

Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition

(2003/C 265/02)

(Text with EEA relevance)

SUMMARY

The Commission has been aware for some time that a large number of economic operators and national administrations are unfamiliar with the principle of mutual recognition in the area of intra-Community transfers of products.

Indeed, since economic operators are primarily interested in gaining rapid access to the national market, they often opt to adapt the composition of the product in line with the national rules of the Member State of destination, even if this makes access to this market more costly. On the other hand, confronted with an unknown product which does not conform to the letter with the technical rules of the Member State of destination, the predominant attitude of the national administrations is uncertainty. This uncertainty is sometimes reflected in excessive caution, leading authorities to refuse to allow the product to be placed on the market or to make access to their market more difficult.

To alleviate these problems, the Commission decided to publish this communication, which outlines the rights and obligations of economic operators and of national administrations in situations where the principle of mutual recognition needs to be applied. It is intended to be a practical guide to enable Member States and economic operators to benefit from the free movement of products in the many economic sectors which have not yet been harmonised.

This communication makes it clear that the Member State of destination of a product must allow the placing on its market of a product lawfully manufactured and/or marketed in another Member State or in Turkey, or lawfully manufactured in an EFTA State that is a contracting party to the Agreement on the European Economic Area, provided that this product provides an equivalent level of protection of the various legitimate interests involved.

Mutual recognition is not always automatically applicable: it can be affected by the right of the Member State of destination to verify the equivalence of the level of protection provided by the product under scrutiny, compared with the level of protection provided by its own national rules. When the Member State of destination exercises this right, it may use the practical tools proposed by this communication to examine the equivalence of the level of protection. These tools define the conditions applicable to the exercise of this right to balance it correctly with the fundamental right of free movement of products.

Despite the direct effect of Articles 28 and 30 of the EC Treaty, the very existence of a national technical rule often discourages economic operators and creates uncertainty for national administrators. For these reasons, this communication includes some suggestions to Member States to foster the proper application of the principle of mutual recognition, in particular the inclusion of a mutual recognition clause in the laws of Member States.

1. INTRODUCTION

1.1. Product diversity: One of the European Union's strengths

One of the features of the internal market is the very wide variety of products which provide a high level of protection for consumers and the environment. This variety is both a source of considerable wealth for European consumers and of competitiveness for European companies. Indeed, the enlargement of the European Union, the expansion of world trade and the greater liberalisation of international trade, combined with rapid progress in new manufacturing and distribution technologies, mean that the variety and technical complexity of products will undoubtedly increase substantially in the years ahead.

In spite of the progress on the free movement of goods that the Commission has seen over the last 15 years, and notwithstanding the EC regulations on product safety ⁽¹⁾, variety can still be a source of uncertainty or disquiet, on the part of both national administrations and economic operators ⁽²⁾. The Commission has already noted that a large number of economic operators and national administrations do not know exactly to what extent products which are not harmonised at Community level may have access to the market of another Member State, without being adapted to the rules of the Member State of destination ⁽³⁾.

Thus, confronted with a product which is not harmonised at Community level and which does not fulfil the technical rules of the Member State of destination, the national administrations and economic operators often do not know how to react. Very often this ignorance results in a refusal to allow a product to be placed on the market (or its withdrawal from the market), obliging the economic operator to refrain from marketing the product in that Member State. The result is that uncertainty and anxiety can act as an important barrier to gaining access to the market of the Member State of destination and to benefiting fully from the opportunity provided by the internal market.

1.2. The purpose of this communication: clarifying rights and obligations

In these circumstances, the Commission considers it advisable to call to mind the general principles which should guide economic operators and national authorities when looking at practical issues which may arise when assessing the conformity of products from the EEA/Turkish with the technical rules of the Member State of destination ⁽⁴⁾.

This communication aims to sum up the rights which economic operators may derive from Community law, and in particular from the principle of 'mutual recognition' arising from Articles 28 and 30 of the EC Treaty ⁽⁵⁾, when they encounter difficulties in placing EEA/Turkish products on the market of another Member State. Likewise, it can serve as a guide for national administrations when assessing the degree of equivalence of the protection that EEA/Turkish products can provide as compared to what is defined in their national legislation (verifying product conformity) ⁽⁶⁾.

The principle of mutual recognition plays an important part in the functioning of the internal market. Thanks to it, the free movement of products is possible in the absence of any Community harmonising legislation. Under it, Member States of destination cannot forbid the sale on their territories of EEA/Turkish products, even if the product in question was manufactured according to different technical and quality rules than those that must be met for their own products. The only exception to this principle are restrictions laid down by the Member State of destination, provided that these are justified on the grounds described in Article 30 of the EC Treaty, or on the basis of overriding requirements of general public importance recognised by the Court of Justice's case law.

This communication reiterates the conditions that must be satisfied to apply the principle of mutual recognition correctly. In particular, it examines the compatibility with Articles 28 and 30 of the EC Treaty of national technical rules which may impede the access of **products** in the non-harmonised field to the market of another Member State.

For the purpose of this communication, a technical rule means a technical specification which defines the

characteristics required of a product, such as its composition (quality level or fitness for use, performance, safety, dimensions, markings, symbols, etc.), its presentation (the name under which the product is sold, its packaging, its labelling) or testing and test methods within the framework of conformity assessment procedures, which is obligatory, in fact or in law, to market or use the product in the Member State of destination.

This communication concerns only certain measures adopted by the Member State of destination which are likely to hinder the access of certain products to the market of another Member State. Consequently, this communication does not deal with:

- national fiscal rules applicable to products, which must conform to other provisions of Community law,
- market surveillance activities and technical rules imposed by Community law,
- selling arrangements for products prescribed by national measures in the Member State of destination, in particular mandatory restrictions on the hours and place of sale, sales promotions, national pricing rules, etc. ⁽⁷⁾,
- difficulties in gaining access to the market of another Member State, attributable entirely to private persons or entities, and which do not arise from powers vested in them by a public authority.

In view of the specific nature of the national rules applicable to products, the principles of this communication are not necessarily applicable in other fields, such as the free movement of services, capital and persons.

The Court of Justice recognises that, in the absence of harmonised Community rules, the Member States have the power to adopt **technical rules**.

However, the Member State of destination must allow an EEA/Turkish product free access to its market, provided that it provides an equivalent level of protection of the various legitimate interests⁽⁸⁾ at stake. This principle will henceforth be referred to as the principle of '**mutual recognition**'⁽⁹⁾.

However, mutual recognition is not always automatically applicable: it can be affected by the **right of the Member State of destination to verify** the equivalence of the level of protection provided by the product under scrutiny, compared with that provided by its own national rules.

The communication describes the right of economic operators to appeal and offers some **suggestions** on how to correctly combine the fundamental right of free movement of products with the oversight of the Member State of destination.

2. TYPES OF PRODUCTS COVERED BY THIS COMMUNICATION

This communication applies only to '**EEA/Turkish products**', i.e. the products⁽¹⁰⁾ which meet the conditions set out in points 2.1 and 2.2.

2.1. Products that are not harmonised at Community level⁽¹¹⁾

This communication does not apply to products:

- which are covered by a marketing authorisation which is valid throughout the Community⁽¹²⁾, or
- which bear the EC mark in accordance with Community directives, for those aspects which are harmonised at Community level⁽¹³⁾, or
- which comply with, and in respect of which placement on the market is guaranteed by, Community legislation⁽¹⁴⁾. It should be noted that Community legislation sometimes provides for a system of national authorisations based on an in-depth examination by the competent authorities of a Member State. Once the marketing authorisation is granted by these authorities, Community legislation generally stipulates that the competent authorities of other Member States must recognise this authorisation and grant their national authorisation, save in exceptional cases⁽¹⁵⁾,

- to which, being in conformity with a European standard whose references have been published by the Commission, the presumption of safety laid down by the Directive on general product safety⁽¹⁶⁾ applies, for the risks and risk categories covered by the standards in question.

This communication relates only to the products or the aspects of products in respect of which intra-Community free movement is guaranteed by Articles 28 and 30 of the EC Treaty, which simultaneously presupposes that the field in question is not the subject of a Community regulation⁽¹⁷⁾.

2.2. Products lawfully manufactured and/or marketed in another Member State or in Turkey, or lawfully manufactured in an EFTA State that is a contracting party to the Agreement on the European Economic Area

- If a product is manufactured in another Member State, in Turkey⁽¹⁸⁾, or in an EFTA State that is a contracting party to the Agreement on the European Economic Area⁽¹⁹⁾, according to the manufacturing rules and methods approved there⁽²⁰⁾, it is considered as being lawfully manufactured. Thus, it covers not only products which are manufactured according to any technical rules laid down in the laws of the Member State of manufacture, but also products which do not infringe any other national rule. It is obvious that a product is also lawfully manufactured when there are no specific national technical rules or other types of rules, laid down by the authorities, which are applicable to this type of product. With regard to products intended for (or which may be used by) consumers, products which are placed on the Community market are subject to the requirements and safety criteria laid down by the Directive on general product safety.
- This communication applies also to products lawfully marketed in another Member State⁽²¹⁾ or in Turkey.

For the purpose of this communication, 'State of origin' means:

- another Member State or Turkey, provided that the product is legally manufactured or marketed there, and
- an EFTA State that is a contracting party to the Agreement on the European Economic Area provided that the product is legally manufactured there.

In any event, the Directive on general product safety provides that responsibility for ensuring that products placed on the market are safe lies with the economic operator. According to the Community definition, a product is safe when, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons ⁽²²⁾.

3. THE RESTRICTIVE IMPACT OF TECHNICAL RULES ON A PRODUCT'S ACCESS TO THE MARKET OF THE MEMBER STATE DESTINATION

In fact, one of the most frequent barriers to intra-Community trade in EEA/Turkish products is the application of technical rules, as defined in paragraph 2 of this communication, to these products, even if these rules apply both to domestic products and to EEA/Turkish products ⁽²³⁾. In practice, problems regarding the application of the principle of mutual recognition arise essentially when an economic operator who decides to market a product there is faced with the problem that the Member State of destination imposes its own technical rules on the product in question.

Such rules may oblige the economic operator to withdraw EEA/Turkish products from the market of the Member State of destination ⁽²⁴⁾. They are also likely to oblige the economic operator to adapt EEA/Turkish products depending on the Member State of destination. This will give rise to additional costs for the economic operator. Even where these additional costs are borne by consumers in the final analysis, the mere prospect of having to advance these costs constitutes a barrier for operators, since it is likely to deter them from entering the market of the Member State in question ⁽²⁵⁾.

A technical rule imposed by a Member State of destination which implements a national standard ⁽²⁶⁾ or makes a national standard obligatory is particularly likely to constitute a barrier to the free movement of products if it makes no provision for alternate technical approaches which provide an equivalent level of protection, even where it applies to all the products marketed on its territory, including EEA/Turkish products ⁽²⁷⁾.

A very precise and excessively detailed technical rule is also particularly likely to constitute a barrier to the free movement of products, even when it applies to all

products marketed on its territory, including EEA/Turkish products ⁽²⁸⁾.

Some examples would be technical rules relating to:

- the composition of the product ⁽²⁹⁾, its quality level ⁽³⁰⁾, its safety ⁽³¹⁾, its dimensions ⁽³²⁾,
- the presentation of the product, its sales name ⁽³³⁾, its packaging ⁽³⁴⁾, its labelling ⁽³⁵⁾.

However, technical rules in the Member State of destination of the product cannot require that the EEA/Turkish products satisfy literally and exactly the same provisions or technical characteristics prescribed for products manufactured in the Member State of destination if these EEA/Turkish products ensure an equivalent level of protection, particularly with regard to the health and life of consumers who use or consume them ⁽³⁶⁾.

It follows that, when the supervisory authorities of the Member State of destination of the product exercise their right to verify the conformity of an EEA/Turkish product to their own technical rules, they must examine to what extent this product provides an equivalent level of protection.

4. SUPERVISION BY THE MEMBER STATE OF DESTINATION

An essential principle of Community law is that an EEA/Turkish product enjoys the basic right of free movement of products, guaranteed by the EC Treaty, provided that the Member State of destination has not taken a reasoned decision of refusal, based on proportionate technical rules ⁽³⁷⁾.

The basic right of free movement of products is not an absolute right: mutual recognition is subject to the right of the Member State of destination to verify the equivalence of the level of protection provided by the product which it is examining compared with that provided by its own national rules.

This supervision must be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authority's discretion so that this discretion is not used arbitrarily.

Consequently, the criteria should be duly published or easily available. In any event, supervision should always be exercised in the framework of a procedure that is as short, effective and inexpensive as possible. In principle, there can be no systematic control in the Member State of destination before release on the market. As a result, as a general rule, the Member State of destination can only examine the conformity of an EEA/Turkish product with its own technical rules as part of an inspection undertaken as part of its market monitoring activities, and after release on the national market. However, an authorisation procedure prior to release on the national market of the Member State of destination may be justified under very strict conditions ⁽³⁸⁾.

Thus, the principles of this communication must also be applied, *mutatis mutandis*, in the framework of an authorisation procedure prior to release on the national market of the Member State of destination.

The Commission considers that, to comply with Articles 28 and 30 of the EC Treaty, the examination of the conformity of an EEA/Turkish product in the light of the legislation of the Member State of destination should take account of the following elements. These are divided into stages:

4.1. First stage: collecting the necessary data

When the competent authority of the Member State of destination submits an EEA/Turkish product to an evaluation of its conformity with its own technical rules, it would be logical that it should first contact the economic operator who is in a position to supply the necessary information within a reasonable time ⁽³⁹⁾. In response to targeted and precise questions, the economic operator will be able to supply the relevant technical information and, where necessary, a sample of the product in question. On the basis of its experience in dealing with complaints and infringements, the Commission considers that a deadline of 20 working days is reasonable.

The competent authority of the Member State of destination also has the right to obtain more extensive information on the conformity of the EEA/Turkish product to the rules of Member States of origin. More specifically:

- If the economic operator has proof of the conformity (such as a written confirmation from the competent authority of the Member State of origin ⁽⁴⁰⁾), the Commission is of the opinion that it would be useful for this proof to be transmitted to the competent authority of the Member State of destination.

- It would also be useful if the economic operator were to provide the references of the applicable provisions of law in the Member State of origin.

The Commission considers that the request for information by the competent authority of the Member State of destination and/or the examination of the product by the competent authority cannot cause the marketing of the EEA/Turkish product in the Member State of destination to be suspended pending a reasoned decision on this marketing by the competent authority in question ⁽⁴¹⁾, except where an emergency measure is adopted following an alert as provided for in Directive 2001/95/EC or in Regulation 178/2002.

The competent authority of the Member State of destination may request a translation of these documents when necessary. Nonetheless, it would be excessive for a Member State to require a translation certified or authenticated by a consular or administrative authority ⁽⁴²⁾, or to impose an excessively short deadline for providing such a translation, unless there are special circumstances which warrant this. The Commission also considers that the competent authority of the Member State of destination should identify the parts of the documents which need to be translated. The authority should also avoid asking for translations when the documents in question are available in another language which the authority is able to understand.

The competent authority of the Member State of destination has the right to take one or, if necessary, several samples of the product in order to examine its conformity with its rules ⁽⁴³⁾. The number of samples must be proportionate to the potential risk the product may pose.

In any event, the competent authority of the Member State of destination cannot duplicate controls which have already been carried out in the context of other procedures, either in the same State, or in another Member State ⁽⁴⁴⁾.

Indeed, Court of Justice case law requires that the following be taken into account:

- the checks carried out by a competent authority in the Member State of origin ⁽⁴⁵⁾,

- the technical or scientific analyses or laboratory tests already carried out in a State of origin ⁽⁴⁶⁾. The Commission is of the opinion that the only valid reason for refusing to take account of tests carried out and certificates granted by an inspection or certification body legally established in the Member State of origin would be that the body does not provide appropriate and satisfactory guarantees of technical ability, professionalism and independence. The Commission considers that certification bodies approved on the basis of criteria taken from the EN 45000 series of standards do provide appropriate and satisfactory guarantees of technical ability, professionalism and independence. It follows that the results of tests carried out by an approved body on the basis of criteria derived from the standards in the Member State of origin on the basis of technical specifications of the same level as those required by the Member State of destination must be accepted by the latter. This State may not call the results of the tests into question on the grounds of a lack of technical or professional ability, or a lack of independence of the body. However, other approaches which make it possible to obtain appropriate and satisfactory verification and proof of the abilities and independence of the certification bodies must also be accepted.

The evidence of controls and/or the technical or scientific reports may be obtained from the economic operator in question ⁽⁴⁷⁾ or, as appropriate, from the competent administration in the Member State of origin ⁽⁴⁸⁾.

However, the Member State of destination will only have the right to require additional tests when all the following conditions have been met:

- these tests have not already been carried out or have not been carried out by a body providing equivalent guarantees to those required for the national bodies ⁽⁴⁹⁾,
- this type of test is also imposed on national product's,
- these tests are necessary to provide the competent authority with the information required to evaluate the level of protection afforded by the product ⁽⁵⁰⁾.

The Member State of destination may always carry out additional tests, but at its own expense ⁽⁵¹⁾.

4.2. **Second stage: Verification of the equivalence of levels of protection**

4.2.1. *Recognition of the conformity of the product with the rules of a Member State of origin*

When the competent authority of the Member State of destination learns that the EEA/Turkish product complies with the rules of one (or more) State(s) of origin, it may sometimes be aware, by virtue of the administrative cooperation between Member States, of the minimum level of protection provided by the legislation of the State or States in question. If this level is equivalent to that of the Member State of destination, a more detailed examination of the product is not necessary. Subject to the occasional checks that the Member State of destination may carry out on the market, the product will then continue to be marketed in the Member State of destination without further action on the part of the economic operator regarding assessment of conformity in the Member State of destination.

The level of protection of the legislation of a State of origin may be helpful in assessing the conformity of the EEA/Turkish product with the rules of the Member State of destination, but it is certainly not the decisive element in drawing conclusions as to the level of protection provided by the product. Indeed, it is possible that the manufacturer of the product has opted for a higher quality than that required in the Member State of origin.

4.2.2. *Identifying the technical rules applicable to the product*

On the basis of the information obtained on the EEA/Turkish product in question, the competent authority of the Member State of destination may examine if and to what extent its national technical rules must apply to the product concerned.

When the Member State of destination has no technical rules for the marketing of EEA/Turkish products on its territory, in principle the marketing of a product will not be restricted there. This will generally be the case for simple or well-known products, which do not pose any risk to health or safety, under normal conditions of use.

However, in the absence of a specific technical rule in the Member State of destination, that Member State may nonetheless restrict the marketing of the product in the event of problems linked to its safety, in accordance with the Directive on general product safety or under Regulation 178/2002, provided, of course, that the conditions for applying this legislation are met.

However, when the Member State of destination lays down technical rules for the marketing of EEA/Turkish products on its territory, the competent authority should examine the documentation relating to the product and, if necessary, the product itself, in the light of these same rules. This examination makes it possible to determine the technical rules to which the EEA/Turkish product does not conform, thus facilitating the exercise of the right of supervision over the product in question.

4.2.3. *The proportionality of the application of the technical rules of the Member State of destination*

The technical rules to which the EEA/Turkish product in question does not conform will be the basis for examining the proportionality of the application of these rules in the case in question.

It should be pointed out that, in the non-harmonised field, and with due regard to the Treaty and thus the principle of proportionality, the Member States remain free to determine the level of protection that they consider appropriate for protecting legitimate objectives, such as public health, consumers, the environment, public order, road safety, etc. ⁽⁵²⁾.

A level of protection is generally fixed on the basis of a risk assessment ⁽⁵³⁾ and by various methods, in particular by technical rules.

The competent authority has the right to apply its technical rule to an EEA/Turkish product only when the replies to the following two questions are in the affirmative:

- Does the technical rule itself satisfy one of the general interest motives recognised in Community law?
- Will the application of the rule to the product be able to guarantee the achievement of the objective sought and does it refrain from going beyond what is necessary to achieve this?

For the application of a technical rule to a product to be proportionate, it must be both necessary and adequate:

- (a) The necessity of the application of the technical rule: the application of the technical rule to an EEA/Turkish product must be based primarily on relevant technical or scientific features ⁽⁵⁴⁾. Secondly, the rule must be necessary for the protection of one or more of the objectives recognised as legitimate by the Treaty or by the Court's case law ⁽⁵⁵⁾.

Example: The Member State of destination prohibits the marketing of bread where the dry matter salt content exceeds the maximum limit of 2 %. Where the Member State does not have scientific justification for this requirement based on consumer health protection, such a requirement cannot be applied to EEA/Turkish products.

- (b) The adequacy of the application of the technical rule: the application of a technical rule will be deemed not to be adequate if the requirements it is intended to protect can be protected equally effectively by measures less restrictive of intra-Community trade. In this context, it is necessary to assess the protection provided by alternative measures ⁽⁵⁶⁾.

Example: The Member State of destination lays down technical rules according to which only durum wheat may be used to make dried pasta. The sale of pasta manufactured from common wheat or from a mixture of common and durum wheat is prohibited. The purpose of these rules is to protect consumers by ensuring trade is fair. This objective can be met in a way that is less restrictive of intra-Community trade in such pasta through appropriate labelling or by providing a specific name for this type of product.

Consequently, the competent authority will be obliged, when examining an EEA/Turkish product, to eliminate, on its own initiative, any technical rules which are not proportionate in the light of one of the imperative reasons recognised by the Court as mandatory requirements or mentioned in Article 30 of the EC treaty.

It should be emphasised that the decision not to apply these disproportionate technical rules to an EEA/Turkish product is a decision which is mandatory under Community law which, in any event, takes precedence over national law.

Moreover, national regulations cannot require that EEA/Turkish products should satisfy literally and exactly the same provisions or technical characteristics laid down for products manufactured in the Member State of destination, when these products afford the same level of protection ⁽⁵⁷⁾.

The examination of the possible application of a technical rule to an EEA/Turkish product may mean that domestic products are treated differently, perhaps even more severely, than the EEA/Turkish product in question. When examining the conformity of an EEA/Turkish product, the competent authority cannot regard such different treatment as a decisive factor.

Lastly, it is possible that the Member State of destination has chosen a different system of protection from that adopted by the Member State of origin. This difference has no impact on the evaluation of the necessity for and proportionality of the technical rules in the Member State of destination. These must be assessed only in the light of the objectives pursued by the national authorities of the Member State of destination and of the level of protection which these rules are intended to guarantee ⁽⁵⁸⁾.

4.3. Third stage: the results of the assessment and communicating them to the applicant

When the Member State of destination has examined the EEA/Turkish product in question, the results of this assessment — whether positive or negative — must be communicated as soon as possible ⁽⁵⁹⁾ to the economic operator concerned.

The Commission considers that the competent authority should provide the economic operator in question with all the facts of the case, not just in the event of a negative assessment, but also in the event of a positive assessment. A positive assessment confirms that the EEA/Turkish product can legally be marketed in the Member State of destination.

However, the restriction of trade which may arise from a negative assessment is, in principle, a measure having an effect equivalent to a quantitative import restriction, prohibited by Article 28 of the EC Treaty.

It is up to the Member State which claims to have a reason justifying a restriction on the free movement of goods to demonstrate specifically the existence of a reason relating to the public interest, the necessity for the restriction in question and the proportionality of the restriction in relation to the objective pursued ⁽⁶⁰⁾.

One of the general principles of Community law is that everybody must have the right to effective legal recourse before the national courts against national decisions which infringe a right recognised by the Treaties or by secondary Community legislation. This principle implies that those concerned may obtain information

regarding the grounds for such decisions from the administration, before any recourse to law ⁽⁶¹⁾.

Other than the measures which may be taken under the Directive on general product safety, the Commission is of the opinion that the competent authority of the Member State of destination that considers that an EEA/Turkish product should be refused access to its market, should in any event:

- inform the manufacturer or distributor in writing of those elements of its national technical rules which in its opinion prevent the marketing of the product in question in the Member State of destination,
- prove to the economic operator concerned, on the basis of all the relevant scientific elements available to the Member State of destination, that there are overriding grounds of general interest for imposing these elements of the technical rule must be imposed on the product concerned and that less restrictive measures could not have been used,
- then invite the economic operator to submit any comments within a reasonable period (approximately 20 working days), before taking any individual measure restricting the marketing of his product,
- duly take account of these comments in the grounds of the final decision,
- once the individual measure restricting the marketing of the product has been taken, notify the economic operator concerned of this recent decision stating the methods of appeal open to him,
- notify this decision to the Commission pursuant to Article 7 of Directive 92/59/EEC on general product safety (and, as from 15 January 2004, pursuant to Article 11 or 12 of Directive 2001/95/EC on general product safety), or pursuant to Article 50 of Regulation 178/2002 laying down the general principles and requirements of food law,
- or, when these articles do not apply, inform the Commission of this decision pursuant to Decision No 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community.

5. METHODS OF APPEAL AVAILABLE TO THE ECONOMIC OPERATOR

5.1. The direct applicability of Articles 28 and 30 of the EC Treaty

The provisions of Articles 28 to 30 of the EC Treaty take precedence over all contrary national measures ⁽⁶²⁾.

Consequently, where provisions of national law incompatible with Articles 28 to 30 of the EC Treaty exist, the national courts and administrations are obliged to guarantee the full impact of Community law by removing, on their own initiative, the conflicting provisions of national law ⁽⁶³⁾.

In addition, penalties, be they criminal or otherwise, involving national restrictive measures which have been recognised as being contrary to Community law are as incompatible with Community law as the restrictions themselves ⁽⁶⁴⁾.

Thus, a national court which is called upon, within the limits of its jurisdiction, to apply provisions of Community law, is under a duty to give full effect to those provisions, if necessary refusing of its own motion to apply any conflicting provision of national legislation, even if adopted subsequently, and it is not necessary for the court to request or await the prior setting aside of such provision by legislative or other constitutional means ⁽⁶⁵⁾.

The national courts can, where necessary, ask the Court of Justice to give a preliminary ruling on the interpretation of Articles 28 and 30 of the EC Treaty, in accordance with Article 234 of that Treaty.

5.2. Contesting a refusal on the part of the competent authority of the Member State of destination

A negative decision by the Member State of destination regarding the access of an EEA/Turkish product to its market is, in principle, likely to constitute a measure having an equivalent effect to a quantitative import restriction, prohibited by Article 28 of the EC Treaty. Thus, the economic operator may always contest under national law a negative decision taken against him.

In appeals to the national courts, the latter must apply Articles 28 and 30 of the EC Treaty, interpreted in the light of the Court of Justice's case law, together with, where appropriate, the principles set out in this

communication, and must consider the negative decision as incompatible with these articles.

6. SOME ADVICE TO MEMBER STATES

Correct application of mutual recognition makes it possible to reconcile competing public interests: on the one hand, the free movement of EEA/Turkish products, guaranteed under Articles 28 and 30 of the EC Treaty and, on the other, the protection of health, the environment, consumers and so on.

As Member States are required to give precedence to Articles 28 and 30 of the EC Treaty over all national rules contrary to these articles, they must ensure that their technical rules comply with Community law. Several options are open to them to achieve this, some of which may be combined.

6.1. Mutual recognition clause

Despite the direct impact of Articles 28 and 30 of the EC Treaty, the existence of a national technical rule sometimes discourages economic operators from marketing their products on the territory of that Member State, even if their products provide an adequate and recognised level of protection in certain other Member States. In addition, the competent administration of the Member State of destination often hesitates to apply Articles 28 to 30 of the EC Treaty when there is no specific legal basis in its national technical laws on which to assess the conformity of an EEA/Turkish product.

For these reasons, the Commission wants Member States to include, in their national laws, a mutual recognition clause designed to apply the principle of mutual recognition correctly ⁽⁶⁶⁾. This clause will be inserted in national laws and should permit the marketing of products lawfully manufactured and/or marketed in another Member State.

In fact, the principles of legal certainty and the protection of individuals require, in areas covered by Community law, that the Member States' legal rules should be worded unequivocally so as to give the persons concerned a clear and precise understanding of their rights and obligations and enable national courts to ensure that those rights and obligations are observed. The Commission considers that the mutual recognition clause is a valid means to implement these principles.

This clause can take one of the following forms:

- a simple clause, when other parts of national laws already include the administrative guarantees outlined in this communication,
- a clause which makes provision for a more detailed procedure, in compliance with the principles outlined in this communication.

Example of a detailed mutual recognition clause:

The requirements of this law do not apply to products lawfully manufactured and/or marketed in another Member State of the European Union or in Turkey, or lawfully manufactured in an EFTA State that is a contracting party to the EEA agreement.

If the competent authorities have proof that a specific product lawfully manufactured and/or marketed in another Member State of the European Union or in Turkey, or lawfully manufactured in an EFTA state that is a contracting party to the EEA agreement, does not provide a level of protection equivalent to that sought by this law, they may refuse market access to the product or have it withdrawn from the market, after they:

- have informed the manufacturer or the distributor in writing which elements of the national technical rules prevent the marketing of the product in question, and
- have proved, on the basis of all the relevant scientific elements available to the the competent authorities, that there are overriding grounds of general interest for imposing these elements of the technical rule must be imposed on the product concerned and that less restrictive measures could not have been used, and
- have invited the economic operator to express any comments he may have within a period of (at least four weeks or 20 working days), before issuing an individual measure against him restricting the marketing of this product, and
- have taken due account of his comments in the grounds of the final decision.

The competent authority shall notify the economic operator concerned of individual measures restricting the marketing of the product, stating the means of appeal available to him.

6.2. Repeal of the technical rule

Another option is the abolition of the technical rule. An assessment of the potentially restrictive effects of the technical rule may lead to the conclusion that it is no longer relevant or that it should be applied only to national products.

In any event, the fact that the requirements imposed on domestic products are more severe than those applied to EEA/Turkish products does not interfere with the correct application of the principle of mutual recognition.

6.3. Ensuring transparency

Some economic operators prefer absolute certainty and wish to avoid any event which might have a negative impact on the reputation of their product, such as the suspension of marketing when the authorities of the Member State of destination establish the non-conformity of an EEA/Turkish product with a technical rule of the Member State of destination. Other economic operators fear the unpredictability of the application of mutual recognition in a Member State of destination, even if the laws contain technical rules which are, even at first sight, disproportionate.

The Commission considers that there are several ways to improve the predictability of mutual recognition, based on the greater transparency. Some examples are:

6.3.1. Improving the accessibility of technical rules

Access to the technical rules is vital for the economic operators wishing to market their EEA/Turkish products in another Member State.

The Commission has noted that, too often, the principle of mutual recognition is undermined because economic operators do not know where to turn and what information to supply to ensure application of the principle.

The Commission invites the Member States to ensure that these rules, drafted in a clear manner, are publicised in such a way as to make them more accessible to economic operators, in particular through detailed Internet sites and through brochures published by product sector, e.g. giving the name of the authorities competent to provide information.

One of the challenges for economic operators is identifying the administration which is competent for applying mutual recognition with regard to their product. The Commission invites Member States to use appropriate means to publicise the services which are responsible for applying technical rules and mutual recognition, so that economic operators can obtain the information needed.

to determine whether the technical approach they have adopted is actually equivalent.

The Member State could make it easier to apply mutual recognition by publicising the references to technical rules and standards from other Member States which have already been accepted because complying with them achieves the level of protection required for the objective pursued.

6.3.2. *Appropriate publicity for equivalent approaches*

Even where the legislation of the Member State of destination includes a mutual recognition clause for products which provide, for example, an equivalent level of safety, it is sometimes difficult for economic operators

6.3.3. *Specifying the purpose of the legislation*

The Commission encourages Member States to specify in their regulatory texts the objectives they are pursuing. Doing so will make it easier for national administrations and economic operators to assess equivalence.

⁽¹⁾ In the absence of a specific Community measures on the safety of products intended for consumers or which may be used by consumers, Directive 92/59/EEC of 29 June 1992 on general product safety (and, from 15 January 2004, Directive 2001/95/EC of the European Parliament and of the Council) has set up a horizontal legislative framework with a view to guaranteeing a high level of protection for individuals' safety and health. This directive places an obligation on economic operators to market only safe products. Therefore, those products which are intended for consumers or which may be used by consumers, and which have been placed on the Community market, are subject to the requirements and safety criteria laid down in the said directive. The same applies to foodstuffs under the provisions of Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, which set out, in particular, general rules intended to ensure that only safe foodstuffs and animal feed are placed on the market.

⁽²⁾ An economic operator is any person who wishes to market products. They include manufacturers, their representatives, wholesalers, distributors and any other professionals in the marketing chain.

⁽³⁾ Communication COM(1999) 299 final to the Council and the European Parliament of 16 June 1999 on mutual recognition in the context of the follow-up to the action plan for the Single Market. First biennial report on the application of the principle of mutual recognition (SEC(1999) 1106 of 13 July 1999) and second biennial report COM(2002) 419 final of 23 July 2002. These documents may be consulted on the Internet at the following address: http://europa.eu.int/comm/internal_market/en/goods/mutrec.htm

⁽⁴⁾ 'EEA/Turkish' products are defined in point 2.

⁽⁵⁾ In the absence of harmonised Community rules, in the trade of products between Member States, the general rule of Article 28 of the EC Treaty prohibits quantitative restrictions on imports of products and/or measures having equivalent effect, which thus constitute obstacles to the free movement of products. Article 30 of the EC Treaty states that the provisions of Article 28 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals and/or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. However the Court of Justice has also indicated that restrictions to access to the market of another Member State, imposed through national measures liable to constitute measures having equivalent effect within the meaning of Article 28 of the EC Treaty, may be justified in the light of certain overriding requirements recognised by it, on condition that these are necessary and proportionate.

⁽⁶⁾ The references to the case law of the Court of Justice in this communication are not exhaustive. They include only the specific judgments which may assist the competent authorities and the economic operators to examine a particular problem in the light of related Community case law.

⁽⁷⁾ This concerns the selling arrangements within the meaning of the Judgment of the Court of Justice of 24 November 1993, criminal proceedings against Bernard Keck and Daniel Mithouard, European Court Reports 1993, p. I-6097 and its subsequent case law on this matter.

⁽⁸⁾ Among the legitimate interests which are most commonly invoked are the protection of health and life of humans, animals or plants, the protection of the environment, the protection of consumers.

- ⁽⁹⁾ This principle originates in the 'Cassis de Dijon' Judgment of 20 February 1979 (*Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein*), Case 120/78, European Court Reports 1979, p. 649. From 1980, the Commission drew up a number of guidelines regarding the application of the principle of mutual recognition arising from Court case law, in particular in the communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in Case 120/78 (*Cassis de Dijon*) (OJ C 256, 3.10.1980).
- ⁽¹⁰⁾ For the purposes of this communication, a product is defined as a moveable good which is capable, as such, of forming the subject of commercial transactions: Judgment of the Court of 21 October 1999, *Peter Jägerskiöld v. Torolf Gustafsson*, Case C-97/98, European Court Reports 1999, p. I-7319. According to Court of Justice case law, goods taken across a frontier for the purposes of commercial transaction are subject to Article 28 of the EC Treaty, whatever the nature of those transactions: see in particular ground 20 of the Judgment of the Court of 28 March, 1995, *The Queen v. Secretary of State for Home Department*, ex parte *Evans Medical Ltd and Macfarlan Smith Ltd*, Case C-324/93, European Court Reports 1995, p. I-563.
- ⁽¹¹⁾ See in particular ground 32 of Judgment of the Court of 13 December 2001, *DaimlerChrysler AG v. Land Baden-Württemberg*, Case C-324/99, European Court Reports 2001 p. I-9897.
- ⁽¹²⁾ These are, for example, certain pharmaceutical products, biocides and plant protection products.
- ⁽¹³⁾ The specific list of the 'new approach' directives, guaranteeing this free movement through conformity to the essential requirements and the EC mark, may be consulted on the site <http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist.html>
- ⁽¹⁴⁾ The applicable Community legislation may be consulted on <http://europa.eu.int/eur-lex/en/lif/index.html>. Please note the importance of a careful reading of the Community legislation to determine to what extent mutual recognition may apply to the product concerned. In fact, certain aspects of a product may be harmonised at Community level whereas other aspects of the same product will not be covered by Community harmonisation. Mutual recognition will continue to apply to these latter aspects.
- ⁽¹⁵⁾ In particular, these are the national applications for market authorisation, awarded pursuant to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, or pursuant to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocide products on the market, and to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.
- ⁽¹⁶⁾ Article 4(2) of Directive 92/59/EEC and, from 15 January 2004, Article 3(2) of Directive 2001/95/EC on general product safety.
- ⁽¹⁷⁾ Ground 25 of the Judgment of the Court of 23 March 2000, *Criminal Proceedings against Berendse-Koenen M.G. in Berendse H.D. Maatschappij*, Case C-246/98, European Court Reports 2000, p. I-1777; Grounds 25 and 26 of the Judgment of the Court of 23 May 1996, *The Queen v. Ministry of Agriculture, Fisheries and Food*, ex parte: *Hedley Lomas (Ireland) Ltd*, Case C-5/94, European Court Reports 1996, p. I-2553. Member States are required to include in their national legislation a reference to the Community legislation which they are transposing. This helps to identify which parts of the national legislation in question transpose Community legislation and which parts are governed by Articles 28 and 30 of the EC Treaty. Nonetheless, close reading of the Community legislation is crucial in order to assess the extent to which mutual recognition may apply to the product in question. Indeed, certain aspects of a product may be harmonised at the Community level while other aspects of the same product are not. Mutual recognition continues to apply to these latter aspects.
- ⁽¹⁸⁾ Articles 5 to 7 of Decision No 1/95 of the EC-Turkey Association Council of 22 December 1995 on implementing the final phase of the Customs Union (OJ L 35, 13 February 1996, p. 1) provide for the elimination of measures having an effect equivalent to customs duties between the European Union and Turkey. Pursuant to Article 66 of Decision 1/95, Articles 5 to 7 must, for the purposes of their implementation and application to products covered by the Customs Union, be interpreted in conformity with the relevant Judgments of the Court of Justice. Consequently, principles resulting from the Court of Justice's case law on issues which are related to Articles 28 and 30 of the EC Treaty, particularly the 'Cassis de Dijon' case, apply to the Member States and to Turkey.
- ⁽¹⁹⁾ Articles 8(2) and 9 of the Agreement on the European Economic Area, and Protocol 4 thereof. The Articles 28 to 30 of the EC Treaty form part of the Community *acquis* included in full in Articles 11 and 13 of the Agreement on the European Economic Area, which are interpreted in accordance with the relevant case law of the Court of Justice of the EC prior to the date of the signing of the Agreement. This communication therefore applies also to products manufactured in Iceland, Liechtenstein and Norway.
- ⁽²⁰⁾ However, it should be noted that, when national rules are contrary to Articles 28 and 30 of the EC Treaty, the Court of Justice has confirmed that the application of those rules is prohibited only in respect of imported products and not national products. See in particular ground 21 of Judgment of the Court of 5 December 2000, *Criminal Proceedings against Jean-Pierre Guimont*, Case C-448/98, European Court Reports 2000, p. I-10663.

- (²¹) Article 24 of the EC Treaty states that 'products coming from a third country shall be considered to be in free circulation in a Member State if the import formalities have been complied with and any customs duties or charges having equivalent effect which are payable have been levied in that Member State, and if they have not benefited from a total or partial drawback of such duties or charges'. In addition, ground 37 of the Judgment of the Court of 22 January 2002, *Canal Satélite Digital SL v. Administración General del Estado*, in the presence of *Distribuidora de Televisión Digital SA (DTS)*, Case C-390/99, European Court Reports 2002, p. I-607, confirms this principle: 'It is well established in case law that a product which is lawfully marketed in one Member State must in principle be able to be marketed in any other Member States without being subject to additional control, save in the case of exceptions provided for or allowed by Community law'.
- (²²) See Directive 2001/95/EC and Directive 92/59/EEC on general product safety.
- (²³) Ground 26 of the Judgment of the Court of 21 June 2001, *Commission of the European Communities v. Ireland*, Case C-30/99, European Court Reports 2001, p. I-4619.
- (²⁴) See in particular ground 36 of the Judgment of the Court of 24 October 2002, *Criminal Proceedings against Walter Hahn*, Case C-121/00, European Court Reports 2002, p. I-9193.
- (²⁵) Grounds 17 and 18 of the Judgment of the Court of 16 November 2000, *Commission v. Belgium*, Case C-217/99, European Court Reports 2000, p. I-10251.
- (²⁶) A national standard means a technical specification adopted by a national standards body for repeated or continuous application, made available to the public and compliance with which is not compulsory.
- (²⁷) Judgment of the Court of 22 September 1988, *Commission of the European Communities v. Ireland*, Case 45/87, European Court Reports 1988, p. 4929.
- (²⁸) Judgment of the Court of 14 June 2001, *Commission of the European Communities v. French Republic*, Case C-84/00, European Court Reports 2001, p. I-4553.
- (²⁹) Judgment of the Court of 14 July 1988, *Criminal Proceedings against Zoni*, Case 90/86, European Court Reports 1988, p. 4285.
- (³⁰) Judgment of the Court of 5 April 2001, *Criminal Proceedings against Christina Bellamy and English Shop Wholesale SA*, Case C-123/00, European Court Reports 2001, p. I-2795; Judgment of the Court of 14 June 2001, *Commission of the European Communities v. French Republic*, Case C-84/2000, European Court Reports 2001, p. I-4553.
- (³¹) Judgment of the Court of 24 October 2002, *Criminal Proceedings against Walter Hahn*, Case C-121/2000, European Court Reports 2002, p. I-9193.
- (³²) Judgment of the Court of 12 October 2000, *Cidrerie Ruwet SA v. Cidre Stassen SA and HP Bulmer Ltd*, Case C-3/99, European Court Reports 2000, p. I-8749; Judgment of the Court of 10 November 1982, *Walter Rau Lebensmittelwerke v. De Smedt PVBA*, Case 261/81, European Court Reports 1982, p. 3961.
- (³³) Judgment of the Court of 5 December 2000, *Criminal Proceedings against Jean-Pierre Guimont*, Case C-448/98, European Court Reports 2000, p. I-10663.
- (³⁴) Judgment of the Court of 4 December 1986, *Commission of the European Communities v. Federal Republic of Germany*, Case 179/85, European Court Reports 1986, p. 3879; Judgment of the Court of 6 June 2002, *Sapod Audic v. Eco-Emballages SA*, Case C-159/00, European Court Reports. 2002, p. I-5031.
- (³⁵) Judgment of the Court of 12 September 2000, *Criminal Proceedings against Yannick Geffroy and Casino France SNC*, Case C-366/98, European Court Reports 2000, p. I-6579; Judgment of the Court of 16 November 2000, *Commission of the European Communities v. Kingdom of Belgium*, Case C-217/99, European Court Reports. 2000, p. I-10251.
- (³⁶) See in particular number 17 of the grounds of the Judgment of 28 January 1986, *Commission of the European Communities v. French Republic* ('Type-approval for woodworking machines'), Case 188/84, European Court Reports 1986, p. 419.
- (³⁷) The Directive on general product safety does however permit Member States to take rapid restrictive measures with regard to products which are dangerous or are likely to be dangerous, pursuant to Articles 6, 7 or 8 and 14 of Directive 92/59/EC and, as from 15 January 2004, pursuant to Articles 8, 11 or 12 and 18 of Directive 2001/95/EC.

- (³⁸) In its Judgment of 22 January 2002, (*Canal Satélite Digital SL v. Administración General del Estado, and Distribuidora de Televisión Digital SA (DTS)*, Case C-390/99, European Court Reports 2002, p. I-607), the Court made it clear that a prior authorisation procedure restricted the free movement of goods. However, to be justified in the light of these fundamental freedoms, such legislation must pursue a motive of public interest recognised under Community law and respect the principle of proportionality, i.e. be able to guarantee the achievement of the objective pursued and not go beyond what is necessary to attain it.
- (³⁹) Ground 15 of the Judgment of the Court of 13 December 1999, *Criminal Proceedings against Jean-Claude Bellon*, Case C-42/90, European Court Reports 1990, p. I-4863.
- (⁴⁰) However, this proof by the competent authority of the Member State where the EEA/Turkish product is lawfully manufactured and/or marketed is only one of several possibilities: it cannot be required by the competent authority of the Member State of destination. See ground 63 of the Judgment of 8 May 2003 (*ATRAL v. Belgian State*, Case C-14/02), where the Court specified that imposing as a condition the attestation of conformity of EEA products with technical standards or rules which guarantee a level of protection equivalent to that required by the Member State of destination is contrary to Article 28 of the EC Treaty.
- (⁴¹) In the exceptional situation of a prior authorisation procedure, marketing may take place only after the authorisation has been obtained.
- (⁴²) See, in this respect, the Judgment of the Court of 17 June 1987, *Commission of the European Communities v. Italian Republic*, Case 154/85, European Court Reports 1987, p. 2717.
- (⁴³) However, in the exceptional situation of a prior authorisation procedure, it is sufficient to refuse the prior authorisation.
- (⁴⁴) See in particular ground 36 of the Judgment of the Court of 22 January 2002, *Canal Satélite Digital SL v. Administración General del Estado, and Distribuidora de Televisión Digital SA (DTS)*, Case C-390/99, European Court Reports 2002, p. I-607.
- (⁴⁵) Judgment of the Court of 8 June 1993, *Commission of the European Communities v. Kingdom of Belgium*, Case C-373/92, European Court Reports 1993, p. I-3107.
- (⁴⁶) Ground 35 of the Judgment of the Court of 17 September 1998, *Criminal Proceedings against Jean Harpegnies*, Case C-400/96, European Court Reports 1998, p. I-5121.
- (⁴⁷) Judgment of the Court of 17 December 1981, *Criminal Proceedings against Frans-Nederlandse Maatschappij voor Biologische Producten BV*, Case 272/80, European Court Reports 1981, p. 3277; ground 23 of the Judgment of 14 July 1983, *Criminal Proceedings against Sandoz BV*, Case 174/82, European Court Reports 1983, p. 2445.
- (⁴⁸) Judgment of the Court of 8 June 1993, *Commission of the European Communities v. Kingdom of Belgium*, Case C-373/92, European Court Reports 1993, p. I-3107.
- (⁴⁹) The Member State of destination should accept the reports and certificates drawn up by a body providing guarantees equivalent to those required for national bodies. It follows from this that these guarantees of independence offered by the body established in the Member State of origin must not necessarily coincide with those laid down in the national law of the Member State of destination: ground 69 of the Judgment of the Court of 21 June 2001, *Commission of the European Communities v. Ireland*, Case C-30/99, European Court Reports, p. I-4619.
- (⁵⁰) See in particular grounds 34 to 36 of the Judgment of the Court of 5 June 1997, *Ditta Angelo Celestini v. Saar-Sektkellerei Faber GmbH and Co. KG*, Case C-105/94, European Court Reports. 1997, p. I-2971.
- (⁵¹) If there is a justified need for a check or inspection, the costs involved are to be covered by the person who is having the check carried out or who is requesting type-approval. These costs must be proportionate, and therefore cannot be greater than what is needed to cover the costs of the inspection procedure: see in particular grounds 41 and 42 of the Judgment of the Court of 22 January 2002 (*Canal Satélite Digital SL v. Administración General del Estado, and Distribuidora de Televisión Digital SA (DTS)*, Case C-390/99). However, as these checks are carried out upstream and on the market, the Court of Justice deemed that such inspections cannot be considered as a service rendered to the importer. Therefore, the expense occasioned by such inspections must be met by the general public which, as a whole, benefits from the free movement of Community goods: Ground 31 of Court of Justice Judgment of 15 December 1993, *Ligur Carni Srl and Genova Carni Srl v. Unita Sanitaria Locale n. XV di Genova and Ponente SpA v. Unita Sanitaria Locale n. XIX di La Spezia and CO.GE.SE.MA Coop arl*, Joined Cases C-277/91, C-318/91 and C-319/91, European Court Reports. 1993, p. I-6621.
- (⁵²) These are, more specifically, requirements recognised as measures which derogate from Article 28 EC by Article 30 EC, together with the overriding requirements recognised by the Court of Justice's case law as being likely to justify a measure having an equivalent effect within the meaning of Article 28 EC.

- ⁽⁵³⁾ The evaluation of the risk involves both determining the level of risk (i.e. the critical threshold of the probability of adverse effects for one of the imperative reasons mentioned in Article 30 EC or recognised by the Court as an imperative requirement liable to justify a measure having equivalent effect within the meaning of Article 28 EC) and, secondly, carrying out a scientific assessment of the risks. The precautionary principle can play an important role in the context of risk management: see communication COM(2000) 1 of the Commission on recourse to the precautionary principle: http://europa.eu.int/comm/food/fs/pp/pp_index_en.html
- ⁽⁵⁴⁾ Judgment of the Court of 14 July 1994, Criminal Proceedings against J.J.J. Van der Veldt, Case C-17/93, European Court Reports. 1994, p. I-35; Judgment of the Court of 4 June 1992, Criminal Proceedings against Michel Debus, Joint Cases C-13/91 and C-113/91, European Court Reports 1992, p. I-3617; Judgment of the Court of 24 October 2002, Criminal Proceedings against Walter Hahn, Case C-121/2000, European Court Reports 2002, p. I-9193.
- ⁽⁵⁵⁾ Article 30 of the Treaty or case law on overriding requirements respectively. See in particular Judgment of the Court of 28 January 1986, Commission of the European Communities v. French Republic ('Type-approval of wood-working machines'), Case 188/84, European Court Reports 1986, p. 419.
- ⁽⁵⁶⁾ For example, the competent authority should ask itself whether appropriate labelling, or the product notice, or other characteristics of the product are sufficient to provide a suitable level of protection for consumers.
- ⁽⁵⁷⁾ This would be contrary to the principle of proportionality. Judgment of the Court of Justice of 28 January 1986, Commission of the European Communities v. French Republic ('Type-approval of woodworking machines'), Case 188/84, European Court Reports 1986, p. 419.
- ⁽⁵⁸⁾ Judgment of the Court of 21 September 1999, Markku Juhani Läärä, Cotswold Microsystems Ltd and Oy Transatlantic Software Ltd v. Kihlakunnansyyttäjä (Jyväskylä) and Suomen valtio (Finnish State), Case C-124/97, European Court Reports 1999, p. I-6067.
- ⁽⁵⁹⁾ This principle applies all the more in the context of the exceptional situation of the obligatory authorisation procedure prior to marketing, which is necessary only if an *a posteriori* control must be considered too late to guarantee real effectiveness and to permit it to obtain the objective pursued. Such a procedure must pursue a public interest objective recognised by Community law and respect the principle of proportionality, i.e. be able to guarantee the achievement of the objective pursued and go no further than is necessary to achieve it. For such a procedure to be proportionate, it must, in any event, be based on objective, non-discriminatory criteria which are known in advance, in such a way as to circumscribe the exercise of the national authorities' discretion so that this discretion is not used arbitrarily. In addition, such a procedure cannot provide for controls which, in essence, duplicate controls which have already been carried out in the context of other procedures, either in the same State or in another Member State. Lastly, a prior authorisation procedure cannot comply with the fundamental principle of the free movement of goods if, through its duration and the disproportionate costs to which it gives rise, is likely to dissuade the operators concerned from continuing their action. In any event the Commission considers that a period of 90 days is disproportionate.
- ⁽⁶⁰⁾ See in particular ground 16 of the Judgment of 13 December 1990, Criminal Proceedings against Jean-Claude Bellon, Case C-42/90, European Court Reports 1990, p. I-4863.
- ⁽⁶¹⁾ Judgment of the Court of 9 May 1985, Commission of the European Communities v. French Republic (postal franking machines), Case 21/84, European Court Reports 1985, p. 1355; Judgment of the Court of 19 March 1991, Commission of the European Communities v. Kingdom of Belgium, Case C-249/88 European Court Reports 1991, p. I-1275.
- ⁽⁶²⁾ Judgment of the Court of 28 March 1995, The Queen v. Secretary of State for Home Department, *ex parte* Evans Medical Ltd and Macfarlan Smith Ltd., Case C-324/93, European Court Reports 1995, p. I-5.
- ⁽⁶³⁾ Ground 18 of the Judgment of the Court of 13 March 1997, Tommaso Morellato v. Unità sanitaria locale (USL) No 11 di Pordenone, Case C-358/95, European Court Reports 1997, p. I-1431.
- ⁽⁶⁴⁾ Judgment of the Court of 20 June 2002, Radiosistemi Srl v. Prefetto di Genova, Combined Cases C-388/2000 and C-429/2000, European Court Reports 2002, p. I-5845.
- ⁽⁶⁵⁾ Judgment of the Court of 4 June 1992, Criminal Proceedings against Michel Debus, Combined Cases C-13/91 and C-113/91, European Court Reports 1992, p. I-3617.
- ⁽⁶⁶⁾ See in particular Judgment of the Court of 22 October 1998, Commission of the European Communities v. French Republic, ('Foie gras' Judgment), Case C-184/96, European Court Reports 1998, p. I-6197. The Commission is making certain that such a clause is included in all new technical regulations, thanks to the notification procedure set out in Directive 98/34/EC. The website <http://europa.eu.int/comm/enterprise/tris> makes available draft technical rules notified under Directive 98/34/EC together with the texts adopted after the procedure has been completed. It thus provides economic operators with easy access to the applicable rules.