prevented regulating in further detail in the Regulation itself, for example in the form of a positive list of all permissible primary products. Recital 8 in the preamble to the Regulation explains, to that effect, that a uniform procedure for the safety evaluation of primary products for smoke flavourings is not possible, for objective, scientific reasons.

63. In this respect, it must also be taken into account in particular that Article 95(3) EC and the first subparagraph of Article 152(1) EC demand a high level of protection of health. But if potential toxic effects of smoke flavourings depend so decisively on their components and proportions that what essentially matters are the primary products

30 — See *Commission* v *Council*, cited in footnote 18, paragraphs 10 and 11, and *Sohl & Sohlke*, cited in footnote 24, paragraph 34.

and their method of production, a list of authorised primary products can be drawn up only on the basis of toxicological evaluations in the individual case. [31] Since it is clear, furthermore, that every single one of the products may be specific in its method of production, chemical composition and toxicological characteristics, it is understandable that every authorisation must lay down individual conditions of use.

64. In the light of the information available on the purposes of the Regulation, its subject-matter and the relevant criteria, it is also unproblematic that under Article 9(1) the Commission has to take into account when making its assessment, as well as the requirements of Article 4(1) and Community law, also 'other legitimate factors relevant to the matter'. What may legitimately be included under 'factors' can be sufficiently delimited by reference to the general main aims of the present basic regulation, the aims of the legal basis in Article 95(1) EC, the criteria laid down and the regulatory context.

65. In the two central material aspects of the matter to be regulated, the fundamental safety requirements for the use and marketing of smoke flavourings and the conditions of production, the Regulation consequently sets out the essential features of the measures of approximation of laws, with sufficient certainty as to the main elements of the delegated powers.

66. Finally, the Regulation lays down in Articles 6, 8 to 12 and 19 how the Commission is to exercise the delegated powers. Its task is to draw up a positive list of authorised primary products. The procedural provisions provide that the Commission is to evaluate the primary products on the basis of the material criteria with the assistance of the Food Safety Authority, and to decide on inclusion in the list with the participation of the regulatory committee. The type, effects, duration, modification, suspension, revocation and renewal of authorisations are referred to, as are the effects of a refusal.

C — *Summary conclusions*

67. In conclusion, then, it may be stated that Article 95(1) EC is an adequate legal basis for the Regulation, its regulatory model is proportionate, and the delegation of imple-

31 — For that reason, it is said, it was also necessary to call on undertakings to submit detailed applications for their products available on the market, which incidentally also reduces the anticipated number of such products to fewer than 20.

menting powers to the Commission is within the sphere of what is permissible under the third indent of Article 202 EC. The action must therefore be dismissed.

V — Costs

68. Under Article 69(2) of the Rules of Procedure, the unsuccessful party must pay the costs if they have been applied for in the other party's pleadings. Since the Parliament and the Council have in the present case made an application within the meaning of Article 69(2) of the Rules of Procedure and the United Kingdom, in accordance with the foregoing considerations, is unsuccessful, the United Kingdom must be ordered to pay the costs.

69. Under Article 69(4) of the Rules of Procedure, institutions which intervene in the case are to bear their own costs. The Commission must therefore bear its own costs.

VI — Conclusion

70. On the basis of the foregoing considerations, I propose that the Court should:

(1) Dismiss the action;

(2) Order the United Kingdom to pay the costs, except for those incurred by the Commission, and order the Commission to bear its own costs.