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PROCEDURES FOR DEROGATIONS FROM THE PRINCIPLE OF APPROXIMATION OF LAWS UNDER ARTICLE 95 EC

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1. Introduction

During the course of the negotiations for the Single European Act, some Member States expressed their reservations over the proposed new Article 100a (since the Treaty of Amsterdam revised and renumbered as Art. 95), a provision from which the original intention was that derogations could not be made. Such an imposed harmonization would not only have restricted these Member States' room for manoeuvre, but would also have forced them to reduce the level of protection which they had granted their workers and consumers, and their environment. In order to allay their fears, the framers of the Single European Act moderated the effects of majority voting by inserting a derogation mechanism into paragraph 4 of Article 100a. This mechanism was not altered by the Maastricht Treaty.

Despite any misgivings which this derogation mechanism may have provoked at the time, few Member States exercised their rights.[1] Before 1 May 1999, the date of entry into force of the Treaty of Amsterdam, Article 100a(4) had only been invoked a few times, generally with the intention of retaining national regulations on chemical substances. Due to the complexity of the scientific questions raised by such derogation requests, the European Commission made, from 1992 to 1999, no more than ten decisions on their validity, in general taking several years to examine the relevant issues.[2] Practice has

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1. Several commentators were of the opinion that para 4 of old Art. 100a would provoke a major rupture in internal market policy. Cf. Pescatore, "Some Critical Remarks on the European Single Act", 24 CML Rev. (1987), 9.

2. See the four decisions of the Commission on the prohibition of pentachlorophenol (PCP) imposed by different countries: for Germany, see the 1992 decision (O.J. 1992, C 334) and Decision 94/783/EC (O.J. 1994, L 316/43); for Denmark, see Decision 96/211/EC (O.J. 1996, L 068/32); for the Netherlands, Decision 1999/831/EC (O.J. 1999, L 329/15). See

thus shown this gap in the principle of the uniform application of EC law not to have been as alarming as was initially thought.[3] Besides being interpreted in a relatively strict manner by advocates general and theorists alike, reliance on the derogation mechanism provided for in paragraph 4 of former Article 100a was discouraged because of the interpretative difficulties which this provision generated.

Due to its ambiguity, Article 100a, paragraph 4 had to be reformed. The growing influence of sustainable development and environmental concerns also gave rise to calls for a rebalancing of the equilibrium between the internal market and non-commercial interests. The search for a new compromise was all the more justified by the fact that consumer law and a substantial part of environmental law were dealt with under the auspices of the internal market.

During the course of the negotiations for the Treaty of Amsterdam, the opportunity presented itself to give greater consideration to non-commercial interests, including the concept of "sustainable development" in Article 2 EC, and affirming in Article 6 the principle of integrating environmental needs with other EC policies.[4] This increased environmental protection in the Treaty logically required the revision of Article 100a – a provision guaranteeing the establishment of the internal market. The new provision would also be duly renumbered as Article 95 EC. Two lines of thought were selected by the framers of the new treaty in order to place non-commercial values on a firmer footing within the context of the construction of the internal market.

also the following decisions: Decision 1999/5/EC relating to national provisions notified by Sweden concerning food colourants (O.J. 1999, L 3/13); Decision 1999/835/EC on notified UK provisions on the restriction of the marketing of creosote (O.J. 1999, L 329/82); Decision 1999/833/EC relating to national provisions notified by Germany relating to restrictions on the marketing of creosote (O.J. 1999, L 329/43); Decision 1999/834/EC relating to national provisions notified by Sweden relating to restrictions on the marketing of creosote (O.J. 1999, L 329/63); Decision 1999/832/EC relative to national provisions notified by the Netherlands relating to restrictions on the marketing of creosote (O.J. 1999, L 329/25); Decision 1999/831/EC relating to mineral wool notified by Germany (O.J. 1999, L 329/100); Decision 1999/830/EC relating to national provisions notified by Denmark relating to the use of sulphites, nitrites and nitrates in foodstuffs (O.J. 1999, L 329/1). The Treaty of Amsterdam does not contain transitional provisions for the amendments made to Art. 95 (ex 100a). The Commission has been assessing several applications of the type mentioned above in accordance with Art. 95(5) EC although these were lodged before the entry into force of the Treaty of Amsterdam. The ECJ has recognized that in the absence of transitional provisions, the new procedural rules of Art. 95 should apply immediately to such notifications (Case C-512/99, cited *infra* note 12, paras. 46–51).

3. Leger (Ed.), *Commentaire article par article des Traités UE et CE* (Brussels, Hebing & Lichtenhahn etc., 2000) p. 931; Craig and De Burca, *EU Law, Text, Cases and Materials*, 3rd ed. (OUP, 2003) p. 1189.

4. On the evolution of thinking on sustainable development and its integration into the EC Treaty, see de Sadeleer, "Les fondements de l'action communautaire en matière d'environnement", in *L'Europe et ses citoyens* (Brussels, P.I.E.- Peter Lang, 2000) pp. 99–150.

First, paragraph 3 of Article 100a, and new Article 95, obliges EC institutions, for the purposes of establishing of the internal market, to pursue a higher level of protection "concerning health, safety, environmental protection and consumer protection". This requirement was supposed to avoid the Commission being swamped by a plethora of demands for derogations by those Member States wishing to achieve a higher level of protection.[5] While the level of protection guaranteed under EC law does not necessarily have to be the highest possible,[6] this does not mean that it is inexistent, weak, feeble or even intermediate. This obligation is additionally subject to judicial review.[7]

Substantial modifications were subsequently made to the derogation procedure to the advantage of Member States wishing to guarantee a higher degree of protection than that accomplished by the EC harmonization measures.[8] Article 95 now includes two derogation mechanisms. In keeping with past practice, one of the derogatory mechanism authorizes – at EC level – Member States to depart from the harmonizing measure (para 10), while the other mechanism allows them, in the absence of an express indication in EC secondary law, to maintain or adopt measures more stringent than EC harmonization measure (paras. 4–7).

2. The maintenance or introduction of national provisions derogating from internal market harmonization measures in accordance with Article 95(4)-(7) EC

Paragraphs 4 and 5 of the new Article 95 authorize the Member States to implement, on condition of respect for certain conditions, more stringent

5. Art. 95(3) provides: "The Commission, in its proposals envisaged in para 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". This obligation is similarly established in Arts. 145(1) (consumers), 152(1) (public health) and 174(2) (environment).

6. Craig and De Burca, op. cit. *supra* note 3, p. 1186.

7. On environmental protection, see Case C-341/95, *Safety High-Tech*, [1998] ECR I-4328, para 47. For consumer protection, see Case C-127/7, *Burstein*, [1998] ECR I-6005.

8. For initial commentary on this new provision, see Albin and Bär, "Nationale Alleingänge nach Amsterdam – Der neue Art. 95 EGV: Fortschritt oder Rückschritt für den Umweltschutz?", (1999) *Natur und Recht*, 185; Krämer, *EC Treaty and Environmental Law*, 3rd ed. (London, Sweet & Maxwell, 1998); Verheyen, "The Environmental Guarantee in European Law and the New Article 95 EC Treaty in Practice – a Critique", 1 RECIEL (2000), 180–187; Sevenster, "The Environmental guarantee after Amsterdam: Does the emperor have new clothes?", I YEEL (2000), 291–310; de Sadeleer, "Les clauses de sauvegarde prévues à l'article 95 du traité CE", 38 RTDE (2002), 54–73; Jans, *European Environmental Law* (Groningen: Europa Law Publishing, 2000), pp. 121–132.

measures than those provided for by a EC harmonizing norm, even though the relevant directive or the regulation does not expressly recognize this right. The two paragraphs run as follows:

> "4. If, after the adoption by the Council or by the Commission of a harmonization 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 harmonization 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 harmonization measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them."

In contrast to Article 153(5) and Article 176,[9] which establish the principle of minimum harmonization in areas relating to consumer and environmental protection,[10] the conditions for implementation of paragraphs 4 and 5 of Article 95 are strictly circumscribed *ratione materiae, personae et temporis*. Due to the significance of the disputes which these derogation mechanisms have given rise to in the recent past, a detailed examination of the manner in which such mechanisms are implemented should be made. Despite the three judgments handed down by the Court of Justice on former Article 100a(4), various questions remain unanswered.[11] Recently, the Court handed down two decisions which make several important clarifications.[12]

9. On the conditions for implementation of Art. 176, see Case C-192/96, *Beside and Besselsen* v. *Minister van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer*, [1998] ECR I-4029. For a critique of the Court exclusion of economic arguments, see de Sadeleer, "Le transfert des déchets valorisables au regard des principes d'autosuffisance et de proximité", 1 *Aménagement-Environnement* (1999), 23–27 and Temmink, "From Danish Bottles to Danish Bees: The dynamics of free movement of goods and environmental protection – a case law analysis", 1 YEEL (2000), 61.

10. Dougan, "Minimum harmonization and the internal market", 37 CML Rev (2000), 853–885.

11. Case C-41/93, *France* v. *Commission* [1994] ECR I-1841; Case C-112/97, *Commission* v. *Italy*, [1999] ECR I-1821; Case C-319/97, *Ministère public* v. *Antoine Kortas*, [1999] ECR I-3160.

12. Case C-512/99, *Germany* v. *Commission* and C-3/00, *Denmark* v. *Commission*, judgments of 21 Jan. and 20 March 2003 respectively, nyr.

2.1. *Scope of application ratione personae of the derogation*

Neither the text of paragraph 4 of former Article 100a nor that of the new Article 95 specifies which Member State can invoke the derogation mechanism. This begs the question whether only the minority Member States enjoy the right, or whether it should extend also to those Member States which voted in favour of the EC harmonization measure.

Since the mechanism of Art 100a(4) was characteristically intended to derogate from the process of majority voting for harmonization norms designed to contribute to the functioning of the internal market, it appeared *a priori* to preclude the possibility of those Member States which voted in favour of the harmonization norm subsequently invoking the derogation mechanism.[13] In support of this argument, some have maintained that the extension to every Member State of the ability to adopt more stringent norms would render the attempt to achieve a common denominator meaningless.[14] Undoubtedly, past threats made by certain Member States to invoke paragraph 4 could have encouraged the Council majority to show a greater understanding for the concerns of the minority.

The theoretically retained impossibility of subsequently invoking paragraph 4 following a favourable vote led to bizarre repercussions. In order to conserve their privileges, several Member States preferred systematically to oppose the adoption of harmonization norms, even though they did not challenge the reasonable character of the degree of protection endorsed by the Commission or by the majority of the members of the Council. For instance, in order to conserve their eco-fiscality on packaging, Belgium and France accordingly, at a particular stage of the negotiations, had to oppose the adoption of the Directive 94/62 on packaging and packaging waste.[15]

13. Jans, "Europees rechtelijke grenzen aan nationaal milieubeleid", (1989) SEW, 225; Jadot, "Mesures nationales de police, libre circulation des marchandises et proportionnalité", (1990) CDE, 437; Mertens de Wilmars, "Het Hof van Justitie van de Europeese Gemeenschap na de Europeese Akte", (1986) SEW, 615; Ehlermann, "The internal market following the Single European Act", 24 CML Rev. (1987), 394, 395; Langeheine, "Le rapprochement des législations nationales selon l'article 100 A du traité C.E.E.: l'harmonisation communautaire face aux exigences de protection nationale", 328 RMC (1989), 354–355; Geradin, "Trade and environmental Protection. EC harmonization and national environmental standards", 13 YEL (1994), 185; Debeuckelaere, "De mogelijkheid voor een lidstaat om af te wijken van een Communautaire harmonisatieregel – Artikel 100 A, vierde lid van het EEG Verdrag", 1 *Tijdschrift voor Milieurecht* (1995), 13. Contra: Flynn, "How will Article 100A(4) work? Comparison with Article 93", 24 CML Rev., 694. This issue was not addressed in *France* v. *Commission* since Germany, able to invoke para 4 of Article 100A to maintain a more stringent norm than the EC harmonization norm, was opposed to the adoption of the harmonization directive.

14. Langeheine, op. cit. *supra* note 13, 355.

15. de Sadeleer, *Le droit communautaire et les déchets* (Brussels, Bruylant, L.G.D.J., 1995), p. 386.

By suppressing the expression "qualified majority" which figured in paragraph 4 of the old Article 100a, the Treaty of Amsterdam put an end to this unproductive debate.[16] Every Member State can now petition for the adoption of more stringent national measures, irrespective of its position within the Council of Ministers.[17] The ability of every Member State to adopt, under Article 95(5), stricter national norms after the coming into force of a EC harmonizing norm, confirms the validity of such an interpretation.

2.2. *Scope of application ratione materiae of the derogation*

Paragraphs 4 and 5 of Article 95 apply only to EC legislation adopted on the basis of paragraph 1 of that Article. It should also be noted that it is now possible for a Member State to derogate not only from a harmonization measure adopted by the Council, but also from a harmonization measure resolved by the Commission through the comitology procedure. This is not without significance in the light of the considerable regulatory power which certain committees have been accorded, in particular to set the threshold for protection.[18] Finally, the ability to derogate from technical harmonization norms adopted by the institutions of normalization in line with the "new approach" could well be invoked in years to come in respect of CEN norms on recycling of packaging waste.

Given that paragraph 4 of the old Article 100a could authorize derogations with the potential to restrict the free internal market, the Advocate General Tesauro judged that it should be subject to a strict interpretation *ratione materiae*.[19] Is this interpretation valid *mutatis mutandis* for the new version of Article 95?

Given the recent evolution of the jurisprudence of the Court of Justice enshrining the principle of integrating environmental concerns within the

16. Fallow and Leclercq, "Vers une dimension nouvelle du marché intérieur plus proche du citoyen?", in Institut d'Études européennes, *Le Traité d'Amsterdam, espoirs et déceptions* (Brussels, Bruylant, 1998), p. 313; Leger, op. cit. *supra* note 3, p. 941. According to the latter author, a distinction should be drawn between cases where the State which wishes to maintain a more stringent measure has to reject the harmonization measure, and those where the State cannot know in advance what risks it will be confronted with.

17. See the Opinion of A.G. Tizzano in case C-3/00, cited *supra* note 12, para 78.

18. Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission.

19. According to A.G. Tesauro, "Since [Article 100a(4)] creates an exception to the principles of uniform application of EC law and unity of the market, it must, like all provisions which allow derogations, be strictly interpreted, so as to ensure that it is not extended to cases other than those specifically provided for in it" (para 4 of his Opinion in *Commission* v. *France*, C-41/93, cited *supra* note 11).

framework of the common market,[20] such a restrictive interpretation is no longer certain to be appropriate where invocation of the derogation clause is justified on environmental grounds.

In actual fact, the modifications introduced into the Treaty constrain the principle of the functioning of the internal market to accommodating other values which the Court similarly regards as being essential.[21]

2.3. *Scope of application ratione temporis of the derogation*

Most authors have argued that the old Article 100a(4) derogation mechanism precluded the adoption of new national legislation more stringent than the EC harmonization measures.[22] The clear and precise formulation of the words, "If, after the adoption ..., a Member State deems it necessary to apply national provisions" seemed *a priori* to preclude the subsequent adoption of more stringent measures. In addition, the term "apply" had in fact to be contrasted with the terms "maintain" and "establish" in the old Article 130t (new Art. 176), a provision conferring on Member States a temporally unlimited right to take more stringent measures than those foreseen under the EC norm.[23]

The Treaty of Amsterdam put and end to this controversy by expressly allowing the introduction of new national measures. Two situations can now be distinguished *ratione temporis*: on the one hand the Member States can "maintain" national measures following the adoption of a EC harmonization measure (Art. 95(4)); on the other hand they can at any moment "introduce" new measures subject to the Commission's approval (Art. 95(5)). It is nonetheless evident that the conditions required for the adoption of new national regulations are much stricter than those applying to the maintenance of existing national norms.

20. Case C-379/98, *Preussen Elektra AG*, [2001] ECR I-2159, para 76. See in particular the arguments set out by A.G. Jacobs in his Opinion in this case (paras. 230–231). See Wasmeier, "The integration of environmental protection as a general rule for interpreting Community Law", 38 CML Rev, 159–177.

21. de Sadeleer, *Environmental Principles* (OUP, 2002), pp. 354–365.

22. See Krämer, "L'Acte unique européen et la protection de l'environnement", 4 *Revue juridique de l'environnement* (1987), 467–469; Langeheine, op. cit. *supra* note 13, 355; Van Rijn, "Europees milieuwetgeving en de interne Markt", *Europees milieurecht* (Den Haag: T.M.C. Asser Instituut, 1987), p. 27; Jans, op. cit. *supra* note 13, p. 225.

23. See also the Opinion of A.G. Tizzano in Case C-3/00, *supra* note 12, para 71.

2.4. *Justification of the request for derogation*

As explained below, the conditions applicable to the maintenance of national measures which predate a EC measure (para 4) differ substantially from those which relate to the adoption *a posteriori* of a national measure (para 5).

2.4.1. *Maintenance of existing national measures derogating from internal market harmonization measures*

In order to gain Commission approval, a national measure imposing a higher level of protection than the EC harmonization measure must respect the following procedural requirements.

The Member State is obliged to notify the Commission of its desire to maintain national measures due to "major needs referred to in Article 30, or relating to the protection of the environment or the working environment". On a narrow reading, these "major needs"[24] justifying recourse to the derogatory mechanism are less numerous that the "compelling reasons" in the general interest laid down in *Cassis de Dijon*.[25] Given the restrictive interpretation which the Article 30 "reasons" are subject to, the framers of the Treaty of Amsterdam nevertheless deemed it necessary to include the phrase "the protection of the environment or the working environment". Whereas the concept of environment is interpreted broadly, the protection of the working environment on the other hand applies to nothing more than non-economic considerations relating to the safety, health and hygiene of workers.

Having said this, Member States should encounter fewer difficulties in conserving protective measures than in adopting new ones, because the latter can relate only to "the protection of the environment or the working environment".

The wording of the fourth paragraph calls for several observations. First, the invocation of concerns of public health, the environment or the working environment seems to preclude the possibility of having regard to considerations extraneous to the supposed hazard. Accordingly, the Commission deemed the arguments based on technological need and risk of misleading consumers, in support of a national regime forbidding the use of sulphites in foods (since these substances did not "perform a technical function . . . [or] correspond to a technical need which . . . [could not] be satisfied by other economically and technically usable methods") was not pertinent for the purposes of public health. In this particular case, the national authorities bore the burden of demonstrating the sanitary risk and could not simply point to the

24. One should not assign too great an importance to the choice of the term "major needs" as opposed to "compelling reasons" found in *Cassis de Dijon*. Cf. e.g. Simon, "Commentaire de l'article 100A", *Traité instituant la CEE. Commentaire article par article* (Paris: Economica, 1992), p. 569; Leger, op. cit. *supra* note 3, 937.

25. Opinion of A.G. Tesauro in *France* v. *Commission*, *supra* note 11, para 5.

possibility of replacing such food additives with other substances.[26] Nevertheless, the Court of Justice judged that the technological need to use food additives was "closely related to the assessment of what is necessary in order to protect public health. In the absence of a technological need justifying the use of an additive, there is no reason to incur the potential health risk resulting from authorization of the use of that additive".[27]

Having said this, nothing prevents Member States from citing non-scientific data with a view to confirming the admissibility of a national measure which has already been justified scientifically. Where the risk is shown to be a plausible one, such reasons can justify the maintenance of a stricter measure.[28] It should be added that the substitution principle, recently established by the Court,[29] will play be a significant factor in reviewing the proportionality of national requests for derogations. The principle of encouraging the replacement of harmful substances with less noxious substances, which as yet appears only sporadically throughout EC law,[30] should have a moderating effect on the need to prove the necessity of the protective measure under review.

As far as the wording of the new paragraph 4 is concerned, the condition of "specificity" of risk – found in paragraph 5 – need not be satisfied in order for national measures to be maintained. The Court of Justice recently confirmed this interpretation: "It follows that neither the wording of Article 95(4) EC nor the broad logic of that article as a whole entails a requirement that the applicant Member State prove that maintaining the national provisions which it notifies to the Commission is justified by a problem specific to that Member

26. Decision 1999/830/EC, cited *supra* note 2, paras. 20 and 21.

27. Case C-3/00, cited *supra* note 12, para 82.

28. Noiville and de Sadeleer, "La gestion des risques écologiques et sanitaires à l'épreuve des chiffres. Le droit entre enjeux scientifiques et politiques", 2 RDUE (2001), 389–450.

29. Case C-473/98, *Kemikalieinspektionen* v. *Toolex Ab*, [2000] ECR I-5681, paras. 46 and 47. The Court recognized in this judgment that the conditions imposed on the granting of a derogation are "compatible with the substitution principle . . . which consists in the elimination or reduction of risks by means of replacing one dangerous substance with another, less dangerous substance" (para 47).

30. Directive 89/391/EC on the introduction of measures aiming to encourage improvements in the health and safety of workers at work; Directive 90/394/EEC on the protection of workers against the risk to carcinogenic agents in the workplace (Art. 4(1)); Directive 98/421/EC on the protection of health and safety of workers relating to the risk of exposure to chemical agents in the workplace; Directive 98/8/EC concerning the placing of biocidal products on the market (Art. 10(5), i); Directive 1999/13/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations (Art. 5(6)). The recent White paper on chemicals (COM(2001) 88) sets out a strategy for future policy on chemical substances confirms this tendency and stipulates that "another important objective is to encourage the substitution of dangerous by less dangerous substances where suitable alternatives are available" (paras. 1, 2.3). On the principle of substitution, see de Sadeleer, op. cit. *supra* note 21, pp. 116–8, 137, 354, 362.

State."[31] Thus the Commission cannot, as it has done in the past, demand that national authorities furnish proof of the specificity of the risks cited.[32] The Advocate General's Opinion in that case went against our interpretation, on the grounds that any derogation from the principle of uniform application of community law and the unity of the common market is subject to a strict interpretation.[33]

Finally the Treaty framers' placing of "the protection of the environment or the working environment" and "major needs referred to in Article 30" on a similar footing in paragraph 4 of Article 95 seems implicitly to have abolished the supplementary *Cassis de Dijon* condition, according to which the national measure should be "indistinctly applicable". This interpretation is not without practical significance for the Member States.[34] Developing this line of thought, national authorities should enjoy greater room for manoeuvre when maintaining regimes of environmental and worker protection than where they, notwithstanding harmonization norms, establish measures which restrict trade. Thus a distinctly applicable national measure could be maintained subject to the approval of the Commission, even where it has already been subject to harmonization. By contrast, such a measure could not in the context of a negative harmonization be covered by *Cassis de Dijon* due to its "distinctly applicable" character.[35]

31. Case C-3/00, cited *supra* note 12, para 59.

32. Accordingly, the Commission, in its 1994 decisions on the maintenance of German and Danish regimes prohibiting pentachlorophenol, placed particular emphasis on the fact that these Member States were exposed to high levels of dioxin (Decision 94/783/EC (Germany), para 7; Decision 96/211/EC (Denmark), para 6). On the other hand, in its decision on the prohibition of PCP in the Netherlands, the Commission no longer applied this condition (Decision 1999/831/EC (Netherlands), para 58). Academic literature confirms the point of view expressed in this article. See Verheyen, 80–187; Sevenster, 236, both cited *supra* note 8.

33. Opinion of A.G. Tizzano in Case C-3/00, *supra* note 12, paras. 67–77

34. Concerning the requirement of applicability without distinction of national measures justified by a compelling requirement of environmental protection, see Case 302/888, *Commission* v. *Denmark (Danish Bottles)* [1988] ECR I-46, para 6.

35. The case law of the ECJ is not clear. For instance, in *Asher-Waggon GmbH* v. *Germany* concerning the discriminatory effects of a German regulation to control noise emissions from aircrafts, the Court ruled that even though there was a difference in treatment between aircraft previously registered in Germany and those that were not, "such a barrier may, however, be justified by considerations of public health and environmental protection" (Case C-203/96, *Asher Waggon* [1998] ECR I-4473). However, the ECJ failed to address the question of the real nature of the national measure, distinctly or non distinctly applicable. Cf. e.g. Duncan French, "The changing nature of environmental protection: Recent developments regarding trade and the environment in the EU and the WTO" (2000) NILR, 21–22; Temmink, op. cit. *supra* note 9, 291. See also the Opinion of A.G. Jacobs of 26 Oct. 2000 in Case C-379/98, *PreussenElektra AG*, [2001] ECR I-2159, para 233: "National measures for the protection of the environment are inherently liable to differentiate on the basis of the nature and origin of the cause of harm, and are therefore liable to be found discriminatory, precisely because they are based on such accepted principles as that 'environmental damage should as a priority be

The fact that conditions relating to the maintenance of a more stringent rule have become less strict seems justified. In such cases the national regime predates EC harmonization. The EC legislature was aware of it, even if it did not consider it opportune to take it further into consideration.[36] The introduction of a new measure could on the other hand constitute a more important danger undermining the internal market.[37]

2.4.2. *Introduction of a new national measures derogating from internal market harmonization measures*

The term "apply" used in the original version of Article 100a(4) was interpreted by the majority of commentators as preventing Member States from adopting more stringent measures after the adoption of a EC harmonization norm. They now find themselves recognizing, under the terms of paragraph 5 of the new Article 95, a right to adopt more stringent measures after the entry into force of the harmonizing norm. Some Member States regard this as one of the principal benefits of the Treaty of Amsterdam. Nevertheless, the second derogation mechanism is subject to stricter conditions because "the adoption of new national legislation is more likely to jeopardize harmonization. The Community institutions could not, by definition, have taken account of the national text when drawing up the harmonization measure."[38]

Therefore, the reasons which can justify invoking this second derogation mechanism appear less numerous than those which justify the maintenance of existing national norms. Only "the protection of the environment" and the "working environment"[39] can be invoked. This precludes the possibility of founding a derogation on a requirement such as the Article 30 protection of human health.[40] There is therefore a fine line between the justifications embodied in paragraph 5 of Article 95 and those contained in Article 30 EC. It should not be forgotten that under Article 174(2), the concept of "environment" includes the protection of public health which is itself expressly

rectified at source' (Article 130r(2) of the EC Treaty). Where such measures necessarily have a discriminatory impact of that kind, the possibility that they may be justified should not be excluded."

36. Cases C-512/19, cited *supra*, para 41, and C-3/00, cited *supra*, para 58.

37. Leger, op. cit. *supra* note 3, p. 936.

38. Case C-512/19, cited *supra*, para 41, and C-3/00, cited *supra*, para 58.

39. The reference to protection of the working environment is more problematic because Art. 95(2) expressly precludes the adoption of measures relating to "the rights and interests of employed persons". It may however be noted that the majority of chemical regulations based on Art. 95 concern worker protection.

40. See Case C-3/00, cited *supra*, para 58. The Commission in particular relied on this argument in rejecting the German prohibition of the commercialization of organostanic compounds (Decision 2001/570/EC of 13 July 2001, O.J. 2001, L 202/37, para 76). See also the Decision 2000/509/EC of 25 July 2000 on Belgian provisions (O.J. 2000, L 205). On the exclusion of human health, see Sevenster's critique, op. cit. *supra* note 8, 301–302.

enshrined in Article 30. The Commission has justified the maintenance of national measures prohibiting pentachlorophenol on both sanitary and environmental grounds (which itself illustrates the indeterminacy of the distinction between the two grounds for justification); yet it has also blocked the adoption of new measures based on the principle of protection of human health. The Commission does not therefore seem to be endorsing a broad interpretation of the concept of "environment". All attempts to determine the precise scope of the public interest at stake appear destined to fail.[41]

In addition, national measures should also satisfy three requirements: the risk that the measure is supposed to counter should be specific to the Member State requesting the derogation, it should manifest itself after the adoption of the harmonization measure, and should be supported by scientific proof. These conditions are clearly cumulative.[42] Each of them requires some clarification.

Specificity of the problem. Firstly, the "problem" or risk justifying the intervention of the Member State should be "specific" to the applicant state. The intention of the framers of the Treaty of Amsterdam was clearly to avoid the adoption of all regulations of general character. In other words, particular demographic, geographic or epidemiological circumstances should render the problem particular to the State requesting the derogation.[43] As under consumer law,[44] the geographic or social conditions of the interested State (for example population density, degree of industrialization, vulnerability of the groundwater, historic record of pollution. . .) exacerbate the impact of particular problems. *A contrario*, the condition of risk specificity prohibits the adoption of national measures designed to solve a problem common to the whole of the European Community. Having said this, the term "specific" should not be given too strict an interpretation; it is not absolutely neces-

41. Leger, op. cit. *supra* note 3, p. 940.

42. See Case C-512/99, cited *supra* note 12, para 81.

43. On this question, see the decisions on the prohibition of pentachlorophenol (PCP) taken in respect of Germany and Denmark (*supra* note 2). In its Decision 1999/830/EC (cited *supra* note 2), the Commission considered whether the Danish population had a greater risk of allergy than other populations, due to genetic disposition, diet and natural environment (para 32). In its Decisions 2001/570/EC and 2000/509/EC on organostanic compounds, the Commission refused to give consideration to the accumulation of the substance TBT in the ecosystems surrounding German and Belgian naval ports (para 74 of Decision 2001/570/EC).

44. In different judgments handed down in the area of food additives, the ECJ has considered consumer habits when conducting its proportionality test of national measures prohibiting particular substances. See Case 174/82, *Sandoz*, [1983] ECR 2445; Case C-227/82, *Van Bennekom*, [1983] ECR 3883; Case 97/83, *Melkunie*, [1983] ECR 2367; Case C-247/84, *Motte*, [1985] ECR 3887. This case law is not however pertinent to the monitoring of the implementation of para 5 of Article 95, to the extent that consumer protection is not covered by this derogation mechanism.

sary that the problem be present exclusively within the State requesting the derogation, since it is potentially possible for it to occur on the territory of other Member States. As emerged during the course of the BSE epidemic, a risk discovered at a given moment on the territory of one Member State can rapidly spread to other countries. This interpretation of the term "specific" seems justified in the light of the wording of paragraph 7 of Article 95, which obliges the Commission immediately to examine the feasibility of adapting the EC harmonizing norm following a decision in favour of a national measure. The possibility of such an adaptation is only meaningful if the problem arises or is susceptible to arise in other Member States.

It is no longer necessary to conclude that the appearance of an identical problem in two Member States would be likely to prevent them from jointly requesting more stringent national measures. This argument already seems to have been confirmed by Commission practice, with the prohibition of the use of pentachlorophenol (PCP) being authorized at the request of Germany and Denmark.[45]

Date of emergence of the problem. The problem must arise after the "adoption" – and not at the end of the implementation period – of the harmonization measure. This does not preclude the possibility of the risk already being present at the moment of drafting, or even adoption, of the EC harmonization measure, and only later manifesting itself.

Scientific evidence. Finally, the right to introduce a national measure more stringent than the EC norm must be justified in the light of "new scientific evidence". To the extent that the draft of the EC harmonization measure proposed by the Commission must already take into consideration in accordance with Article 95(3) "any new development based on scientific facts", the novel character of the scientific evidence has to be assessed in the light of those scientific discoveries which occurred after the adoption of the norm. This requirement must not however be subject to a literal interpretation, as it is possible for scientific evidence already existing at the time of the adoption of the EC harmonization norm, but not entirely validated at that point in time, to justify the pursuit of a higher level of protection.[46] In addition, nothing prevents new scientific evidence from being advanced by a minority of researchers. The serious nature of the scientific evidence gathered by the

45. Cf. the decisions mentioned in note 2 *supra*.

46. The rate of adoption of regulatory measures designed to protect stratospheric ozone demonstrates the point at which political decisions become dependent on the result of scientific research resulting from the work of many years. There is thus always a time-lag between the scientific discovery and the political decision.

Member State matters more than the scientific consensus, which may even be clear.

There is a noticeable lack of congruence in the Article between the term "scientific facts" in paragraph 3 and the "scientific evidence" of paragraph 5. In the German version, the terms correspond to "*Wissenschaftliche Ergebnisse*" and "*Wissenschaftliche Erkenntnisse*". In the French version, the "*faits scientifiques*" of paragraph 3 are placed in opposition to the paragraph 5 "*preuves scientifiques nouvelles*". On a semantic analysis, the English word "evidence" – as opposed to "proof" – does not necessarily imply that the cause of damage to the environment or workers' health must be proved; "evidence" can consist of an indication of a possible link between the factor in question and the damage which occurs.[47] Also the Member States requesting the derogation should only have to provide a minimum of data on the relation of cause and effect between the regulated activity and the suspected damage, rather than having to furnish irrefutable proof.

This last interpretation seems in any case justified, given the Commission's obligation to take into account the precautionary principle – a general principle of Community law[48]– when examining the serious nature of the scientific proof advanced by a Member State.[49] The Commission already applies this principle when it addresses requests for derogation. EC authorities have accordingly, in four decisions handed down on 26 October 1999 relating to the prohibition of the use of a chemical agent (creosote), found that measures aimed at reducing the probability of prolonged exposure of the skin to this substance were justified in the light of the principle.[50]

47. Bär and Krämer, "European environmental policy after Amsterdam", 10 JEL 22.

48. In Case T-74/00, *Artegodan* v. *Commission*, judgment of 26 Nov. 2002, nyr, the CFI confirmed that the precautionary principle's scope of application went wider than environmental policy insofar as it is intended to apply in all areas of Community action, with a view to ensuring an increased level of protection of health, the environment and consumer safety. According to the CFI, the extension of its field of application is justified by the requirement to pursue an increased level of consumer (Art. 153), environmental (Art. 174(2)) and health (Art. 3(b)) protection, as well as by the different integration clauses which the Treaty contains in the areas of environmental (Art. 6) and health (Art. 152(1)) protection (para 183). Due to its highly abstract nature and particularly broad scope of application, the precautionary principle could then be defined "as a general principle of Community law requiring the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests" (para 184). Cf. e.g. de Sadeleer, "Le principe de précaution: un nouveau principe général de droit communautaire", (May 2003), *Journal des Tribunaux de Droit Européen*, 129–134.

49. For a critical treatment of the origins of the legal extent of this principle, see de Sadeleer, op. cit. *supra* note 21, pp. 91–226. See also the Communication from the European Commission of February 2000 on the precautionary principle (COM(2000) 1 final) and the Nice Resolution of the Council of Ministers 9 Dec. 2000 on the precautionary principle.

50. Decision 1999/835/EC, para 110; Decision 1999/833/EC, para 99; Decision 1999/

Having said this, recent decisions made by the Commission in respect of measures proposed by Belgium and Germany intending to restrict the commercialization of organostanic products due to the endocrinal disturbances which these substances cause (notably on the sex of marine mussels) show that it is intent on giving a particularly strict interpretation to the aforementioned conditions.[51]

Nevertheless, the Court of Justice is keen to adopt a more lenient view regarding the nature of the risk assessment. The Court, for instance, has recently accepted that: "the applicant Member State may, in order to justify maintaining such derogating national provisions, put forward the fact that its assessment of the risk to public health is different from that made by the Community legislature in the harmonization measure. In the light of the uncertainty inherent in assessing the public health risks posed by, inter alia, the use of food additives, divergent assessments of those risks can legitimately be made, without necessarily being based on new or different scientific evidence."[52]

This case law is consistent with the precautionary principle which allows public authorities to base their assessment either on qualitative or on quantitative methods.[53]

3. Control of requests for derogations provided for in Article 95(4) and (5) EC

3.1. *The control procedure*

Paragraph 6 of the new Article 95 sets out both the formal and substantive conditions which must be fulfilled in order to secure a derogation

> "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

834/EC, para 108; Decision 1999/832/EC, para 104. See also the criticisms of Verheyen, op. cit. *supra* note 8, 180–187.

51. Decisions 2001/570/EC and 2000/509/EC on organostanic compounds.

52. Case C-3/00, cited *supra*, para 63.

53. *European Communities – Measures Concerning Meat and Meat Products*, WTO Doc. WT/DS26&48/AB/R (16 Jan. 1998), paras. 184–6.

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."

3.1.1. *Formal conditions*

The Court of Justice declared in a ruling in 1999 that the possibility provided for in paragraph 4 of old Article 100a presupposed respect for the procedure laid down for this purpose. It accordingly concluded that Italy was not entitled to invoke this derogation mechanism in order to derogate from a directive harmonizing gas appliances, since it had not adhered to the appropriate procedures.[54] Member States requesting the granting of derogations must therefore respect the formal requirements of Article 95(6).

The request for derogation must be registered with the Commission; however, a deadline for notification is not specified. Justification of the request is a prerequisite for effective control by EC authorities, with Article 95(4) and (5) requiring that the Member State reveal "the grounds" for maintaining or adopting national measures. This can be founded on any scientific argument (epidemiological, ecological. . .) capable of providing a sound basis for the level of protection. The implementation of the notification system inevitably requires close cooperation between the Commission and the Member States. As far as the latter are concerned, they are bound by Article 10 EC to notify as early as possible such national measures which they intend to continue applying as are incompatible with a harmonization norm.[55] Notification of the maintenance of existing measures should thus follow as quickly as possible, allowing the Commission to rule before the expiry of the implementation period of the harmonization norm, thus avoiding the situation where measures having direct effect conflict with the application of the national measures. The Member State should therefore ensure that a period of at most six months separates the notification of its measures from the end of the implementation period of the EC norm. As far as the Commission is concerned, it must display corresponding diligence in examining the national provisions submitted to it as quickly as possible.

Although not mandatory under Article 95, the Commission has adopted the practice of informing the other Member States when it receives a request under Article 95(4)–(5), with a view to giving them the chance to express an opinion on the request for derogation. Because the procedure is initiated at the request of a Member State seeking the approval of national provisions

54. Case C-112/97, *Commission* v. *Italy*, [1999] ECR I-1821.
55. *Kortas* cited *supra* note 11, para 35.

derogating from a harmonization measure adopted at Community level, the Commission in turn must be able, within the prescribed period, to obtain the information which proves to be necessary without being required once more to hear the applicant Member State.[56] This informal procedure is in fact similar to that provided for in Directive 98/34/EC of June 22 1998,[57] which laid down a procedure for the provision of information in the field of technical standards and regulations by which the Commission immediately brought any notifications of proposed technical rulings to the attention of other Member States in order to allow them to make observations.

It should be pointed out that no provision allows for the application in favour of the applicant Member State of the principle of the right to be heard in the decision-making procedure laid down in Article 95(4) and (6) EC, which relates to the approval of national provisions derogating from a harmonization measure adopted at Community level. Due to the specificity of the procedure, the Court of Justice has held that "the principle of the right to be heard does not apply to the procedure provided under Article 95(4) and (6) EC."[58]

Where a Member State's request is considered to be incomplete, one might wonder when the clock should start running for the Commission's decision. The central issue is whether the Commission must in such cases reject the request or whether it can demand additional information, which would then have the effect of delaying the start of the time period.

3.1.2. *Substantive conditions*

Once it receives the notification the Commission is obliged, as guardian of the Treaties, to verify whether the maintenance or adoption of the national provisions responds to the requirements contained in paragraph 6. The measures must be proportional, and must not constitute either "a means of arbitrary discrimination or a disguised restriction on trade between Member States or an obstacle to the functioning of the internal market". The two first criteria ("a means of arbitrary discrimination or a disguised restriction on trade between Member States") have been taken from Article 30; this once again shows how close the links between this provision and Article 95 are. The third criterion (no "obstacle to the functioning of the internal market") is particularly ambiguous and is not incidentally found in so many words anywhere else in the Treaty, although similar terms can be found elsewhere in the Treaty.[59] At first sight, any national norm derogating from the EC harmonizing rule is capable of hindering the free circulation of goods and should as such be

56. Case C-3/00, cited *supra*, para 48.
57. O.J. 1998, L 204/37.
58. Case C-3/00, cited *supra*, para 50.
59. E.g. Art. 87(3)(c).

precluded. Since this interpretation is problematic, the third requirement is taken to constitute just one element to be considered by the Commission when testing the validity of the national measure. In other words, the Commission can only apply a proportionality test and is thus only able to reject those national measures which constitute major obstacles "to the functioning of the internal market".[60]

If it finds that all three conditions are satisfied, the EC Commission approves the relevant provisions; in the contrary case, it rejects the request.

Article 95 expressly places the burden of proof of showing that the conditions are satisfied on the Member State requesting the derogation.[61] At this stage the Commission can be confronted with three possibilities:
– the information provided by the Member State is incomplete; the Commission must then reject the request on the grounds that it does not have a sufficiently sound basis in science;
– whilst the information provided by the national authorities is complete, it does not demonstrate the necessity of deviating from the harmonization norm; the Commission rejects the request unless it can be justified by recourse to the precautionary principle;
– the request is so complex that the Commission has neither the time nor the expertise to verify the data submitted to it. In this last case, the Commission must make a *prima facie* ruling.

The structure of Article 95 allows the European Commission to enjoy a certain degree of discretion when exercising its control.[62] One might wonder whether the Commission must at this stage be as strict as the Court of Justice when it examines the proportionality of a national measure under Article 30 or in the light of a rule of reason according to the *Cassis de Dijon* case law.[63] In other words, can the Commission restrict itself to verifying whether a national measure satisfies the requirements of paragraph 6 of Article 95, or should it also assess the measure's proportionality? In his Opinion in the case *France* v. *Commission* Advocate General Tesauro stressed that "the principle of proportionality, a general principle of EC law, must also be applied in appraising the grounds relied on by a Member State as a basis for continuing to

60. Leger, op. cit. *supra* note 3, p. 943, para 82.

61. The ECJ recently stressed that "it falls to the applicant Member State to prove that those national provisions ensure a level of health protection which is higher than the Community harmonization measure and that they do not go beyond what is necessary to attain that objective". (Case C-3/00, cited *supra*, para 64). See e.g. the Decision 1999/830/EC, para 18; Decision 2001/570/EC, para 65. See the Opinion of A.G. Tizzano in Case C-3/00, para 101.

62. Leger, op. cit. *supra* note 3, p. 943, para 81.

63. For a critical analysis of the implementation of this principle in the field of environmental protection, see de Sadeleer, op. cit. *supra* note 21, pp. 291–301.

apply its own rules by way of derogation from the harmonization measures".[64] He went on to say that this control should even "be inspired by more stringent criteria" than those adopted by the court for the purposes of the application of Article 30 "in that there is no possibility of not taking account of the standards of protection already laid down by the harmonization rules".[65] Against this background, the Commission, did not accept the Danish measure concerning the use of sulphites, nitrites and nitrates in food products on the grounds that they went beyond that which was necessary in order to achieve the objective of the protection of health.[66] Advocate General Tizzano supported this strict interpretation in his Opinion on the validity of the Commission Decision prohibiting Danish food safety measures.[67] However, in this case the Court found that, in its Decision on the application of the Danish authorities, the Commission had failed to take into account the "highly critical" opinion of the Scientific Committee for Food regarding the scientific basis of the EC harmonization measure's thresholds of the permissible residual amounts of nitrites and nitrates in foodstuffs.[68]

In accordance with the decision of the Court in the pentachlorophenol case, the Commission is bound to explain its decision in such a way that, on the one hand the Court can exercise its control, and on the other hand that both Member States and interested nationals can understand the circumstances in which the Commission has correctly applied EC law.[69] It cannot therefore restrict itself to merely observing that the national regulation is compatible with paragraphs 4 and 5 "without explaining the reasons of fact and law on account of which the Commission considered that all the conditions contained in Article 100a(4) were to be regarded as fulfilled in the case in point".[70]

64. Various authors considered that derogations requested under para 4 of former Art. 100a could not avoid a proportionality test. See Langeheine, op. cit. *supra* note 13, 357; Glaesner, "L'article 100A: un nouvel instrument pour la réalisation du marché commun", (1989) CDE, 622, 624.

65. See the Opinion of A.G. Tesauro in *France* v. *Commission*, cited *supra*, para 6.

66. Decision 1999/830/EC of 26 Oct. 1999 on national provisions notified by Denmark concerning the use of sulphites, nitrites and nitrates in foodstuffs. In its statement on the single market and the environment (COM(99) 263), the European Commission nonetheless indicated that the principles contained in Art. 175 EC would be rigorously applied when assessing national provisions invoked under paragraphs 4 and 5 of Art. 95. According to the Commission, the justifications advanced by the Member States must be substantiated, not only legally but also from a scientific, technical and economic perspective.

67. Opion of A.G. Tizzano in case C-3/00, cited *supra* note 12, paras. 99–105.

68. Case C-3/00, cited *supra*, paras. 109–115.

69. Case C-41/93, *France* v. *Commission*, cited *supra* note 11, para 34. In this particular case, France contested the validity of a Commission decision confirming German regulations concerning the prohibition of pentachlorophenol, which were more stringent than the EC harmonizing norm. Following the judgment in this case, the Commission reconfirmed the derogation, adopting Decision 94/783/EC, cited *supra* note 2.

70. Case C-41/93, cited *supra*, para 36.

The Treaty of Amsterdam introduced a major modification into the control procedure. Whilst the procedure provided for in former Article 100a(4) precluded Member States from applying a national regulation which departed from the harmonizing rules without having first obtained Commission approval,[71] paragraph 6 of Article 95 now allows for an extension of the period within which the Commission has to make a ruling. The authors of the Treaty intended, in the interest of both the applicant Member State and the proper functioning of the internal market, that the approval procedure "should be speedily concluded".[72] Thus the Commission has six months either to approve or reject the national request. In the absence of a Commission decision, the national measure is deemed to have been approved.[73] The complexity of the risk assessment procedures[74] can however lead the Commission to postpone the inquiry's six-month deadline for up to six more months (i.e. up to a total of twelve months), unless a prolongation of this time limit constitutes a danger for human health.[75]

This implicit authorization mechanism puts the Member States in a stronger position because the silence of the Commission is now equivalent to tacit approval of the national measure, whereas this would previously have prevented the measure's maintenance.

3.2. *Impact of the control procedure on national law*

In the *Kortas* case, the Court of Justice confirmed the primacy of the provisions of a directive adopted on the basis of old Article 100a – to the extent that it satisfied general requirements as to clarity, precision and unconditional character and that the period for implementing the directive into national law had passed – over a more stringent national regime (prohibition of a colourant in food products) justified by major needs based on Article 30 EC (public health).[76] The fact that the Commission delayed in assessing a Swedish request for derogation did not prejudice the primacy of EC law over national law. This case law indicated that Member States intending to invoke paragraph 4 of Article 100a could not apply their own regulatory regimes after the end of the EC norm's implementation period until the Commission

71. *Kortas*, cited *supra* note 11, para 27.
72. Case C-3/00, cited *supra*, para 49.
73. This condition is valid both for requests to maintain norms predating the act of harmonization and for requests to adopt new national norms.
74. See de Sadeleer, op. cit. *supra* note 21, pp. 180–195.
75. Whilst the six-month deadline cannot be extended where there is a danger for human health, it could be extended in the case of irreversible damage to the environment.
76. *Kortas* cited *supra* note 11.

confirmed the request. The provisions of the harmonized measure which have direct effect could not apply any more after such approval was given.[77]

The Court justified its position on the grounds that the EC harmonization measures would have been deprived of their effect if Member States could retain the right unilaterally to apply national regulations departing from them. The ambiguity occasioned by any other conclusion as to the regime applicable in a particular State would not only have gone against the principle of legal certainty, but also would have undermined the primacy of EC law.[78]

Viewed from a more practical perspective, the solution accepted by the Court of Justice obliged the Member States to suspend the effects of their regulations until the Commission could rule on their request, running the risk of having to wait several years for the Commission's decision. This gave rise to significant difficulties for Member States wishing to maintain coherent normative policies at national level. As has been shown above, these difficulties led the framers of the Treaty to impose on the Commission a strict deadline for assessing derogation requests (either six months, or at most one year).

Under the new Article 95, Member States have the right to maintain national measures during the implementation period, to the extent that this does not compromise the realization of the objectives of the EC harmonization measure.[79] They should nevertheless give the Commission the necessary time to process their application (6 or 12 months). If the Commission rejects the application, the provisions of the harmonized measure which have direct effect will immediately apply. They will preclude the Member State from maintaining its national measures. The words "approve or reject" of paragraph 6 of Article 95 must accordingly be understood as authorizing Member States to apply more stringent national measures on the sole condition that they have first been approved by the Commission. The result of this is that it is entirely in the interests of national authorities wishing to maintain a more stringent measure to lodge their request as quickly as possible after the publication of the harmonization norm in the Official Journal of the European Communities, so that the Commission can rule before the expiry of the implementation period.

A remaining doubt concerns the suspension mechanism where paragraph 9 of Article 95 permits both Member States and Commission to contest before the Court of Justice the validity of such national measures as should in the light of paragraph 6 of Article 95 have their effects suspended. One may wonder at the utility of court proceedings where the contested national measure would

77. Opinion of A.G. Saggio of 28 Jan. 1999 in *Kortas*.
78. On this point, see the Opinion of A.G. Tesauro in *France* v. *Commission* (para 9).
79. Case C-129/96, *Inter-Environnement Wallonie*, [1997] ECR I-441.

not have been applied anyway. The modifications incorporated by the Treaty of Amsterdam do not therefore remove all doubts relating to suspensions resulting from the assessment procedure.

3.3. *Impact of the Commission's decision on harmonized EC law*

Where the Commission rejects the application, the Member State must, in conformance with Article 10 EC, refrain from adopting any measure liable to jeopardize the realization of the Treaty's aims.[80] The national authority must therefore bring its regulation into line with the standard set by the harmonization rule.

On the other hand, if the Commission approves the application, the Member State can, depending on the case, maintain its national regulation or adopt a rule more stringent than the EC harmonization norm. The new Article 95 does not specify whether there is any temporal limitation for the maintenance of a existing norm or the adoption of a new national norm. Where the derogation has been approved, it should in principle subsist as long as the conditions set out in paragraph 6 are satisfied.[81]

Under paragraph 7, a favourable decision moreover entails an obligation for the Commission to "immediately examine whether to propose an adaption" to EC law.[82] Although it is not bound to reach any particular conclusion, this requirement nevertheless enhances the dynamic forces driving the realization of the internal market.[83] The EC norms which shape this market would therefore be adapted in conformity with the regulatory progress achieved by particular Member States. It would though be inconceivable for the Commission to be censured for any delay in proposing an amendment for EC legislation.[84] In order to reinforce this dynamic, Article 95(8) provides that "when a Member State raises a specific problem on public health in a field which has been the subject of prior harmonization measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council". If the Commission refuses

80. In his Opinion in *France* v. *Commission*, A.G. Tesauro considered that, given the exceptional nature of the Member States' recognized powers, the Commission approval constituted "in every sense an authorization . . . to derogate from the harmonizing measure, with the result that a refusal would place the State in question under an obligation to bring its own legislation into line with the requirements decided on by the Commission" (para 8).

81. See Glaesner, op. cit. *supra* note 64, 622.

82. Para 7 of Art. 95.

83. According to the ECJ, "such an adaptation could be appropriate when the national provisions approved by the Commission offer a level of protection which is higher than the harmonization measure as a result of a divergent assessment of the risk to public health." (*Kortas*, cited *supra* note 11, para 65).

84. Leger, op. cit. *supra* note 3, p. 946, para 88.

to set in motion this levelling-up procedure, it has a duty to show that it is not possible to extend the protection regime to the internal market as a whole. Be that as it may, this obligation should allow space for national initiatives to contribute to the constant adaptation of EC law in the light of scientific progress, as required by Article 95 (3).

Finally, any modifications made to EC harmonizing norms following the granting of a derogation by the Commission should at the very minimum guarantee, in accordance with Article 95(3), a higher level of environmental protection.

3.4. *Objections by other Member States*

Since the approval – or absence of thereof – of the request for derogations constitutes a decision of the Commission for the purposes of Article 249 EC, the Member State making the request can contest it under Article 230(1) EC.[85]

Article 95(9) establishes a simplified breach procedure before the Court of Justice, under which the Commission or Member State claiming injury can bring the matter directly before the Court if they consider "that another Member State is making improper use of the powers provided for in this Article". Avoiding pre-trial procedures, this action can be brought even before the Commission has ruled on the request, as well as after the request's refusal by the Commission. It can thus lead to a rapid judicial condemnation of every abuse of the derogatory regime. This specific remedy does not prejudice the right of appeal contained in Article 230(1).

4. Safeguard clauses in harmonization mesures

4.1. *Clauses provided for in paragraph 10 of Article 95*

The existence of a safeguard clause in a directive based on Article 95 is often necessary to allow the Court of Justice to treat EC legislation as being exhaustive; this has the effect of preventing Member States from invoking Article 30 EC.[86]

85. Glaesner, op. cit. *supra* note 64, 625.

86. ECJ case law holds that where EC directives provide for the harmonization of measures designed to safeguard the protection of the health of animals and people and setting down Community procedures to ensure adherence, recourse to Art. 30 EC is no longer justified; appropriate controls must be made and protective measures undertaken within the framework laid down by the harmonization directive. See inter alia: Case 5/77, *Tedeschi*, [1977] ECR 1555,

Moderating the effects of majority voting, paragraph 10 of Article 95 provides that directives and regulations which have as their object the establishment and functioning of the internal market can:

> "in appropriate clauses include a safeguard clause authorizing Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a EC control procedure."

The purpose of this paragraph 10 – replicating paragraph 5 of former Article 100a – is to allow a Member State, subject to a Community control procedure, to adopt temporary measures in the event of a sudden and unforeseen danger to health, life, etc.[87] This paragraph does nothing beyond giving formal recognition to a practice followed for a long time by the Council of Ministers when adopting harmonization measures under Article 94 (ex Art. 100) EC.[88] This practice notwithstanding, several EC directives founded on old Article 100a already contain safeguard clauses of this type.[89] To the extent that this possibility is addressed directly to the EC legislature and not to the Member States, the safeguard clause provided for in paragraph 10 is different from the derogation procedures under paragraphs 4 and 5 of Article 95.

The insertion of such a safeguard clause into an instrument of EC legislation must satisfy several conditions.

Firstly the clause must allow the Member States to deal with exceptional situations of limited duration. In *Greenpeace* v. *France*, the Court of Justice held that the precautionary principle was in particular expressed in the safeguard clause of the Directive 90/220/EC, which provided for provisional limitations or bans on the use and sale of GMOs. When relying on the wording of this safeguard clause, the measures of prohibition or limitation taken

para 35; Case 148/78, *Ratti* [1979] ECR 1629, para 36; Case 251/78, *Denkavit Futtermittel* [1979] ECR 3369, para 14; Case 190/87, *Moormann*, [1988] ECR 4689, para 10; Case C-323/93, *Centre d'insémination de la Crespelle*, [1994] ECR I-5077, para 30; Case C-99/01, *Linhart*, 24 Oct. 2002, para 18.

87. Craig and De Burca, op. cit. *supra* note 3, p. 1186.

88. Ehlermann, op. cit. *supra* note 13, 398.

89. See inter alia Art. 4 of Directive 89/107/EEC concerning food additives authorised for use in foodstuffs intended for human consumption; Art. 7 of Directive 98/34/EC laying down a procedure for the provison of information in the field of technical standards and regulations and of rules on information society services; Art. 23 of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC; Art. 3 of Directive 94/63/EC on the control of volatile organic compound (VOC) emissions authorizes the adoption of more stringent national measures in respect of final storage installations where these are necessary for the protection of the environment and of human health. Art. 6 of Directive 94/62/EC on packaging and packaging waste provides for a derogation from the rate of recycling and recovery in favour of "Member States which have, or will, set programmes going beyond the targets of para 1(a) and (b) and which provide to this effect appropriate capacities for recycling and recovery".

by national authorities are only authorized for as long as is necessary for a new decision to be taken by the EC authorities.[90]

Secondly, it must be justified in the light of the non-economic reasons mentioned in Article 30 EC (public morality and the protection of health and life of humans, animals or plants).[91] No reference is made to the protection of the environment. The absence of an "ecological" safeguard clause is all the more incomprehensible given the particular emphasis placed on environmental protection in paragraphs 4 and 5 of Article 95 and that several environmental directives are based on Article 95.[92] It would nevertheless be possible to fill the substantive gap in paragraph 10 by reference to the second subsection of Article 174(2)(2), which provides that: "in this context, harmonization measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a Community inspection procedure".

Thirdly, the subsequent reference in paragraph 10 to "non-economic reasons referred to in Article 30" is also problematic. Nevertheless, the concept of "protection of industrial and commercial property" as understood in Article 30 encompasses economic aspects.

Finally, in accordance with principles traditionally applicable to safeguard clauses, the application of a derogation clause under paragraph 10 should also be subject to a "control procedure" normally undertaken by the Commission. In practice, the safeguard clause entails an obligation for the Member State to notify the Commission of the derogating measures taken, in order to enable the latter to ascertain whether they are consistent with the relevant legislation. It can also be concluded that such a clause can be subject to a proportionality test identical to that used by the Court in respect of quantitative restrictions contrary to Articles 28 and 29 EC.

Is the effect of Article 95(10) to preclude the possibility of the EC legislature enacting, in line with procedure under the old Article 100 regime, provisions expressly authorizing Member States to preserve more stringent rules on environmental protection in the long term? In the light of the general context within which this paragraph is situated, the adoption of a long-term derogation

90. Case C-6/99, *Greenpeace France*, [2000] ECR I-1676, para 44. Comments by Legal and Romi in (2000) A.J.D.A., 452; Gonzalez Vaqué, "El principio de precaucion en la jurisprudencia del TJCE: la sentecia 'Greenpeace France"', 2 *Comunidad Europea Aranzadi* (2001), 33–43.

91. The requirement only to consider arguments of a non-economic nature is redundant since Art. 30 precludes arguments of a purely economic nature (Case C-120/95, *Decker*, [1998] ECR I-1884, para 39).

92. Case C-300/89, *EC Commission* v. *Council* ("Titanium Dioxyde") [1991] ECR I-2867; Case C-155/91, *Commission* v. *Council* [1993] ECR I-971. See also the ECJ Opinion 2/00, on the legal basis of the Cartagena Biosafety Protocol of 6 Dec. 2001.

mechanism would at first sight appear to be precluded. The safeguard clause should be temporary insofar as it is required to cover "provisional measures". The Commission's capacity to grant derogations definitively by applying paragraphs 4 and 5 of Article 95 confirms moreover a restrictive interpretation of the scope *ratione materiae et temporis* of paragraph 10. Nevertheless, this practice shows that the insertion of safeguard clauses which permit the granting of long-term derogations remains generally admissible.[93]

Finally, the insertion of a safeguard clause into a directive does not preclude the possibility of a Member State invoking paragraphs 4 and 5 of Article 95. However, the existence of such a clause could be beneficial to the Member State.

4.2. *Safeguard procedures under the "new approach"*

According to the new approach for technical normalization,[94] the institutions of normalization (CEN, CENELEC) can find themselves entrusted with the task of developing technical specifications "needed for the production and placing on the market of products conforming to the essential requirements established by the Directives" adopted on the basis of Article 95 EC. While these technical specifications maintain their status as voluntary norms,[95] they effectively oblige the Member States to recognize a presumption of conformity with the essential requirements established by the directives for those products manufactured in accordance with these technical specifications. The resolution of 7 May 1985 on the "new approach" provides that safeguard procedures be inserted into the directives with a view to allowing either the Commission or a Member State to challenge norms emanating from the institutions of normalization. For example, Directive 94/62/EC of 20 December 1994 on packaging and packaging waste authorizes both Member States and Commission to appeal to the committee established by Directive 98/34/EC

93. See in particular the 14th para of the preamble to the Directive 91/112/EC setting out the terms for programmes to reduce (with a view to elimination) pollution caused by waste in the Titanium Dioxide industry. See also Art. 6(6) of Directive 94/62/EC on packaging and packaging waste which permits Member States, in certain circumstances, to set recycling targets higher than provided for in the Directive. On this question, see de Sadeleer, op. cit. *supra* note 15, pp. 394–397.

94. Resolution of the Council of Ministers 7 May 1985 on a new approach to technical harmonization and normalization (O.J. 1985, C 136/1). Resolution of the Council 2000/C141/01 on the role of normalization in Europe (O.J. 2000, C 141/1).

95. Annex II of the Resolution of 7 May 1985 states that "these technical specifications are not mandatory and maintain their status of voluntary standards". See also Art. 4 of Directive 2001/95/EC on general product safety which requires that the Commission shall call the European standardization bodies to draw up standards which satisfy general safety requirements.

if they consider that the norms elaborated by the CEN "do not entirely meet the essential requirements" in respect of production, composition, reusability and value of the packaging. On the basis of advice given by the committee, the Commission can "withdraw" such norms adopted by the institutions of normalization from the Official Journal of the European Communities. In this way (answering the Danish and Belgian challenge to the validity of several norms proposed by the CEN concerning packaging on the grounds that the priority given to incineration and energy conservation compromised the prevention principle, and as such went contrary to the compelling reasons provided for in Annex II of the Directive) the Commission decided not to publish certain norms harmonized by the CEN.[96]

5. Conclusion

In spite of the clarifications brought about by the coming into force of the Treaty of Amsterdam in relation to the safeguard clause mechanisms which Member States can invoke in order to adopt more stringent norms than those in EC law, the new Article 95 in turn generates its own share of questions. Where certain modifications appear at first sight to be favourable to Member States, others, notably those which regulate the process of scrutiny for new measures, strongly limit their room for manoeuvre. The Court of Justice will inevitably be called upon to settle disputes, which will not fail to result from EC law's attempt to strike a balance between the efficacy of the internal market and the defence of a range of interests dear to a "risk society". Once again, the importance which will be accorded by the EC to certain meta-principles – the requirement for a high degree of protection, precaution, substitution, free movement of goods – will be a determining factor in the resolution of these disputes.

96. Decision of the Commission 2001/524/EC of 28 June 2001 on the publication of references to the norms EN 13428:2000, EN 13429:2000, EN 13430:2000, EN 13431:2000 and EN 13432:2000 in the Official Journal of the European Communities within the context of the implementation of the Directive 94/62/EC on packaging and packaging waste (O.J. 2001, L 190/21).