JUDGMENT OF THE COURT (Grand Chamber)

6 December 2005 *

In Case C-66/04,

ACTION for annulment under Article 230 EC, brought on 11 February 2004,

United Kingdom of Great Britain and Northern Ireland, represented by R. Caudwell and M. Bethell, acting as Agents, and Lord Goldsmith QC, N. Paines QC and T. Ward, Barrister, with an address for service in Luxembourg,

applicant,

v

European Parliament, represented by K. Bradley and M. Moore, acting as Agents, with an address for service in Luxembourg,

* Language of the case: English.

Council of the European Union, represented by M. Sims, E. Karlsson and F. Ruggeri Laderchi, acting as Agents,

defendants,

supported by:

Commission of the European Communities, represented by J.-P. Keppenne, N. Yerrel and M. Shotter, acting as Agents, with an address for service in Luxembourg,

intervener,

THE COURT (Grand Chamber),

composed of V. Skouris, President, P. Jann, C.W.A. Timmermans, A. Rosas and K. Schiemann, Presidents of Chambers, S. von Bahr, J.N. Cunha Rodrigues, R. Silva de Lapuerta (Rapporteur), K. Lenaerts, P. Kūris, E. Juhász, A. Borg Barthet and M. Ilešič, Judges,

Advocate General: J. Kokott,
Registrar: K. Sztranc, Administrator,

having regard to the written procedure and further to the hearing on 3 May 2005,

after hearing the Opinion of the Advocate General at the sitting on 8 September 2005,

gives the following

Judgment

1 By its application the United Kingdom of Great Britain and Northern Ireland seeks the annulment of 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 (OJ 2003 L 309, p. 1, 'the contested regulation').

2 By order of the President of the Court of 24 June 2004, the Commission of the European Communities was granted leave to intervene in support of the form of order sought by the European Parliament and the Council of the European Union.

Legal context

3 Article 3 of 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, 'the Directive') provides that Member States are to take the necessary measures to ensure that flavourings may not be marketed or used if they do not comply with the rules laid down in the Directive.

4 Article 1 of the contested regulation, which was adopted on the basis of Article 95 EC, provides:

'1. The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to smoke flavourings used or intended for use in or on foods, whilst providing the basis for securing a high level of protection for human health and the interests of consumers.

2. To this end, this Regulation lays down:

(a) a Community procedure for the evaluation and authorisation of primary smoke condensates and primary tar fractions for use as such in or on foods or in the production of derived smoke flavourings for use in or on foods;

(b) a Community procedure for the establishment of a list of primary smoke condensates and primary tar fractions authorised to the exclusion of all others in the Community and their conditions of use in or on foods.'

5 Under Article 2 of the contested regulation, it applies to smoke flavourings used or intended for use in or on foods, source materials for the production of smoke flavourings, the conditions under which smoke flavourings are prepared, and foods in or on which smoke flavourings are present.

6 Article 4 of the contested regulation, 'General use and safety requirements', reads as follows:

'1. 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.

Each authorisation may be subject to specific conditions of use.

2. No person shall place on the market a smoke flavouring or any food in or on which such a smoke flavouring is present if the smoke flavouring is not a primary product authorised in accordance with Article 6, or i[t] is not derived therefrom, and if the conditions of use laid down in the authorisation in accordance with this Regulation are not adhered to.'

7 Article 5 of the contested regulation, which sets out a number of conditions of protection relating to the wood used for the production of primary products, provides:

'1. The wood used for the production of primary products shall not have been treated, whether intentionally or unintentionally, with chemical substances during

the six months immediately preceding 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.

The person who places on the market primary products must be able to demonstrate by appropriate certification or documentation that the requirements laid down in the first subparagraph have been met.

2. The conditions for the production of primary products are laid down in Annex I. The water-insoluble oily phase which is a by-product of the process shall not be used for the production of smoke flavourings.

3. Without prejudice to other Community legislation, primary products may be further processed by appropriate physical processes for the production of derived smoke flavourings. Where opinions differ as to whether a particular physical process is appropriate, a decision may be reached in accordance with the procedure referred to in Article 19(2).'

8 That procedure, known as the 'regulatory procedure', is defined in Articles 5 and 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23).

9 Under Article 6(1) of the contested regulation, the Commission, acting in accordance with the regulatory procedure, is to establish a list of the primary products authorised to the exclusion of all others in the Community for use as such in or on foods and/or for the production of derived smoke flavourings ('the positive list').

10 Under Article 7 of the contested regulation, to obtain the inclusion of a primary product in the positive list, the person concerned must apply to the competent authority of a Member State. The application must be accompanied inter alia by a reasoned statement affirming that the product complies with the first indent of Article 4(1) of the regulation.

11 Article 8(1) of the contested regulation provides that, within six months of the receipt of a valid application, the European Food Safety Authority ('the Authority') is to give an opinion as to whether the product and its intended use comply with Article 4(1) of the regulation. Under Article 8(4), in the event of an opinion in favour of authorising the evaluated product, the opinion may include conditions or restrictions attached to the use of the primary product evaluated. Under Article 8(5), the opinion must be forwarded to the Commission, the Member States and the applicant.

12 The grant of Community authorisation and the establishment of the positive list are governed by Articles 9 and 10 of the contested regulation.

13 Under Article 9(1), within three months of receiving the opinion of the Authority, the Commission is to prepare a 'draft of the measure' to be taken in respect of the application for inclusion of a substance in the positive list, taking into account the requirements of Article 4(1) of the regulation, Community law and other legitimate factors relevant to the matter under consideration.

14 That measure is either a draft regulation establishing or modifying the initial list of authorised primary products or a draft decision refusing to authorise the inclusion of the product in the positive list.

15 Where authorisation is granted, it is valid throughout the Community for 10 years. Under Article 11 of the contested regulation, an authorisation may be modified on application by the authorisation holder to the competent authority of the Member State. Under Article 12 of the regulation, an authorisation may also be renewed on application by the authorisation holder to the Commission.

The action

16 By its action the United Kingdom seeks the annulment of the contested regulation and that the Parliament and the Council be ordered to pay the costs, arguing that Article 95 EC is not an appropriate legal basis for the adoption of the regulation.

17 The Parliament and the Council, supported by the Commission, contend that the application should be dismissed as unfounded and the United Kingdom ordered to pay the costs.

Arguments of the parties

18 The United Kingdom submits that Article 95 EC does not provide a correct legal basis for the adoption of the contested regulation, as the regulation does not harmonise national laws but sets up a centralised procedure at Community level for the authorisation of smoke flavourings for foods. The legislative power conferred by

Article 95 EC is a power to harmonise national laws, not a power to establish Community bodies or to confer tasks on such bodies, or to establish procedures for the approval of lists of authorised products.

19 It accepts that a measure adopted under Article 95 EC may contain provisions which do not themselves harmonise national laws, where those provisions merely contain elements incidental to or constitute the implementation of the harmonising provisions.

20 The United Kingdom further asserts that, while it is indeed permissible to harmonise national laws by a Community regulation, such a regulation must lead to a result which could have been achieved by the simultaneous enactment of identical legislation in each Member State. However, the system of evaluation of smoke flavourings laid down by the contested regulation is a Community mechanism which no Member State considered individually had the power to establish. Consequently, such a system cannot itself be regarded as a harmonisation measure.

21 The United Kingdom considers that, even if the measures provided for by the contested regulation are 'harmonisation measures' within the meaning of Article 95 EC, they do not harmonise the 'essential aspects' or 'standards' for the use and marketing of smoke flavourings. The provisions of the regulation leave entirely open the question of which smoke flavourings are authorised and how they are to be evaluated. Thus, on the basis of the provisions of the regulation, neither a producer nor a national authority can determine whether or not a particular smoke flavouring is authorised.

22 As regards the tasks conferred on the Commission in the regulatory procedure, the United Kingdom submits that under Article 202 EC the Commission may indeed play a part in the implementation of measures adopted under Article 95 EC, but only on condition that such action can be described as 'implementation' of those measures.

23 The United Kingdom concedes that Articles 4 and 5 of the contested regulation, read together with Annex I to the regulation, contain some uniform conditions which smoke flavourings have to meet. However, those conditions do not amount to a set of standards for those substances, in the context of which the evaluation procedure consists solely of checking products against a list of conditions laid down by the regulation. The requirement in Article 4(1) of the regulation that the products must not present risks to human health is an important requirement but is not sufficiently precise. Similarly, the production methods listed in Annex I to the regulation are far from constituting an exhaustive list.

24 The United Kingdom submits that the Authority, when forming its opinion on whether a particular product is safe for human consumption, and the Commission, when taking a decision on this point, must not confine themselves to examining whether the production methods set out in Annex I to the contested regulation have been followed. In its view, it is necessary to provide information going well beyond a mere demonstration that that annex has been complied with, for example details of the chemical composition of the primary product and toxicological data.

25 It observes in this respect that compliance with the methods of production laid down in that annex does not guarantee that the product is safe for human consumption. The Authority's assessment of its safety and the Commission's 'risk management' require a detailed analysis by experts in the field.

26 The United Kingdom concludes that the only appropriate legal basis for the adoption of the contested regulation is Article 308 EC.

27 The Parliament submits that the contested regulation harmonises the national provisions on smoke flavourings used in foods and that Article 95 EC constitutes a proper and sufficient legal basis for the establishment of the authorisation procedure laid down by the regulation.

28 The Parliament observes that Article 95 EC does not require that the measures adopted themselves harmonise the relevant national provisions. A legal approximation of those provisions may be carried out by the legislation itself or by measures adopted under the legislation or both. Article 95 EC does not require the Community legislature to lay down all the details of measures 'approximating' the laws of the Member States, and leaves the legislature a discretion as to the legislative technique to be followed, in particular in the case of the establishment of a harmonised list of authorised products, provided that the essential elements of the matter to be regulated are contained in the basic act.

29 It also observes that the Community legislature is not obliged to lay down exhaustively, in the primary legislation, a set of criteria which are precise enough to be able to be applied themselves.

30 The Parliament points out that the contested regulation carries out an approximation of national legislation with regard to the most fundamental aspects of the use

and marketing of smoke flavourings, namely the definition of the conditions under which those flavourings may be used in or on foods and the prohibition of the marketing of smoke flavourings which are not authorised or do not comply with those conditions.

31 The Parliament submits that the absence of a common approach to evaluating the safety of smoke flavourings means that the Community legislature was unable, for objective scientific reasons, to draw up an exhaustive list of approved products in the text of the contested regulation itself. In those circumstances, and to ensure a high level of protection of human health and at the same time guarantee the free movement of products containing smoke flavourings, the Community legislature was forced to provide that the list of authorised products would be drawn up on the basis of a toxicological evaluation of each of the products concerned, and to entrust the Commission with that task.

32 The Parliament considers that nothing in the contested regulation supports the view that the evaluation procedure is anything other a means to an end, namely the establishment of a harmonised list of authorised primary products, valid throughout the Community, with the aim of improving the functioning of the internal market.

33 The Council submits that the contested regulation falls within the scope of Article 95 EC, as it lays down harmonised substantive provisions on the content of smoke flavourings, by prescribing the type of primary products from which the smoke must be obtained. The regulation also lays down other harmonised rules concerning the identification of primary products, the harmonised substantive conditions governing the scientific evidence needed in order to apply for authorisation to add to the positive list primary products intended to be used in smoke flavourings, the effects of authorisations, and public access to the relevant data, confidentiality and data protection.

34 The Council observes that the contested regulation does not therefore derogate from the principle governing Community law relating to food that there must be a separation between the provision of independent scientific expertise (risk assessment) and the making of decisions (risk management).

35 The Council submits that authorisation for the entire Community of products such as smoke flavourings requires complex scientific evaluations. It would be practically impossible to draw up a legislative instrument in which all the technical parameters were described in such detail that all discretion could be ruled out in the making of those evaluations.

36 The Council admits that, when implementing powers are delegated, it must be ensured that the conditions set out in Article 202 EC and in Decision 1999/468 are complied with. That applies in particular to the obligation to establish the 'essential elements' of the matter to be regulated. As regards technically complex issues, the legislature is entitled to confer extensive implementing powers on the Commission and, consequently, the concept of 'essential elements' should not be interpreted restrictively. In the present case, the authorisation procedure is no more than a procedure aimed at including in the positive list, by means of implementing measures, the substances which satisfy the substantive requirements laid down by the contested regulation.

37 The Commission observes that Article 95 EC refers generally to 'measures for the approximation' of national provisions, rather than to 'measures which approximate'. While the latter expression corresponds to provisions which directly carry out the approximation of national laws, the wording of the provision is much wider and

leaves open the question of the legislative technique to be chosen to achieve that result. The only condition to which recourse to Article 95 EC is subject is that the measures adopted must be 'for' the approximation of national provisions, in that they must lead to an approximation, but as long as that criterion is complied with the Community legislature may choose the mechanism that is most appropriate to the specific circumstances.

38 In the Commission's view, it follows that a measure adopted on the basis of Article 95 EC may perfectly well include a two-stage process such as that introduced by the contested regulation, in which an authorisation procedure is set up only in order to create a harmonised list of authorised primary products as its end result, since this is a measure leading directly to an approximation of the national rules relating to those products.

39 The Commission emphasises that this two-stage process constitutes in the present case a proportionate and scientifically founded approach, since it is necessary to draw up a list which is both detailed and open-ended and capable of being amended in the light of scientific and technical developments. It would have been impossible — and nonsensical — to include in the actual text of the contested regulation a list of all the authorised primary products.

40 The Commission concludes that, having regard to the many technical constraints of the necessary toxicological evaluations, the Community legislature was obliged to provide for a system incorporating a case-by-case evaluation of the safety of primary products and the progressive establishment of a harmonised list, on the basis of the substantive criteria set out in the contested regulation.

Findings of the Court

The scope of Article 95 EC

41 To begin with, it should be recalled that, according to the Court's case-law, where there are obstacles to trade, or it is likely that such obstacles will emerge in the future, because the Member States have taken, or are about to take, divergent measures with respect to a product or a class of products which bring about different levels of protection and thereby prevent the product or products from moving freely within the Community, Article 95 EC authorises the Community legislature to intervene by adopting appropriate measures, in compliance both with Article 95(3) EC and with the legal principles mentioned in the EC Treaty or identified in the case-law (Case C-434/02 *Arnold André* [2004] ECR I-11825, paragraph 34; Case C-210/03 *Swedish Match* [2004] ECR I-11893, paragraph 33; and Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health and Others* [2005] ECR I-6451, paragraph 32).

42 In the present case, according to the statements in the fifth recital in the preamble to the regulation which have not been disputed by the United Kingdom, at the time when the regulation was adopted there were differences between national laws, regulations and administrative provisions concerning the evaluation and authorisation of smoke flavourings which could hinder their free movement, creating conditions of unequal and unfair competition.

43 In those circumstances, action by the Community legislature on the basis of Article 95 EC was justified with respect to smoke flavourings used or intended for use in or on foods.

44 It must also be emphasised that, as the Advocate General observes in point 18 of her Opinion, that provision is used as legal basis only where it is actually and objectively apparent from the legal act that its purpose is to improve the conditions of the establishment and functioning of the internal market.

45 Next, it should be observed that by the expression 'measures for the approximation' in Article 95 EC the authors of the Treaty intended to confer on the Community legislature a discretion, depending on the general context and the specific circumstances of the matter to be harmonised, as regards the harmonisation technique most appropriate for achieving the desired result, in particular in fields which are characterised by complex technical features.

46 That discretion may be used in particular to choose the most appropriate harmonisation technique where the proposed approximation requires physical, chemical or biological analyses to be made and scientific developments in the field concerned to be taken into account. Such evaluations relating to the safety of products correspond to the objective imposed on the Community legislature by Article 95(3) EC of ensuring a high level of protection of health.

47 Finally, it should be added that where the Community legislature provides for a harmonisation which comprises several stages, for instance the fixing of a number of essential criteria set out in a basic regulation followed by scientific evaluation of the substances concerned and the adoption of a positive list of substances authorised throughout the Community, two conditions must be satisfied.

48 First, the Community legislature must determine in the basic act the essential elements of the harmonising measure in question.

49 Second, the mechanism for implementing those elements must be designed in such a way that it leads to a harmonisation within the meaning of Article 95 EC. That is the case where the Community legislature establishes the detailed rules for making decisions at each stage of such an authorisation procedure, and determines and circumscribes precisely the powers of the Commission as the body which has to take the final decision. That applies in particular where the harmonisation in question consists in drawing up a list of products authorised throughout the Community to the exclusion of all other products.

50 Such an interpretation of Article 95 EC is also borne out by the fact that, according to their very wording, paragraphs 4 and 5 of that article recognise that the Commission has power to adopt harmonisation measures. The reference to that power of the Commission in those paragraphs, read in conjunction with paragraph 1 of that article, indicates that an act adopted by the Community legislature on the basis of Article 95 EC, in accordance with the codecision procedure referred to in Article 251 EC, may be limited to defining the provisions which are essential for the achievement of objectives in connection with the establishment and functioning of the internal market in the field concerned, while conferring power on the Commission to adopt the harmonisation measures needed for the implementation of the legislative act in question.

Classification of the contested regulation as a harmonisation measure within the meaning of Article 95 EC

51 In the light of the above considerations, it must be determined whether the contested regulation satisfies the two conditions recalled in paragraphs 48 and 49 above, so as to be regarded as a harmonisation measure within the meaning of Article 95 EC.

52 It must be stated, first of all, that the matter harmonised by the contested regulation has the features referred to in paragraph 46 above. The sixth to ninth recitals in the preamble to the regulation refer to special features of smoke flavourings used for foods, in particular the complexity of the chemical composition of the smoke, the possible toxic properties of those substances, and the methods of production concerned.

53 As to the first condition stated in paragraph 48 above, it must be examined whether that regulation contains the essential elements concerning the approximation of the laws, regulations and administrative provisions of the Member States that regulate the characteristics of smoke flavourings used or intended for use in or on foods.

54 It should be recalled here that, as its Article 1(2) states, the contested regulation defines the parameters for the evaluation and authorisation of primary smoke condensates and primary tar fractions used or intended for use as such in or on foods or in the production of derived smoke flavourings used or intended for use in or on foods.

55 Moreover, as is apparent from Article 4(1) of the regulation, the two fundamental safety rules set out in that provision must be observed before smoke flavourings can be the subject of an authorisation valid throughout the Community. Their use in or on foods can be authorised only if it has been demonstrated that there are no risks to human health. In addition, authorisation is granted only if the use of those substances does not mislead consumers.

56 It should also be noted that Article 5(1) of the contested regulation lays down a large number of conditions which must be satisfied by the wood used for the production of the primary products. As to the conditions for the production of primary products, Article 5(2) states that they are laid down in Annex I to the regulation, which defines the type of products from which the smoke must be obtained, the ingredients allowed in the combustion process, the combustion technique, the environment required, the maximum combustion temperature, the way in which the smoke is condensed, the chemical composition of the condensates, the maximum content of certain substances, and other factors which influence the production process.

57 The information relating to the scientific evaluation of primary products must, moreover, be included in the application for authorisation made under Article 7 of the regulation read together with its Annex II. In addition, Articles 9(4) to (6) and 13 to 16 of the contested regulation lay down harmonised rules concerning the effects of authorisations granted, the consequent rights and obligations, the identification and traceability of primary products, as well as public access, the confidentiality of certain information and data protection.

58 It follows from all those factors that the contested regulation contains the essential elements typifying a harmonisation measure.

59 It also follows that, contrary to the United Kingdom's submissions, the regulation does not have the incidental effect of harmonising the conditions of the internal market (see on this point Case C-209/97 *Commission* v *Council* [1999] ECR I-8067, paragraph 35), but is intended to approximate the laws, regulations and administrative provisions of the Member States in the field of smoke flavourings.

60 As to the second condition stated in paragraph 49 above, it must be recalled that the Community authorisation procedure provided for in the contested regulation is defined in Article 19(2) of the regulation, referring to Articles 5 and 7 of Decision 1999/468, as a 'regulatory procedure'.

61 Under Articles 7 to 9 of the contested regulation, after an application has been made for a primary product to be included in the positive list and the application has been transmitted to the Authority by the competent national authority, it is for the Authority and the Commission to apply to that product the evaluation criteria set out in Articles 4 and 5 of the regulation in conjunction with Annexes I and II to the regulation.

62 It follows from such a legal framework that not only are the tasks conferred on the Authority and the Commission clearly defined by the provisions of the contested regulation, the procedure provided for therein also leads to the adoption of the positive list of substances authorised throughout the Community.

63 The procedure provided for by the regulation thus constitutes an appropriate means for achieving the desired approximation, namely the establishment of a positive list of substances authorised throughout the Community.

64 Having regard to all the foregoing considerations, the conclusion must be that the contested regulation was rightly based on Article 95 EC. The action must therefore be dismissed.

Costs

65 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Parliament and the Council have applied for costs and the United Kingdom has been unsuccessful, the latter must be ordered to pay the costs. In accordance with Article 69(4), the Commission must bear its own costs.

On those grounds, the Court (Grand Chamber) hereby:

1. **Dismisses the action;**

2. **Orders the United Kingdom of Great Britain and Northern Ireland to pay the costs;**

3. **Orders the Commission of the European Communities to bear its own costs.**

[Signatures]