BIS | Department for Business Innovation & Skills

GUIDANCE FOR OFFICIALS

AVOIDING NEW BARRIERS TO TRADE

DIRECTIVE 98/34/EC
(as amended by Directive 98/48/EC)

Laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services

SEPTEMBER 2009

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SECTION I: INTRODUCTION

THE TECHNICAL STANDARDS AND REGULATIONS DIRECTIVE 98/34/EC[1] as amended by Directive 98/48/EC

1. Directive 98/34/EC[2], as amended by Directive 98/48/EC[3], (the "Directive", commonly known as the Technical Standards and Regulations Directive) lays down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services. Within its scope are measures relating to:

- industrially manufactured products;
- agricultural products, including fish products;
- information society services.

2. The Directive is intended to help avoid the creation of new technical barriers to trade within the Community. It requires Member States to notify technical regulations to the Commission in draft, and then generally to observe a standstill period of at least three months before adopting the regulation, in order to allow other Member States and the Commission an opportunity to raise concerns about potential barriers to trade. Regulators should note the following concerning the meaning of "draft technical regulation" under the Directive:

'Draft technical regulation' has a very broad meaning. It can include primary legislation (Government Bills, Private Bills, Private Members' Bills and Private Legislation Procedure (Scotland) Act 1936 measures) and any form of secondary legislation. It can also include measures such as administrative circulars, departmental guidelines, advice notes, codes of practice, voluntary agreements etc., if such documents recommend the use of given specifications or standards and the consequences (not necessarily legal consequences) of following or not following the specifications or standards are such that they have de facto obligatory effect.

3. This Guidance describes:

- the basic structure of the Directive (**Section II**);
- the procedures to be followed for United Kingdom notifications (**Section III**);
- the procedures to be followed on notifications by other member States, by EFTA States within the EEA Agreement, by EFTA States outside the EEA Agreement, and by non-EC member States of the Council of Europe (**Section IV**).

EUROPEAN COURT OF JUSTICE (ECJ) JUDGMENT: UNENFORCEABILITY OF TECHNICAL REGULATIONS NOT NOTIFIED

4. The importance of notifying measures, which come within the scope of the Directive, has become more critical since the ECJ made a ruling which has the effect that technical regulations which member States have failed to notify in draft under the Directive are unenforceable in national Courts.

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[1] Directive 98/34/EC is a codification of Directive 83/189/EC, as amended
[2] Official Journal reference L204 of 21 July 1998.
[3] Official Journal reference L217 of 5 August 1998.

5. Earlier versions of this Guidance on the Directive included a reference to the Commission's view on the unenforceability of non-notified technical regulations. Up until 1996 referrals from domestic courts in the Community to the ECJ on non-notified cases ruled only on the specific issue of the case and the question of notifiability and not on the wider issue of the enforceability or otherwise of a non-notified technical regulation. However the ECJ made a ruling on 30 April 1996 on a referral from a court in Liege, Belgium (Case No 194/94 CIA Security International SA -v- Signalson SA, Securitel SPRL) both on the specific issue of the notifiability and the wider issue of enforceability on a non-notified measure.

6. On the question of the enforceability of a non-notified technical regulation, the ECJ ruled in the Belgian case that:

> *Articles 8 and 9 of Directive 83/189 are to be interpreted as meaning that individuals may rely on them before the national court which must decline to apply a national technical regulation which has not been notified in accordance with the Directive.*

For all practical purposes this ruling will have the effect that non-notified measures are unenforceable against individuals.

7. **In view of the ruling, Departments need to be ever more vigilant about their obligations under the Directive and to ensure that officers who are engaged in preparing and drafting national measures are fully aware of the Directive and its requirements to notify any new draft technical regulations, so as to avoid the possibility of national courts not being in a position to apply (enforce) the regulations or the inability of enforcement authorities to take action in respect of contravention of such regulations.** In cases of doubt regulators will wish to consult their lawyers but the Central Contact Point is also happy to advise on the notifiability or otherwise of any measure[4]. Regulators should not, however, notify a measure "just in case" where it is clear that the measure is not notifiable under the provisions of the Directive. If the Central Contact Point has strong doubts about the notifiability of any proposed UK notification, it will explain why and ask the regulator for the reasoning behind the decision to notify.

OTHER GUIDANCE AND INFORMATION

8. The Commission has produced a guidance booklet on the Directive which officials may find helpful: Directive 98/34/EC - A guide to the procedure for the provision of information in the field of technical standards and regulations and of rules on information society services. The booklet can be downloaded from the Commission's website (TRIS) at the address given in the next paragraph. Annex G reproduces text from this guidance booklet on Article 1 of the Directive. Article 1 defines the meaning given by the Directive to key terms and is therefore useful towards understanding the basis and scope of the Directive. For those regulations concerning information society services, officials may find helpful Annex H which reproduces text from the vademecum on Directive 98/48/EC, which is also available on the Commission's website (TRIS).

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[4] The Central Contact Point should also be consulted if Departments discover an existing measure which was not notified under the Directive (as it existed at the time of making the measure) but which the Department now believes should have been notified.

9. To make the process more transparent, the Commission has a website site which contains details of new notifications and the draft text of notified technical regulations. The site also contains reference documents like text of the Directive, case law, Commission's interpretation of ECJ judgements and reports of the functioning of the Directive. The address of this site ('TRIS') is:

http://ec.europa.eu/enterprise/tris/index_en.htm

10. Some regulations notified through the procedure set up under this Directive may also require to be notified, separately, under obligations of the WTO Agreement on Technical Barriers to Trade (TBT) or the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). WTO Members are required to notify the WTO Secretariat of all proposed government regulations and conformity assessment procedures that might significantly affect international trade. Annex D gives further brief information on the notification procedures and contact details. However, the Commission also wishes to use the notification procedure under the Directive to act as a reminder, or prompt to Member States to consider the need also to notify under the TBT or SPS Agreements (see the notification Form A).

11. We would welcome any feedback on any aspect of the procedure you may have, please see Annex J for contact details.

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SECTION II: BASIC STRUCTURE

NOTIFICATION OF DRAFT TECHNICAL REGULATIONS

12. The starting point for Directive 98/34/EC is the obligation of Member States to notify any technical regulation to the Commission **in draft** and then, apart from the 'emergency procedure' described below, to observe an initial standstill period of **three months** during which the regulation may not be made[5].

13. Only technical regulations laid down by Central Government[6] are required to be notified as technical regulations laid down by local authorities are, in effect, excluded from the scope of the Directive. **Details of the scope of the Directive and other information to assist Departments who are considering whether a measure is notifiable is contained in Annex E which in particular provides the definitions of product, service (of the information society), draft technical regulations, technical regulations, technical specifications and rules on services; Annex A provides some points in greater detail; Annex F contains a simplified flow chart; Annex G also provides guidance on the scope of the Directive; and Annex H provides specific guidance on rules on information society services.** Annex B contains information about the slightly different procedures in respect of EEA/EFTA countries.

14. The Commission circulates the draft technical regulation to the other Member States.

15. If neither a Member State nor the Commission takes any action on the notification in the three-month standstill period, the originating Member State is free to make the draft technical regulation at the end of the **three-month** standstill period.

16. If one or more Member States and/or the Commission '**make comments**'[7] on the draft technical regulation, the originating member State is required to take such comments into account as far as possible in the subsequent preparation of the regulation but is otherwise free to make the draft regulation at the end of the **three-month** standstill period. There is no obligation to respond formally to the comments.

17. If one or more Member States and/or the Commission deliver a **'detailed opinion'**[8] (which should be to the effect that the measure envisaged should be amended in order to eliminate or reduce any barriers which it might create to the free movement of goods or, in respect of rules on services, the free movement of services or the freedom of establishment of service operators), the originating Member State must report to the Commission on the action it proposes to take on those detailed opinions and must not make the regulation for a total of **six months** (from receipt of notification by the Commission) for notifications relating to

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[5] The initial 3 month standstill period commences on the receipt, by the Commission, of the notification and all relevant documents (including the draft measure). The Commission advises Member States of the date of expiry of all standstill periods as appropriate.

[6] Central Government in this instance includes, for example, agencies or other bodies responsible on behalf of Government for technical regulations which apply to the UK or to a major part of England, Wales, Scotland and Northern Ireland.

[7] Article 8(2), Directive 98/34/EC as amended

[8] Article 9(2), Directive 98/34/EC as amended

goods/products (except voluntary agreements) and **four months** in the case of notifications relating information society services and all voluntary agreements. In other words the initial 3 month standstill is extended by a further 3 months or, in the case of information society services or voluntary agreements, by a further 1 month.

DETAILED OPINION AND THE STANDSTILL PERIOD

18. There is no precise definition of what constitutes a 'detailed opinion' under Article 9(2), but that phrase has been taken to mean that the case has to be precisely argued on a proposal that could be a potential technical barrier to trade or information society services. A detailed opinion from another Member State on a notified draft is valid provided that it is delivered by that Member State to the Commission **within the three-month standstill period**. If it is received outside the three-month standstill period it will be treated as 'comments' under Article 8(2). The Commission has agreed to forward the properly delivered detailed opinion to the other Member States at the latest within two working days of the end of the 3-month period. Any detailed opinion should, therefore reach the originator within one week of the expiry of the initial standstill period. In the case of UK notifications, if time is of the essence, regulators are advised to check the position with the Central Unit on the expiry of the initial standstill period and before making the measure.

19. The originating Member State should respond to detailed opinions from the Commission or Member States before adopting the technical regulation/specification. It should report on the action it proposes to take on such detailed opinions and, in the case of information society services, shall indicate (if appropriate) why the detailed opinion cannot be taken into account.

20**.** With the exception of draft rules relating to information society services and voluntary agreements, if the Commission, within the three month standstill period, announces its intention to propose or adopt a Directive, Regulation or Decision on the subject, the originating Member State may not make the regulation for **twelve months** from the date of receipt by the Commission of its notification. If the Commission announces within the three-month standstill period, that a proposal for a Directive, Regulation or Decision on the subject has already been submitted to the Council of Ministers, with the exception of voluntary agreements, the Member State may not make the regulation for **twelve months** which takes effect from the beginning of the initial three-month standstill. If the Council of Ministers adopts a Common Position during the twelve-month standstill mentioned in this paragraph, the **twelve months** will be extended to **eighteen months**.[9]

21. The standstill periods in the paragraph 20 **will lapse** in the following circumstances:

- when the Commission informs the Member States that it no longer intends to propose or adopt a Community measure;
- when the Commission informs Member States of the withdrawal of the originating Member States' draft or proposal;
- when the Commission or the Council has adopted a Community measure.

[9] Article 9(4)&(5), Directive 98/34/EC as amended

22. The table in Annex C summarises the various standstill periods. **It is important for regulators to observe all standstill periods and to ensure that draft regulations are not made before the end of the appropriate deadline**.

EXEMPTIONS FROM ALL STANDSTILL PERIODS

23. **The following are the only exemptions from the standstill periods:**

- Fiscal and financial agreements referred to in Article 1(11) (see annex E), third indent are subject only to the notification procedure with **no standstill periods**.
- The **'emergency procedure'** applies where, for urgent reasons relating to the protection of public health or safety, or the protection of health and life of animals or plants and, for rules on services, public policy notably the protection of minors and serious circumstances relating to the protection of the security and integrity of financial systems, a Member State is obliged to prepare regulations in a very short space of time in order to enact and introduce them immediately without any consultations being possible. The Member State is required to give the reasons which warrant the urgency of the measures taken and the Commission will comment on them. However, the Member State is free to adopt the regulation without there being any standstill period. **Urgent proposed technical regulations (however immediate) must be notified together with their basic texts, in draft, under the emergency procedure before being made - there are no exceptions to this rule. If a Department is proposing to use the emergency procedure, the Central Unit for the Directive should be given as much notice as possible.**

24. The Directive does not apply to rules enacted by or for regulated markets within the meaning of Directive 93/22/EC or by or for other markets or bodies carrying out clearing or settlement functions for those markets **except** for communicating the definitive text to the Commission without delay.

PUBLICATION AND SENDING OF FINAL TEXT TO THE COMMISSION

25. It is **important** for regulators to note that a reference to the Directive must be made on the official publication of the measure (see paragraph 36 and Form A) **and** an electronic copy of the definitive text must be sent to the Commission via the Central Unit. A hard copy will be accepted in exceptional circumstances (e. g. if the document is too large to be sent electronically). Please note, however, that a hyperlink to the definitive text will not be accepted by the Commission.

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SECTION III: PROCEDURE FOR UNITED KINGDOM NOTIFICATIONS

26. All notifications and all subsequent exchanges of information are made between a Central Unit in each Member State and the Commission.

27. The Commission has accepted responsibility for circulating notifications etc., to all the Member States; and also for arranging for, and circulating to them, translations of those notifications etc.

28. In the case of the United Kingdom, the Central Unit is:

Department for Business, Innovation and Skills
1 Victoria Street
London SW1H 0ET

Email: 9834@bis.gsi.gov.uk

HOW TO NOTIFY

29. **A Department, Directorate, other agency or body wishing to notify a draft technical regulation should email[10] the following to the Central Unit:**

- a completed copy of the notification form (preferably in Microsoft Word format but other formats acceptable) by email of Form A. The form may be obtained from the Central Unit and is also available from our website.

- a copy of the draft technical regulation **together with one copy of any document specifically referred to in the draft or required for an understanding of the draft. If a Regulatory Impact Assessment (RIA) is publicly available (whether draft, interim, partial, full or final), this should also be made available (if it is in a larger document a reference to where in the larger document it is to be found should be made).[11]**

30. The system of information exchange is undertaken on the basis of transmissions of messages by email between the Commission and the Member States and vice versa. To make this possible, it is essential to keep to the agreed, predetermined formats.

31. The form at Form A follows the format laid down for the notification message. It is essential that the specified information be provided but the limits on length are indicative only.

[10] If it is not possible to email documents (eg because of their size) they can alternatively be put on CD-rom and sent to the Central Unit.

[11] For supporting documents, it is not necessary to send documents sent with an earlier notification but a reference to the earlier notification should be made. It is also acceptable to provide the exact reference to a public website where the supporting document can be viewed. The draft text being notified must, however, always be provided.

32. **The Central Unit will normally not proceed with a notification until all the required material is to hand**.

33. Whilst notification as early as possible is desirable, to avoid any standstill period delaying the eventual adoption of the technical regulation, the draft text does need to be sufficiently firm to avoid the need for re-notification on the grounds as mentioned in Annex A.

DETAILED OPINIONS/COMMENTS AND CONFIDENTIALITY

34. The Central Unit will circulate to the originating official any 'comments' or 'detailed opinion' received (see paragraphs 18 to 22 above regarding the standstill in the event of a detailed opinion). Unless otherwise stated or agreed any detailed opinions or comments from the Commission or other Member States are treated as **in confidence** and should not be released to any person or organisation outside of government. There is an obligation to respond to detailed opinions from the Commission or Member States before adopting the measure. The originating official should send the Central Unit a brief note, suitable for onward transmission to the Commission, indicating the action the UK proposes to take on such detailed opinions and, in the case of information society services, indicating (if appropriate) why the detailed opinion cannot be taken into account. There is no similar obligation to respond to comments but the originating official is welcome to send a response via the Central Unit. Where a Member State or the Commission's detailed opinion or comment is to be treated in confidence this may restrict the ability of the UK to publicly release in full any response it makes, depending on the nature of the response.

DEFINITIVE TEXT AND REFERENCE TO NOTIFICATION

35. When published, the **definitive text** of the notified technical regulation **must** be sent to the Central Unit for onward transmission to the Commission (see paragraph 25 above).[12]

36. Article 12 of the Directive requires that:

> **"When Member States adopt a technical regulation, it shall contain a reference to this Directive [i.e. 98/34/EC (as amended)] or shall be accompanied by such reference on the occasion of its official publication. The methods of making such reference shall be laid down by Member States."**

It is advisable, where possible, to include such a reference in an explanatory note to the measure and, if possible, to include this in the notified draft. The illustrative form at Form A provides suggested wording for inclusion in the draft, or when notifying a draft.

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[12] Article 8(3), Directive 98/34/EC as amended

SECTION IV: PROCEDURE FOR NOTIFICATIONS BY OTHER MEMBER STATES AND EEA/EFTA COUNTRIES

37. The notification of draft technical regulations by other Member States and EFTA countries provides an opportunity to challenge changes that may adversely affect UK interests.

38. The Central Unit circulates notifications by other Member States of the European Community and EEA countries (Iceland, Norway, and Liechtenstein) and EFTA (Switzerland) and subsequent exchanges of information to the lead Department and to other interested Departments.

WHAT TO DO

39. **When they receive these notifications, it is the responsibility of the lead Department/Directorate to:**

- **consult as appropriate;**
- **in the case of a notification by a Member State, decide whether to make 'comments' or to deliver a 'detailed opinion' (in the case of a notification by an EEA/EFTA country whether to make 'comments'). Such decision is primarily the responsibility of the lead Department/Directorate (the Central Unit can advise as necessary);**
- **if comments/detailed opinion are received direct from industry by the Central Unit, they will be forwarded to the lead Department/Division for clearance and confirmation of their status i.e. whether to be treated as comments or a detailed opinion;**
- **send any comments/detailed opinion to the Central Unit in good time for notification to the Commission, particularly remembering to allow sufficient time to make any detailed opinion within the 3 month standstill period.**

40. If you are going to make comments/detailed opinion, it is important that you specify whether your response is under Article 8.2 (comment) or Article 9.2 (detailed opinion). Your response should be sent to the Central Unit by email to the address as shown in paragraph 28 above. It is important that the Central Unit receives the response in good time and if you are within 48 hours of the deadline, please telephone the Central Unit to expect a response.

41. It is the responsibility of Departments to include in their consultations interested trade associations etc., as appropriate. If confidentiality has been requested by the notifying party greater care should be taken in consultations.

DETAILED OPINIONS/COMMENTS AND CONFIDENTIALITY

42. Unless otherwise stated or agreed any detailed opinions or comments from the Commission or other Member States are treated as in confidence and should not be released to any person or organisation outside of government. However, the UK has informed the Commission and other Member States that detailed opinions or comments from the UK can be made available to interested parties outside of government unless we have specifically requested confidentiality.

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ANNEX A

SOME POINTS OF GREATER DETAIL

1. The scope of the Directive is set out in Annex E and this annex provides some additional points of detail which may assist Departments.

Notification

2. Technical regulations to be notified are in draft and the draft texts should be at a stage of preparation where substantial amendments can still be made. If there is an amendment to the draft text after notification or an amendment to the adopted regulation, which has the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive, the amended **draft** text must be notified again and the usual three-month initial standstill will, of course, apply again.

3. **Amendments to adopted Technical Regulations**: when introducing amendments to technical regulations which require notification under the Directive, regulators should ensure that any original technical regulations made after 28 March 1984, were notified, if notification was required, under the Directive. If the original was not notified, but should have been, it is recommended that the regulations be consolidated, with amendments, and notified as a whole to avoid the problems which would otherwise arise over non-notification of a technical regulation.

4. **Deregulating/Relaxing/Consolidating Technical Regulations**: a measure which **relaxes or deregulates** a technical regulation by replacing it with another, albeit a less onerous measure, comes within the scope of the Directive and will require notification. Measures which **consolidate** existing technical regulations and merely replicate them in new legislation are not notifiable. Where an amendment removes some products from the scope covered by a technical regulation, in so far as this was all that it achieved, the measure would be unlikely to be notifiable, being akin to a repeal for these products where the measure is disapplied. However if, in addition, the measure has the effect of revising a technical specification for other products that remain within its scope, the measure will require notification, even if the new technical specification is considered to be less onerous. It is possible that there may be instances where it is difficult to establish whether a new specification is being established and in such a case notification is recommended.

Risk assessment

5. If the draft measure seeks to limit the marketing or use of a chemical (hazardous) substance, preparation or product on grounds of public health, protection of consumers or the environment, it must be accompanied by a risk assessment. This must enable the Commission and the Member States to determine the proportionality of the measure with regard to its anticipated effects on public health and protection of the consumer and of the environment. The assessment must be carried out in accordance with the general principles for risk evaluation of chemical substances as referred to in Article 10(4) of Regulation 793/93/EEC in the case of an existing substance or Article 3(2) of Directive 92/32/EEC in the case of a new substance. 'Chemical substance' does not include medicinal products or

veterinary medicinal products for in vitro diagnosis. It has also been agreed that, where one exists, a Regulatory Impact Assessment (whether draft, interim, partial, full or final as long as it is publicly available) should be sent with a notification (see the notification Form A).

Fiscal or financial measures

6. If the draft text relates to fiscal or financial measures, only the aspects which might hinder trade or, in respect of rules on services, the free movement of services or the freedom of establishment of service operators should be considered (not the fiscal or financial aspects).

Other issues, including exceptions to the requirement to notify

7. Draft technical specifications or a standard for specific products drawn up by standards institutions (eg BSI) on the request of public authorities for the purposes of enacting a technical regulation for such products are notifiable as draft technical regulations.

8. In the case of draft technical regulations which merely transpose the full text of an international or European standard, it is sufficient to let the Commission have information regarding the relevant standard, when notifying through the Central Unit.

9. **The only exceptions to the requirement to notify** draft technical regulations are specified in Article 10 (see Annex E) and, in particular include regulations which fulfil obligations arising out of Community measures, and regulations which fulfil obligations arising out of international agreements which result in the adoption of uniform technical specifications in the Community[13]. (But see also Section II paragraph 24 in relation to regulated markets).

10. The Directive stipulates that, where appropriate, Member States shall simultaneously communicate the text of the basic legislative or regulatory provisions principally and directly concerned should knowledge of such text be necessary to assess the implications of the draft technical regulation.

11. **The standstill period starts** on the date that the draft technical regulation and any basic legislative or regulatory provisions are **received by the Commission**. (The Commission clearly indicates the date when the standstill period will end when it acknowledges receipt of the notification.)[14]

Article 5 Committee

12. The Commission may refer a draft technical regulation to the Committee set up by Article 5 of the Directive for its opinion. This is becoming increasingly the practice where a notification gives rise to detailed opinions. This Committee also monitors the progress of Member States responses to detailed opinions and the provision of final texts.

[13] The exception relating to international agreements only applies when all Member States are a party to the international agreement. If one or more Member State is not a party to the agreement the draft technical regulation should be notified.

[14] Annex C is a table providing a guide to the standstill provisions.

Confidentiality

13. Information supplied under the Directive (for example, the completed notification form or the draft measure itself) is not confidential except at the express request of the notifying Member State who should give reasons for the request. Under such a request Member States may, provided the necessary precautions are taken, consult, for an expert opinion, natural or legal persons, including persons in the private sector.[15]

Mutual Recognition Clause

14. A requirement in a draft technical regulation to comply with a national standard will meet with the objection that it constitutes a barrier to trade which is not justifiable unless it allows for recognition of standards in other States of the European Economic Area which provide equivalent levels of performance, safety, health, consumer protection etc. Similar considerations apply in the case of stipulation of particular test methods or forms of certification.

General Mutual Recognition Clause: The following text for a mutual recognition clause is for guidance only and should be adapted as necessary to suit specific cases.

Any requirement for goods or materials to comply with a specified standard shall be satisfied by compliance with:

(i) a relevant standard or code of practice of a national standards body or equivalent body of any EEA State

or (ii) any relevant international standard recognised for use in any EEA State

or (iii) any relevant technical regulation with mandatory or de facto mandatory application for marketing or use in any EEA State

in so far as the standard, code of practice, technical regulation or process in question enables the [objectives pursued by the present regulation*] to be met in an equivalent manner.

* specify as appropriate: protection of health, safety etc.

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[15] However, unless otherwise stated or agreed any detailed opinions or comments from the Commission or other member States are treated as **in confidence** and should not be released to any person or organisation outside of government (see Section III, paragraph 34, and Section IV, paragraph 42, above).

ANNEX B

COMMUNITY/EFTA/EEA AGREEMENT LAYING DOWN A PROCEDURE FOR THE EXCHANGE OF INFORMATION IN THE FIELD OF TECHNICAL REGULATIONS

THE EFTA AGREEMENT

1. On 19 December 1989, the Community and the countries of the European Free Trade Association (EFTA) signed an Agreement laying down a procedure for the exchange of information in the field of technical regulations. This Agreement entered into force in November 1990.

2. The Community, through the Commission, notify to the EFTA countries, through the EFTA Secretariat, draft technical regulations notified under Directive 98/34/EC as amended.

3. The EFTA countries, through the EFTA Secretariat, notify to the Community, through the Commission, draft technical regulations notified under the corresponding EFTA procedure.

4. The Agreement for the moment does not cover draft technical regulations concerning production methods and procedures.

5. The Community and the EFTA countries may make collective comments on the draft technical regulations so notified.

6. The Community and the EFTA countries may ask for further information about a notification, and for meetings to exchange views on comments made.

7. The Agreement provides for information supplied to be considered confidential upon request.

8. The Agreement does not:

- affect the starting-date, or the duration, of the three-month standstill period under the Directive;
- explicitly require Member States to 'take into account' comments made by the EFTA countries;
- provide for the EFTA countries to deliver detailed opinions, or for there to be any extension of the three month standstill period on account of action taken by the EFTA countries;
- affect the emergency procedure.

9. The Agreement is concerned with communications between the Community and EFTA countries via the Commission and the EFTA Secretariat: it does not allow for direct communications between Member States and individual EFTA countries.

10. There are, however, extensive communications between Member States and the Commission relating to the Agreement.

THE EUROPEAN ECONOMIC AREA (EEA) AGREEMENT

11. The EC/EFTA Agreement of 19 December 1989 was superseded by the European Economic Area (EEA) Agreement which came into force on 1 January 1994 and applies to all EFTA countries apart from Switzerland. The details on the EC/EFTA procedure which are outlined above continue to apply to Switzerland until further notice; they also apply to the remaining EFTA countries which now form part of the EEA Agreement (i.e. Liechtenstein, Norway and Iceland) apart from the following requirement:

- the EEA Agreement requires EC Member States to take into account comments made by EFTA countries and also EFTA states (for the purposes of the EC/EFTA procedure, EFTA members of the EEA Agreement will continue to be referred to as EFTA states) to take account of comments from EC Member States. Court action through the European Court of Justice or the EFTA Courts may be pursued if EC or EFTA states fail to observe this provision.

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ANNEX C

TABLE OF INFORMATION RELATING TO STANDSTILL PROVISIONS

	Products	**Information Society Services**	**Voluntary Agreements**
Notification: initial standstill[1]	3 months (from date of receipt of all relevant papers by the Commission)		
Comments	No further standstill		
Detailed opinion	6 months [3 + 3]	4 months [3 +1]	4 months [3 +1]
Intention to propose a Directive etc.	12 months [3 + 9] [2]	Not applicable	Not applicable
Existing proposal for a Directive	12 months [3 + 9] [2]	12 months [3 + 9] [2]	Not applicable

[1] Except where the urgency clause ('emergency procedure') is invoked, when measure may be made immediately after notification of the draft measure; or in the case of regulated markets within the meaning of Directive 93/22/EEC or by or for other markets or bodies carrying out clearing or settlement functions for those markets when notification is made immediately after the measure has been made (this is the only instance when a notification of a measure within the scope of the Directive, as amended, is not made in draft).

[2] If common position is reached within the 12 months period the standstill is extended to 18 months.

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ANNEX D

WTO Agreements on Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary (SPS)

WTO Agreement on Technical Barriers to Trade (TBT)

The WTO TBT Agreement came into force on 1st January l995 (when the UK became a Member) and sets out the parameters for WTO Members who are involved in the preparation, adoption and application of technical regulations, standards and conformity assessment procedures, along with their obligations under the Agreement. The TBT Agreement has the objective of eliminating unnecessary technical barriers to trade, encouraging the development of international standards and conformity assessment systems and places certain obligations upon WTO Members. The TBT Agreement applies to all products with the exception of certain products which are dealt with under the Sanitary and Phytosanitary (SPS) Agreement.

Notification requirements: To achieve transparency, all central government bodies wishing to adopt a technical regulation, standard or conformity assessment procedure which may have a significant effect on trade of other WTO Members and does not accord with an international standard must notify the measure to other WTO Members (via the WTO Secretariat who in turn, disseminates the notifications to all other Members) before the measure is adopted. This includes proposed bans for consumer safety, health or environmental reasons. If measures covered by the TBT Agreement do not meet the requirements of WTO rules, they can be challenged by other WTO Members. If successfully challenged through the WTO's binding dispute settlement process, Members must comply with the findings.

The Commission notify all regulations and procedures in the harmonised field (i.e. concluded at European level). Therefore the UK must notify everything outside the harmonised field which is devised and implemented nationally and falls within the notification requirements.

Further information on this notification procedure can be obtained from:

WTO Unit
Department for Business, Innovation & Skills
1 Victoria Street
London SW1H 0ET

Telephone: +(44) 207 215 5580
Email: marilyn.swain@bis.gsi.gov.uk

WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)

The SPS Agreement requires that all sanitary and phytosanitary regulations which have been adopted are published promptly and, except in urgent circumstances to allow WTO Members a reasonable period between publication and entry into force in order to allow time for producers to adapt their products and methods of production to the requirements of the

importing Member. Unlike the TBT Agreement the Commission notifies both harmonised regulations and national regulations on behalf of EU Member States.

Further information on this procedure can be obtained from:

Katherine Quinteros
CAP Reform and EU Strategy Team
Department for Environment, Food and Rural Affairs (Defra)
Area 5D, 9 Millbank
17 Smith Square
London SW1P 3JR

Telephone: +(44) 207 238 3016
Email: Katherine.quinteros@defra.gsi.gov.uk

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ANNEX E

SELECTED ARTICLES OF DIRECTIVE 98/34/EC (as amended)

Scope:

The Directive lays down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services. It requires Member States to notify technical regulations, which include technical specifications and other requirements and rules concerning information society services, at the draft stage with the intention of exposing potential new trade barriers. Member States and the Commission may comment on the proposed measures and the Commission can also propose harmonisation. National measures (except those linked to certain fiscal or financial measures) falling within the terms of the Directive are subject to a stand-still period, initially of 3 months but extendible in certain circumstances (see main text). The Directive has an emergency procedure which applies where, for urgent reasons relating to the protection of public health or safety, or the protection of health and life of animals or plants and, for rules on services, public policy notably the protection of minors and serious circumstances relating to the protection of the security and integrity of financial systems, a Member State is obliged to prepare a technical regulation in a very short space of time in order to enact and introduce it immediately without any consultations being possible. When this procedure is used it is a requirement to give the reasons which warrant the urgency of the measures being taken and the European Commission will comment on them. The technical regulation must still be notified to the Commission in draft but, once the notification has taken place, the regulation may be adopted without there being any standstill period (the Commission will, however, take appropriate action in cases where improper use is made of the procedure). Departments should understand that this procedure can only be used in genuinely urgent cases and, for example, cannot be used following consultations if it is realised only shortly before the intended date of making the regulation that notification under the Directive is required. In any case where a Department is considering using the emergency procedure the Central Contact Point in the BIS should be contacted as early as possible.

Amendments to the Directive have generally widened the scope of the Directive to its current scope which includes any industrially manufactured product, agricultural product including fish products and rules on information society services. The definition of terms relating to the scope of the Directive are in Article 1. Relevant Articles of the Directive are reproduced below.

Article 1 [definitions]

For the purposes of this Directive, the following meanings shall apply:

1. "product": any industrially manufactured product and any agricultural product, including fish products;

2. "service": any Information Society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.

For the purposes of this definition:

- "at a distance": means that the service is provided without the parties being simultaneously present,
- "by electronic means": means that the service is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means,
- "at the individual request of a recipient of services": means that the service is provided through the transmission of data on individual request.

An indicative list of services not covered by this definition is set out in Annex V.

This Directive shall not apply to:

- radio broadcasting services,
- television broadcasting services covered by point (a) of Article 1 of Directive 89/552/EEC[16].

3. "technical specification": a specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures.

The term "technical specification" also covers production methods and processes used in respect of agricultural products as referred to Article 38(1) of the Treaty, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 65/65/EEC[17], as well as production methods and processes relating to other products, where these have an effect on their characteristics;

4. "other requirements": a requirement, other than a technical specification, imposed on a product for the purpose of protecting, in particular, consumers or the environment, and which affects its life cycle after it has been placed on the market, such as conditions of use, recycling, reuse or disposal, where such conditions can significantly influence the composition or nature of the product or its marketing;

5. "rule on services": requirement of a general nature relating to the taking-up and pursuit of service activities within the meaning of point 2, in particular provisions concerning the service provider, the services and the recipient of services, excluding any rules which are not specifically aimed at the services defined in that point.

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[16] OJ L 298, 17.10.1989, p. 23. Directive as last amended by Directive 97/36/EC (OJ L 202, 30.7.1997, p. 1).

[17] Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ 22, 9.2.1965, p. 369/65), Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22). [Current definitions are in Directive 2001/82/EC for veterinary medicinal products and Directive 2001/83/EC for medicinal products for human use].

This Directive shall not apply to rules relating to matters which are covered by Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC[18].

This Directive shall not apply to rules relating to matters which are covered by Community legislation in the field of financial services, as listed non-exhaustively in Annex VI to this Directive.

With the exception of Article 8(3), this Directive shall not apply to rules enacted by or for regulated markets within the meaning of Directive 93/22/EEC or by or for other markets or bodies carrying out clearing or settlement functions for those markets.

For the purposes of this definition:

- a rule shall be considered to be specifically aimed at Information Society services where, having regard to its statement of reasons and its operative part, the specific aim and object of all or some of its individual provisions is to regulate such services in an explicit and targeted manner,
- a rule shall not be considered to be specifically aimed at Information Society services if it affects such services only in an implicit or incidental manner.

[6 - 10. Not relevant to this Guidance]

11. "technical regulation": technical specifications and other requirements or rules on services, including the relevant administrative provisions, the observance of which is compulsory, de jure or de facto, in the case of marketing, provision of a service, establishment of a service operator or use in a Member State or a major part thereof, as well as laws, regulations or administrative provisions of Member States, except those provided for in Article 10, prohibiting the manufacture, importation, marketing or use of a product or prohibiting the provision or use of a service, or establishment as a service provider.

De facto technical regulations include:

- laws, regulations or administrative provisions of a Member State which refer either to technical specifications or to other requirements or to rules on services, or to professional codes or codes of practice which in turn refer to technical specifications or to other requirements or to rules on services, compliance with which confers a presumption of conformity with the obligations imposed by the aforementioned laws, regulations or administrative provisions,
- voluntary agreements to which a public authority is a contracting party and which provide, in the general interest, for compliance with technical specifications or other requirements or rules on services, excluding public procurement tender specifications,
- technical specifications or other requirements or rules on services which are linked to fiscal or financial measures affecting the consumption of products or services by encouraging compliance with such technical specifications or other requirements or rules on services; technical specifications or other requirements or rules on services linked to national social security systems are not included.

This comprises technical regulations imposed by the authorities designated by the Member States and appearing on a list to be drawn up by the Commission before 5 August 1999, in the framework of the Committee referred to in Article 5.

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[18] OJ L 192, 24.7.1990, p. 1. Directive as amended by Directive 97/51/EC (OJ L 295, 29.10.1997, p. 23).

The same procedure shall be used for amending this list;

12. "draft technical regulation": the text of a technical specification or other requirement or of a rule on services, including administrative provisions, formulated with the aim of enacting it or of ultimately having it enacted as a technical regulation, the text being at a stage of preparation at which substantial amendments can still be made.

This Directive shall not apply to those measures Member States consider necessary under the Treaty for the protection of persons, in particular workers, when products are used, provided that such measures do not affect the products.

Article 8 [notification]

1. Subject to Article 10, Member States shall immediately communicate to the Commission any draft technical regulation, except where it merely transposes the full text of an international or European standard, in which case information regarding the relevant standard shall suffice; they shall also let the Commission have a statement of the grounds which make the enactment of such a technical regulation necessary, where these have not already been made clear in the draft.

Where appropriate, and unless it has already been sent with a prior communication, Member States shall simultaneously communicate the text of the basic legislative or regulatory provisions principally and directly concerned, should knowledge of such text be necessary to assess the implications of the draft technical regulation.

Member States shall communicate the draft again under the above conditions if they make changes to the draft that have the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive.

Where, in particular, the draft seeks to limit the marketing or use of a chemical substance, preparation or product on grounds of public health or of the protection of consumers or the environment, Member States shall also forward either a summary or the references of all relevant data relating to the substance, preparation or product concerned and to known and available substitutes, where such information may be available, and communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out as appropriate in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Regulation (EEC) No 793/93[19] in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC[20], in the case of a new substance.

The Commission shall immediately notify the other Member States of the draft and all documents which have been forwarded to it; it may also refer this draft, for an opinion, to the Committee referred to in Article 5 and, where appropriate, to the committee responsible for the field in question.

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[19] Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ L 84, 5.4.1993, p. 1).

[20] Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196, 16.8.1967, p. 1). Directive, as amended by Directive 92/32/EEC, (OJ L 154, 5.6.1992, p. 1).

With respect to the technical specifications or other requirements or rules on services referred to in the third indent of the second subparagraph of point 11 of Article 1, the comments or detailed opinions of the Commission or Member States may concern only aspects which may hinder trade or, in respect of rules on services, the free movement of services or the freedom of establishment of service operators and not the fiscal or financial aspects of the measure.

2. The Commission and the Member States may make comments to the Member State which has forwarded a draft technical regulation; that Member State shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

3. Member States shall communicate the definitive text of a technical regulation to the Commission without delay.

4. Information supplied under this Article shall not be confidential except at the express request of the notifying Member State. Any such request shall be supported by reasons.

In cases of this kind, if necessary precautions are taken, the Committee referred to in Article 5 and the national authorities may seek expert advice from physical or legal persons in the private sector.

5. When draft technical regulations form part of measures which are required to be communicated to the Commission at the draft stage under another Community act, Member States may make a communication within the meaning of paragraph 1 under that other act, provided that they formally indicate that the said communication also constitutes a communication for the purposes of this Directive.

The absence of a reaction from the Commission under this Directive to a draft technical regulation shall not prejudice any decision which might be taken under other Community acts.

Article 9 [standstill, including detailed opinion]

1. Member States shall postpone the adoption of a draft technical regulation for three months from the date of receipt by the Commission of the communication referred to in Article 8(1).

2. Member States shall postpone:

- for four months the adoption of a draft technical regulation in the form of a voluntary agreement within the meaning of the second indent of the second subparagraph of point 11 of Article 1,
- without prejudice to paragraphs 3, 4 and 5, for six months the adoption of any other draft technical regulation (except for draft rules on services),

  from the date of receipt by the Commission of the communication referred to in Article 8(1) if the Commission or another Member State delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged may create obstacles to the free movement of goods within the internal market;
- without prejudice to paragraphs 4 and 5, for four months the adoption of any draft rule on services, from the date of receipt by the Commission of the communication referred to in Article 8(1) if the Commission or another Member State delivers a detailed opinion, within three months of that date, to the effect that the measure envisaged may create obstacles to the free movement of services or to the freedom of establishment of service operators within the internal market.

With regard to draft rules on services, detailed opinions from the Commission or Member States may not affect any cultural policy measures, in particular in the audiovisual sphere, which Member States might adopt in accordance with Community law, taking account of their linguistic diversity, their specific national and regional characteristics and their cultural heritage.

The Member State concerned shall report to the Commission on the action it proposes to take on such detailed opinions. The Commission shall comment on this reaction.

With respect to rules on services, the Member State concerned shall indicate, where appropriate, the reasons why the detailed opinions cannot be taken into account.

3. With the exclusion of draft rules relating to services, Member States shall postpone the adoption of a draft technical regulation for twelve months from the date of receipt by the Commission of the communication referred to in Article 8(1) if, within three months of that date, the Commission announces its intention of proposing or adopting a directive, regulation or decision on the matter in accordance with Article 189 of the Treaty.

4. Member States shall postpone the adoption of a draft technical regulation for 12 months from the date of receipt by the Commission of the communication referred to in Article 8(1) if, within the three months following that date, the Commission announces its finding that the draft technical regulation concerns a matter which is covered by a proposal for a directive, regulation or decision presented to the Council in accordance with Article 189 of the Treaty.

5. If the Council adopts a common position during the standstill period referred to in paragraphs 3 and 4, that period shall, subject to paragraph 6, be extended to 18 months.

6. The obligations referred to in paragraphs 3, 4 and 5 shall lapse:

- when the Commission informs the Member States that it no longer intends to propose or adopt a binding Community act,

- when the Commission informs the Member States of the withdrawal of its draft or proposal,

- when the Commission or the Council has adopted a binding Community act.

7. Paragraphs 1 to 5 shall not apply in cases where:

- for urgent reasons, occasioned by serious and unforeseeable circumstances relating to the protection of public health or safety, the protection of animals or the preservation of plants and, for rules on services, also for public policy, notably the protection of minors, a Member State is obliged to prepare technical regulations in a very short space of time in order to enact and introduce them immediately without any consultations being possible or

- for urgent reasons occasioned by serious circumstances relating to the protection of the security and the integrity of the financial system, notably the protection of depositors, investors and insured persons, a Member State is obliged to enact and implement rules on financial services immediately.

In the communication referred to in Article 8, the Member State shall give reasons for the urgency of the measures taken. The Commission shall give its views on the communication as soon as possible. It shall take appropriate action in cases where improper use is made of this procedure. The European Parliament shall be kept informed by the Commission.

Article 10 [exceptions to the requirement to notify]

1. Articles 8 and 9 shall not apply to those laws, regulations and administrative provisions of the Member States or voluntary agreements by means of which Member States:

- comply with binding Community acts which result in the adoption of technical specifications or rules on services,
- fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Community;
- make use of safeguard clauses provided for in binding Community acts,
- apply Article 8(1) of Directive 92/59/EEC[21],
- restrict themselves to implementing a judgment of the Court of Justice of the European Communities,
- restrict themselves to amending a technical regulation within the meaning of point 11 of Article 1, in accordance with a Commission request, with a view to removing an obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.

2. Article 9 shall not apply to the laws, regulations and administrative provisions of the Member States prohibiting manufacture insofar as they do not impede the free movement of products.

3. Paragraphs 3 to 6 of Article 9 shall not apply to the voluntary agreements referred to in the second indent of the second subparagraph of point 11 of Article 1.

4. Article 9 shall not apply to the technical specifications or other requirements or the rules on services referred to in the third indent of the second subparagraph of point 11 of Article 1.

Article 12 [reference to Directive when measure adopted]

When Member States adopt a technical regulation, it shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of its official publication. The methods of making such reference shall be laid down by Member States.

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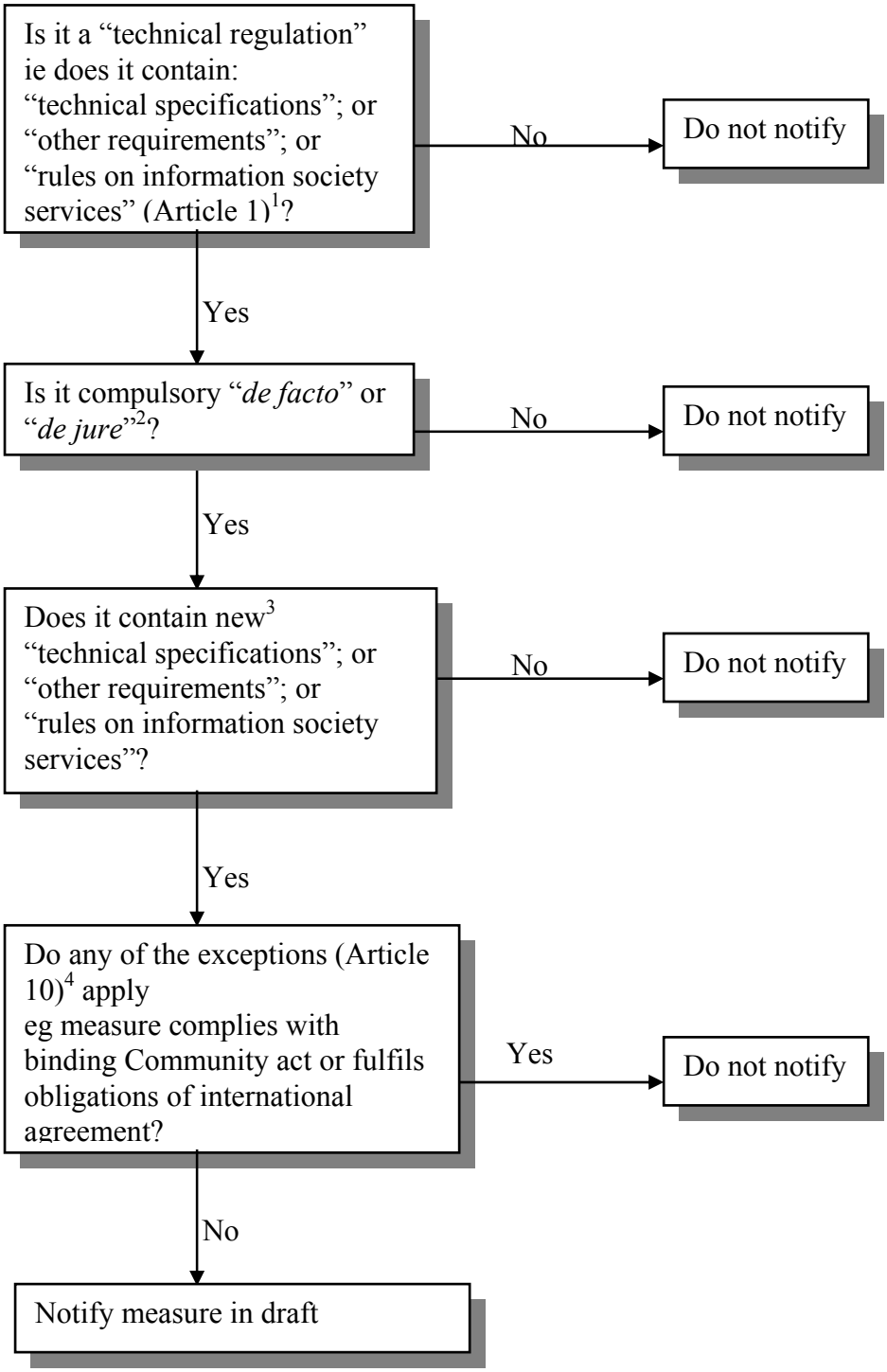
[21] Council Directive 92/59/EEC of 29 June 1992 on general product safety (OJ L 228, 11.8.1992, p. 24).

ANNEX F

To notify or not – a simplified flow chart



[1] See Annexes E, G and H of this Guidance
[2] See Section I, paragraph 2, Annexes E and G
[3] For example, it is not a consolidation of existing measures, or removal (without replacement) of existing of requirements – see Annex A
[4] See Annexes A and E

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ANNEX G

Article 1 of the Directive - explanation of key terms taken from Chapter 1 of the Commission guidance document 'Directive 98/34/EC - A guide to the procedure for the provision of information in the field of technical standards and regulations and of rules on information society services'

NOTE: For Directive 83/189/EEC read Directive 98/34/EC. This guidance does not specifically cover Directive 98/48 - information society services - for which see Annex H. The guidance was discussed with member States but the final document represents Commission's interpretation of the Directive.

'product'

The scope of the initial version of Directive 83/189/EEC excluded cosmetic products within the terms of Directive 76/768/EEC, medicinal products within the terms of Directive 65/65/EEC, and products destined for human and animal consumption and agricultural products [22].

The scope of the directive has been extended, since the operation of the information procedure revealed that numerous national regulations and standards involving barriers to intra-Community trade had not been monitored by the Commission and the Member States because certain products were not covered. In order to clarify the very broad definition which is now used, it is worth recalling that the Court of Justice included in the framework of the provisions relating to the free movement of goods under Article 30 of the Treaty 'products which can be valued in monetary terms and which may, as such, form the subject of commercial transactions'[23]. In this context, the Court also ruled that waste, whether recyclable or not, is to be considered to be a product whose movement should not, in principle, be prevented[24]. It is appropriate to take this into consideration in determining the scope of the directive.

'technical specification'

This provision defines the concept of technical specification, a generic term which covers standards as well as technical regulations. It stipulates that the document containing the technical specification defines 'the characteristics required of a product'. The examples given are not exhaustive; the composition of the product, its shape, weight, packaging, presentation, performance, life span, energy consumption, etc., could have been added.

The specification can serve a multitude of goals: for example, protection of the consumer, the environment, public health or safety, standardisation of production, improvement of quality, fairness of commercial transactions, maintenance of public order.

The initial version of the Directive limited the definition of technical specification to the characteristics required of the product. The broadening of the concept of technical

[22] Within the meaning of Article 38(1) of the Treaty.
[23] Judgement of 10 December 1968 in Case 7/68, ECR. p. 617.
[24] Judgement of 9 July 1992 in Case 2/90, ECR I, p. 4431.

specification to include production processes and methods was carried out in two stages: firstly in 1988 (by Directive 88/182/EEC) with regard to agricultural products, products for human and animal consumption and medicinal products, at the time of their inclusion in the scope of the Directive; secondly in 1994 (by Directive 94/10/EC) with regard to other products, for the sake of consistency.

In the field of agriculture, products for human and animal consumption and medicinal products, production methods and processes generally affect the product itself (for example, the obligation to use certain equipment for reasons of hygiene). This is not always the case in the other product sectors, and here the directive makes impact on the product a condition of notification of the production methods and processes concerned, with the specific exclusion of regulations relating to the organisation of work, which does not affect products.

Testing and test methods, quoted as examples of technical specifications, cover the technical and scientific methods to be used to evaluate the characteristics of a given product. The conformity assessment procedures, which are also mentioned, are those used to ensure that the product conforms with specific requirements. They are the responsibility of specialist bodies, whether public or private, or of the manufacturer. The inclusion of these parameters within the scope of the directive is of the utmost importance, because testing and conformity assessment procedures can, under certain conditions, have negative effects on trade. The multiplicity and disparity of the national systems of conformity certification can cause technical barriers to trade in the same way as the specifications applicable to the products, which are even more difficult to overcome as a result of their complexity.

‘other requirements’

The concept of ‘other requirement’ did not exist in the initial version of Directive 83/189/EEC. It was introduced by Directive 94/10/EC, at the time of the second amendment of the text.

This term covers requirements which can be imposed on a product during its life cycle, from the period of use through to the phase of management or disposal of the waste generated by it.
The provision specifies that this type of requirement is principally imposed for the purpose of protecting consumers or the environment. These are two of the grounds of major needs which could, in exceptional circumstances, justify a Member State departing from the principle of the free movement of goods by imposing trading bans or restrictions.

The ‘conditions of use, recycling, reuse or disposal of a product’, quoted as examples of ‘other requirements’, refer to the most important specific cases. In order to qualify as ‘other requirements’, these conditions must be likely to have a significant effect on the composition, the nature or the marketing of the product. A decree relating to the management of medicinal waste or a national regulation seeking to impose a return or reuse system for packaging, or even the separate collection of certain products, such as discharged batteries, can therefore be expected to contain provisions which fall into the category of 'other requirements'.

‘technical regulation’

In defining the concept of ‘technical regulation’, the definition provides information

regarding the type of texts which must be notified under the procedure for the provision of information established by the Directive in this field.

On the one hand there are the technical specifications or other requirements or rules on services, which are laid down by the Member States and which are applicable to industrial and agricultural products and to information society services, and on the other there are the laws, regulations and administrative provisions of the Member States which prohibit certain specified activities.

In order to qualify as a technical regulation, a technical specification or 'other requirement' must fulfil the following conditions:

- it must be 'compulsory'. This characteristic, which is inherent in the documents prepared by the public authorities, to which this directive applies, constitutes the major difference between a technical regulation and a standard, which is prepared by private bodies and is in essence voluntary [25];
- it must influence the marketing or use of industrial and agricultural products in a Member State or a significant part of that State.

The administrative provisions applicable to a specification or 'other requirement' are also technical regulations within the meaning of the directive. These measures, as with all technical regulations, must be notified under the directive when they emanate from the central governments of the Member States or from one of their bodies as specified in the list drawn up by the Commission in the framework of the Standing Committee of the directive. On the other hand, certain technical specifications or other requirements which meet the definition of technical regulations are excluded from the scope of the directive, particularly if they comply with binding Community acts or are limited to implementing a judgement of the European Court of Justice, as specified in Article 10 of the directive.

The 'compulsory' nature of a technical specification, an 'other requirement' or a rule on services may be conferred upon them in two ways:

1. *de jure*, when compliance with the technical specification or other requirement is made compulsory by a measure emanating directly from the relevant public authorities or attributable to the latter. By way of example, the conditions regarding the small-scale production of jam and preserved fruit, laid down by decree, will be considered to be a technical regulation which is mandatory de jure. The same will apply to a ban on using plastic bottles for the marketing of mineral water, as laid down by ordinance, etc.

2. *de facto*, where the technical specification is not laid down by a formal and binding act of the State concerned, but where the State encourages its observance; as a result of the similar effects which they may have upon trade, these measures are considered equivalent to binding regulations.

De facto technical regulations include:

- The laws, regulations or administrative provisions referred to are measures adopted by the national authorities which refer to technical specifications or other requirements usually laid

[25] Under Article 7(2) of the directive, in certain cases, compliance with the standard may become mandatory, so that it then acquires the status of a 'technical regulation'.

down by bodies other than the State (by a national standardisation body, for example), which are not compulsory as such (standards, professional codes or codes of practice), but observance of which is encouraged since it confers on the product a presumption of conformity to the provisions of the aforementioned measures. Such is the case, in particular, if a law relating to insurance releases the users of products complying with certain non-mandatory standards from the responsibility of proving conformity to mandatory requirements, since these products benefit from a presumption of conformity to the requirements.

- Agreements entered into between economic operators which establish technical specifications or other requirements for certain products are not binding as such owing to their origin in the private sector. They are nevertheless considered to be de facto technical regulations when the State is a signatory to one of these agreements. This circumstance is becomingly increasingly frequent, since such agreements have become instruments of national regulatory policy. They are often used by Member States in the north of the Community in sectors such as the automobile industry, chemical industry and oil industry, in most cases for environmental reasons: to reduce pollutant vehicle emissions or the discharge of harmful substances into water, promote the use of certain types of packaging, etc. These agreements allow greater flexibility in implementing the measures necessary to attain the objectives of the legislation, and the voluntary participation of the industry involved ensures that they will be achieved. The State has to be involved in these agreements if they are to fall within the scope of Directive 83/189/EEC. For the public authority to be able to fulfil the information obligation incumbent on it and take account of comments by the Commission or a Member State in the framework of the information procedure laid down by the directive, the State must actually be a contracting party.

- The fiscal or financial measures referred to in the definition are laid down by the national public authorities for a purpose other than that traditionally pursued by the fiscal legislation of the Member States. They are considered to be efficient instruments for implementing policies decided at a national level, particularly with a view to protecting the environment and consumers, since they are basically aimed at influencing the behaviour of the latter with regard to a specific product or service.

This provision of the directive came about because of certain cases of tax incentives granted to 'clean vehicles' which meet certain emission limits or are equipped with catalytic converters. Experience has shown that Member States often linked incentives to conditions, with the result that the system introduced was contrary to Community law, so that it became clear that there was a need to examine such drafts.

The category of measures in question includes, in particular, those which seek to encourage the purchase of products complying with certain specifications, by granting financing facilities (for example, subsidies for the purchase of certain heating appliances or the use of alternative sources of energy such as wind power) or, alternatively, to discourage their purchase (for example the exclusion of grants in the building industry when certain materials are used). It also includes fiscal or financial measures which may affect consumption by encouraging compliance with 'other requirements' within the meaning of the directive (for example, exemption from ecotax for the packaging of given products when a deposit system is set up, or exemption from ecotax for certain products when a collection and recycling system is established). Similarly this category of measures concern those aiming at encouraging or discouraging the purchase of services having certain features (e.g. services received via specific devices or originating from operators established in certain areas).

Directive 98/34/EC does not cover the whole of the fiscal or financial legislation of the Member States; it only refers to technical specifications or 'other requirements' linked to fiscal or financial measures which have the objective of changing consumer behaviour. The fiscal or financial measure does not, as such, form the subject of examination by the Commission or the Member States; but only that aspect of the technical specifications or other requirements or of rules on services which may form barriers to trade is examined.

It should be emphasised that this provision of the directive does not cover the fiscal or financial measures carried out in support of certain enterprises or products, pursuant to Articles 92 and 94 of the Treaty, relating to State aid, which form the subject of the specific procedure stipulated by the latter. Measures connected with the national social security systems are also excluded (for example the regulation which makes the refund of a medicine conditional on a certain type of packaging).

National laws, regulations and administrative provisions intended to prohibit the manufacture, importation, marketing and use of a product are considered to be technical regulations, in addition to the technical specifications and other compulsory requirements *dejure* or *de facto*. To fall within this category of technical regulation concerning a prohibition inter alia on use, the measures must have a scope which goes well beyond a limitation to certain possible uses of the product or the service in question and must not be confined to a mere restriction of their use. That category of technical regulation is particularly intended to cover national measures which leave no room for any use which can reasonably be made of the product concerned other than a purely marginal one (Case C-267/03 'Lars Erik Staffan Lindberg').

Such prohibitions constitute, as it were, the ultimate form of technical regulation. Unless they can be justified under Article 30 or Article 46 of the Treaty or proportionate in relation to essential requirements within the terms of the case law of the Court of Justice, they constitute barriers par excellence to the free movement of goods and services and to the freedom of establishment within the Community.

'draft technical regulation'

In order to be considered a draft, the technical regulation must be at a stage of preparation which will enable 'substantial amendments' to be made to the text. The procedure for the provision of information laid down by the Directive in the field of technical regulations provides that, on completion of the examination of drafts which it has been sent, the Commission and the Member States can request the regulatory authority to amend any text which is considered to be contrary to the rules of the internal market. It is a matter for each Member State to decide, in accordance with the nature of its legislative process, the stage at which its draft technical regulations should be sent to the Commission, as long as it is still possible to make substantial amendments.

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ANNEX H

Extracts from the Vademecum - Directive 98/48/EC

NOTE: The Commission's guidance was discussed with member States but the final document represents Commission's interpretation of the Directive.

Is it a "rule on services"?

Article 1, new point 5 defines the concept of a "rule on services" as a "requirement of a general nature" relating to the taking-up and pursuit of service activities and, in particular, to the service provider or the recipient of services (the parties) or the service as such (the service).

Recital 18 of Directive 98/48/EC cites, as an example, rules on the establishment of service providers, in particular those on authorisation or licensing arrangements.

The general concept of a "technical regulation" derives from Directive 98/34/EC (Article 1, new point 11) and, as in the case of products, is not aimed at all national measures but only instruments having general regulatory scope.

Excluded therefore from this definition of a "rule on services" (and not covered by the Directive) are those measures which, instead of laying down abstract and general requirements, are "of direct and individual concern to certain specific recipients" (see recital 18), e.g. administrative or judicial decisions in individual cases. Thus recital 18 cites, as an example of a measure other than a technical regulation, the granting of telecommunications licences to one or more specific operators.

Similarly, private-law acts or agreements concluded by natural and/or legal persons and to which the Member States are not a party are not covered by the Directive. The last clause of recital 5 cites as an example agreements governed by private law between credit institutions.

Other important elements which should be taken into account in interpreting the concept of a rule on services are comprised in Article 1, point 11 - in particular with regard to de facto technical regulations, which are covered by the concept of a technical regulation and must consequently be notified in advance.

The concept of a de facto technical regulation covers in particular: national provisions which refer to other rules on services and to professional codes or codes of good conduct,[26] compliance with which confers a presumption of conformity; voluntary agreements to which a public authority is a contracting party; and rules on services linked to fiscal or financial measures (which must be notified, but without being subject to a standstill period).

- Examples of measures likely to constitute a rule on information society services

- Measures concerning the conditions for taking up an activity:
  Draft law establishing the legal arrangements governing the issue of electronic money: conditions concerning professional qualifications and good repute, financial guarantees,

[26] It should be emphasised that codes of good conduct and self-regulation codes are not covered by the concept of a technical "regulation" (and need not therefore be notified in advance), unless the Member State is a contracting party to them or they are referred to in a national provision: in the latter case, as well as the national provision, the code itself will have to be notified (or, if it is already in existence, transmitted) to the Commission so that a complete assessment of the draft national regulation can be made.

obligation to obtain a licence and arrangements for its issue, etc.

- Measures concerning the conditions for pursuing an on-line activity:
  Draft decree concerning the procedures for practice as an on-line lawyer: ban on practising as a company; incompatibility of the profession with other activities; compulsory scales of fees; general ban on commercial promotion or certain forms of advertising, etc.
- Measures concerning the provider of on-line services:
  Draft regulation concerning the activity of on-line tax consultant: professional experience required, special registration procedures, requirements as to good repute and financial guarantees, etc.
- Measures concerning the supply of on-line services:
  Draft law concerning the procedures inherent in the supply of on-line architect services: obligatory clauses in contractual relations, scales of fees, ban on promotional offers, etc.
- Measures concerning the recipient of on-line services:
  Draft regulation on participation in certain games of chance on the Internet: possibility of, or facility for, participation determined in the light of certain criteria (age, residence); ban on participation in unauthorised schemes, etc.
- Examples of mandatory de facto rules on services:
  Concerning on-line translation activities: a regulation referring to non-regulatory instruments or to a code of professional conduct regarding the supply of on-line services, compliance with which confers a presumption of conformity; a voluntary agreement to which a public authority is a contracting party and which is designed to ensure compliance with rules on services; a ministerial decree laying down the tax arrangements designed to encourage compliance with certain rules on services (in the latter case, there is no standstill period following notification), etc.

- Examples of instruments not constituting a rule on services

– a licence for, or a refusal to grant a licence to, one or more individual operators,

– a fine imposed on a firm,

– a survey or a study launched by a national supervisory authority,

– a judgment by a court, tribunal or magistrate,

– a private-law agreement to which the State is not a contracting party.

Does the rule concern an "information society service"?

To determine whether an activity may be regarded as an information society service, the following two, cumulative questions must be answered in the affirmative:

(i) first, is the activity in question a "service" in Community law ?

(ii) second, is the "service", in the terms of the Directive, an "information society service", i.e. is it simultaneously supplied (a) "at a distance", (b) "by electronic means" and (c) "at the request of a recipient" ?

Is there a "service" in accordance with Community law?

Before defining the concept, specific to Directive 98/48/EC, of an "information society service", it is necessary to recall briefly the meaning of the general concept of a "service" given in the Treaty of Rome.

As stated in recital 19 of the Directive, "under Article 60 of the Treaty as interpreted by the case-law of the Court of Justice, 'services` means those normally provided for remuneration".

The Court of Justice explained in *Wirth* (Case C-109/92 [1993] I-6447, paragraph 15) that "the essential characteristic of remuneration lies in the fact that it constitutes consideration for the service in question".

In the interests of clarification, the same recital 19 adds "whereas that characteristic is absent in the case of activities which a State carries out without economic consideration in the context of its duties in particular in the social, cultural, educational and judicial fields; whereas national provisions concerning such activities are not covered by the definition given in Article 60 of the Treaty and therefore do not fall within the scope of this Directive" (see *Wirth*, cited above).

Thus, for instance, services supplied by the State with regard to compulsory schooling or hospital care, the issuing of certificates and documents by government offices (ministry, local authority, land register, etc.), measures relating to national defence, civil protection or the maintenance of law and order, or the activities associated with the exercise of civil, criminal, administrative and tax justice, etc. are excluded. In such contexts, any sums of money paid by the individual are not, in the proper sense, an economic consideration for the activity carried out by the State, on the pattern of a purely economic service available on the market.

It is, however, important to supplement these elements with the statement of the Court's[27] concerning the need not to interpret the concept of services restrictively, since "Article 60 does not require the service to be paid for by those for whom it is performed". The consideration, therefore, may exist independently of the direct or indirect arrangements for financing a service:[28] accordingly, activities financed entirely by advertising are remunerated and therefore constitute services.

In short, any economic activity - not governed by the provisions of the Treaty concerning the free movement of goods, capital and persons - may constitute a "service" for the purposes of Article 60 and is therefore likely to come under the definition provided for in Article 1 of the Directive. Only activities performed without economic consideration by the State as part of its function in the social, cultural, educational, administrative and judicial fields are in principle excluded.

Is there an "information society service" in accordance with the Directive?

A clear understanding of the novel concept of information society services can be obtained from both the substantive provisions and certain recitals of Directive 98/48/EC, which provide useful definitions and pointers. A few additional explanations should be given.

The basic definition of "information society service" is given in Article 1, new point 2 as "any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services".

The three features which together characterise the new category of information society services are therefore:

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[27] Case C-352/85 *Bond van Adverteerders* [1988] ECR 2085.

[28] For examples of consideration not paid by the recipient, see *Bond van Adverteerders*: the Court cites the situation of cable operators who provide a service for television broadcasters but are remunerated from the fee paid by subscribers and of broadcasters who are paid by advertisers for disseminating their messages to the public.

(a) supply at a distance;

(b) supply by electronic means; and

(c) supply at the individual request of a recipient of services.

The combination of these three features differentiates information society services from all other economic activity. However, if only one of these features is missing from a supply of services, that activity cannot be considered as an information society service. An indicative list of services not covered is to be found for this reason in Annex V to Directive 98/48/EC (examples of services not covered are given in the following pages).

Is the service supplied "at a distance"?

In accordance with the sub-definition contained in the first indent of the second subparagraph of Article 1, new point 2, the phrase "at a distance" means: a "service provided without the parties being simultaneously present".

Such a concept is not new. Its wording echoes the Distance Selling Directive.[29]

The concept "at a distance" relates to situations where the service is supplied via remote communication techniques characterised by the fact that the parties (i.e. the provider of the service and the recipient) are not physically present simultaneously.

- Examples of services supplied at a distance (covered):

– general on-line information services: electronic newspapers and magazines; electronic libraries; databases; information on current events, weather news, traffic information, local news, environmental information; information searches (search engines); computer graphics; etc.;

– educational on-line services supplied to students at home from private education centres: interactive courses, virtual universities and schools, guidance services for students and families, etc.;

– remote surveillance activities: remote health checks or on-line surveillance of private dwellings or business premises from surveillance centres;

– on-line consumer services: interactive teleshopping, information on, and assessments of, products and services, searches for bargains, etc.

- Examples of services not supplied at a distance (not covered; see Annex V to Directive 98/48/EC):

– medical examinations or treatment at a doctor's surgery using electronic equipment where the patient is physically present;

– consultation of an electronic catalogue in a shop with the customer on site;

– reservation of a plane ticket through a computer at a travel agency in the physical presence of the customer (the service supplied by the travel agency to the customer not being "at a distance");

– electronic games made available in a video-arcade where the customer is physically present.

[29] Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts (OJ L 144, 4.6.1997, p. 19).

Is the service supplied "by electronic means"?

In accordance with the second indent of the second subparagraph of Article 1, new point 2, the expression "by electronic means" signifies: a "service sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means".

Through this definition, the Directive is intended to cover services whose component parts are transmitted, conveyed and received within an electronic network. The service must be conveyed from its point of departure to its point of arrival:

– by means of electronic (processing and storage) equipment and

– through telecommunications channels (the reference to wire, radio, optical means and other electromagnetic means appears in Article 2(3) of Directive 90/387/EEC,[30] as amended by Directive 97/51/EC[31]).

- Examples of services supplied by electronic means:

– on-line entertainments offered on the Internet: video games on demand; music on demand; video on demand; sports events on demand; lotteries, betting and gaming; virtual tours of archaeological sites, monuments and museums; etc.;

– services for accessing the Internet and the World Wide Web: electronic mail, discussion forums, file transfer, chat conferencing;

– on-line validation services: authentification, registration, dating and verification services (acknowledgement of receipt, check on the simultaneity of supply and consideration, etc.), electronic stamps, etc.;

– on-line telecommunications services (see also point 1.4.2.): videotelephony, videoconference, telephony and facsimile services involving the processing and storage of data, etc.;

- Examples of services not provided by electronic means (not covered; see Annex V to Directive 98/48/EC):

– services having material content even though provided via electronic devices: automatic teller machines; access to road networks and car parks, even if there are electronic devices at the entrance/exit controlling access and/or ensuring correct payment;

– off-line services: distribution of CD-ROMS or software on diskettes;

– services which are not provided via electronic data storage and processing systems: voice telephony and facsimile services supplied by traditional means (in real time).

Is the service supplied "at the individual request of the recipient"?

In accordance with the sub-definition in the third indent of the second subparagraph of

[30] Council Directive 90/387/EEC of 28 June 1990 on the establishment of the internal market for telecommunications services through the implementation of open network provision (OJ L 192, 24.7.1990, p. 1).

[31] Parliament and Council Directive 97/51/EC of 6 October 1997 amending Council Directives 90/387/EEC and 92/44/EEC for the purpose of adaptation to a competitive environment in telecommunications (OJ L 295, 29.10.1997, p. 23).

Article 1, new point 2, the expression "at the individual request of a recipient of services" means: "a service provided through the transmission of data on individual request".

The services covered by this definition, therefore, are those which are provided in response to the individual request of their recipient.

This interactive feature characterises information society services and distinguishes them from other services, which being distributed without the need for a request from the recipient are not covered by the Directive.

This is why Article 1 states that the Directive does not apply to:

– radio broadcasting services,

– television broadcasting services covered by Article 1(a) of Directive 89/552/EEC as last amended by Directive 97/36/EC (the Television without Frontiers Directive). The last sentence of Article 1(a) stipulates that "communication services providing items of information or other messages on individual demand ..." are not included.

• Examples of services supplied on individual request (covered):

– on-line tourist services: booking of flights, trains and hotels; booking tickets for museums and theatres; tourist information; hire-car reservations, etc.;

– on-line services offered to firms: information, management and assistance with regard to supplies, inventory, dispatch, contracts, accounts, etc.;

– on-line agency services: estate, advertising, marketing, public relations, and employment agencies, marriage bureaux, auctioneers, etc.;

– on-line professional services: of lawyers, consultants, tax advisers, accountants, translators, computer scientists and software designers, engineers, designers, couturiers, psychologists, doctors (computer medicine), etc., consisting of services such as access to databases, data and file management, consultation, diagnosis, preparation of plans, projects and designs, personalised search and selection of information, addresses and job offers, etc.;

– on-line financial services: insurance and banking services (especially telebanking and electronic payment), investment and stockbroking services (see also points 1.4.3. and 1.4.4.).

• Examples of services not supplied on individual request (not covered; see Annex V to Directive 98/48/EC):

– services supplied by transmitting data, but not at individual request, for simultaneous reception by an unlimited number of recipients (point to multipoint transmission): television broadcasting services (including near-video on demand); radio broadcasting services; (televised) teletext services.

Is the rule aimed "specifically" at an information society service?

The new services are affected in one way or another by a large number of national general and sectoral regulations: one need only think, as far as the regulated professions are concerned for instance, of the systems of contract law and strict liability laid down in a civil code, of the framework laws laying down the rules on taking up and pursuing an economic activity, and of the rules on advertising, etc.

It is extremely important to emphasise that the obligation to notify in advance does not apply

to all draft national regulations which - directly or indirectly, explicitly or implicitly - may concern information society services.

Only a limited number and a well-defined category of draft national regulations will, for the purposes of the Directive, have to be notified in advance, namely the regulations specifically aimed at information society services. All other regulations affecting services are not notifiable.

This is clear from the wording of Article 1(5), which, after defining a "rule on services" as a "requirement of a general nature relating to the taking-up and pursuit of service activities within the meaning of point 2, in particular provisions concerning the service provider, the services and the recipient of services", explicitly excludes "any rules which are not specifically aimed at the services defined in that point".

It is appropriate in this context to recall recital 17, which explains that "specific rules on the taking-up and pursuit of service activities which are capable of being carried on in the manner described above should thus be communicated even where they are included in rules and regulations with a more general purpose; whereas, however, general regulations which do not contain any provision specifically aimed at such services need not be notified".

For a draft regulatory instrument to be notifiable, it is not enough, therefore, that it should be described as a "rule" on services; it must also be aimed "specifically" at information society services.

The Directive contains certain clues which make it easier to understand this concept, indicating at one and the same time what is meant and what is not meant by "***specifically***". Thus, the fifth subparagraph of the Article 1, new point 5 states that:

– "a rule shall be considered to be specifically aimed at information society services where, having regard to its statement of reasons and its operative part, the specific aim and object of all or some of its individual provisions is to regulate such services in an explicit and targeted manner"; and

– "a rule shall not be considered to be specifically aimed at information society services if it affects such services only in an implicit or incidental manner."

In view of the above, it must be concluded that the Directive requires the notification of regulatory drafts whose justification, content and purpose indicate that they are directly and openly devoted, in whole or in part, to controlling information society services. In such a case, the provision(s) in a national regulatory instrument will be specifically designed and expressly drafted to reflect the fact that the activity/service is supplied "at a distance, by electronic means and at the individual request of a recipient of services".

Thus, not only are regulatory instruments covered which as a whole are devoted to information society services (e.g. a law on electronic signatures), but also regulations of which only a part (possibly an article or even a paragraph) specifically concerns an information society service (e.g. within a law on pornography, a specific provision on the liability of an Internet access supplier).

This idea is clearly expressed by recital 18, which states that "a provision specifically aimed at information society services must be considered as being such a rule even if part of a more general regulation".

In these scenarios, the whole draft has to be communicated to the Commission, accompanied where appropriate by any other provisions, knowledge of which is necessary to assess the scope of the draft technical regulation (in accordance with the second subparagraph of

Article 8(1) of Directive 98/34/EC). However, the standstill obligation will apply only to rules specific to information society services.[32]

On the other hand, draft regulations need not be notified which relate only indirectly, implicitly or incidentally to information society services, i.e. which concern an economic activity in general without taking into consideration the typical technical procedures for supplying the information society services (e.g. a provision which prohibits the distribution of paedophile material by any means of transmission, including the Internet or electronic mail, among the various possible means of dissemination.

It is precisely with this consideration in mind that recital 5 asserts that the Directive "is not intended to apply to national rules relating to fundamental rights, such as constitutional provisions concerning freedom of expression and, more particularly, freedom of the press" and that "it is not intended to apply to the general criminal law either". Constitutional provisions and basic rules of criminal law - and of civil and company law - in theory sanction only fundamental and general principles, which do not relate specifically therefore to on-line activities.

Similarly, the basic provisions of a civil code or general laws on company and labour matters would not be covered by the Directive.

- Examples of measures covered (as rules specifically aimed at information society services) :

– an instrument of a legislative nature (an Act of Parliament) on the liability of the Internet access supplier;

– an instrument of a regulatory nature (a Presidential or Royal Decree) on digital signatures;

– a provision of an administrative nature (a ministerial decree) on consumer protection in the field of interactive teleshopping;

– an administrative circular (from a ministry or public or authorised supervisory body under an obligation to notify) having specific legal effects and explaining the advertising laws applying specifically to services supplied on the Internet in the light of the general arrangements already in force.

- Examples of measures not covered (provided they do not contain any provision aimed specifically at information society services and without prejudice to examination of the measure with regard to the "goods" part of Directive 98/34/EC):

– a framework law on the protection of minors;

– a law on the system of press ownership;

– a law on press freedom and the protection of privacy, including the civil and criminal penalties applicable if the rules laid down are infringed;

– a regulation on the tax arrangements applicable to discography;

– a regulation laying down or amending the general arrangements applicable to a liberal profession;

– a decree establishing the new scale of fees for lawyers' services;

[32] Case C-279/94 *Commission v Italy* [1997] ECR I-4743.

– a decree concerning the introduction and management of an official register for marketing consultants;

– a ministerial order on the legal arrangements applicable to travel agencies (licences, professional and financial guarantees, etc.);

– a circular concerning certain administrative procedures to be followed when organising promotional games.

Does the rule fall within one of the areas exempted by the Directive?

(Categories of rules relating specifically to information society services which do not need to be notified)

The Directive provides for a number of exemptions: in other words, particular categories of national rules which, although aimed specifically at information society services, are explicitly excluded from the Directive's scope and need not therefore be notified in advance.

Such draft rules:

(1) satisfy the criteria referred to in Article 10 of Directive 98/34/EC;

(2) concern questions covered by Community rules on telecommunications services;

(3) concern questions covered by Community rules on financial services;

(4) relate to regulated markets and other financial markets or bodies (in this case, a partial exemption is involved; see below).

These four exempt categories are examined below.

Does the rule come under one of the exemptions provided for by Article 10 of the Directive (relating in particular to draft measures implementing Community directives)?

A very broad exemption is already provided for by the basic Directive 98/34/EC: the new Article 10 merely reproduces and extends the previous wording relating to products and provides that the obligation to notify in advance and the standstill periods (provided for in Articles 8 and 9) do not apply to a number of national provisions specifically relating to information society services.[33]

[33] The new wording of Article 10 reads as follows (parts amended by Directive 98/49/EC in bold):

"1. Articles 8 and 9 shall not apply to those laws, regulations and administrative provisions of the Member States or voluntary agreements by means of which Member States:

- comply with binding Community acts which result in the adoption of technical specifications or rules on services,
- fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications or rules on services in the Community,
- make use of safeguard clauses provided for in binding Community acts,
- apply Article 8(1) of Directive 92/59/EEC (10),
- restrict themselves to implementing a judgment of the Court of Justice of the European Communities,
- restrict themselves to amending a technical regulation within the meaning of point 11 of Article 1, in accordance with a Commission request, with a view to removing an

For instance, attention should be drawn in this respect to the exemption, as regards rules on services, of national measures ensuring compliance with binding Community instruments, international agreements resulting in the adoption of common rules on services and measures which merely carry out a judgment of the Court of Justice or amend a technical regulation, as requested by the Commission with a view to removing an obstacle to the free movement of services or the freedom of establishment of a service provider.

All such national measures pursue the same objective of removing obstacles to the freedom of movement, and it must be possible rapidly to adopt those which are already subject to Community supervision.

On the other hand, provisions would not be covered by the exemption in Article 10 (and would therefore have to be notified in advance) which, while part of a national legislative instrument implementing a Community directive, nevertheless related to questions not covered by the directive to be transposed (e.g. in a law implementing the Distance Selling Directive,[34] only the articles implementing the Directive would be covered by the exemption in Article 10; other articles in the same law relating to questions other than distance selling, e.g. on information of a promotional or statistical nature aimed at consumers, would definitely have to be notified in advance if they fall within the scope of Directive 98/48/EC).

Similarly, measures subsequent to or complementing national regulations implementing Community directives are not, as a general rule, to be considered as instruments ensuring compliance and are thus not covered by the exemption in Article 10: they must therefore be notified in advance.

- Examples of measures excluded from the scope of the Directive

National measures implementing Community directives are the classic example.

For instance, national measures implementing the Distance Selling Directive 97/7/EC are not subject to the obligation of prior notification laid down in Directive 98/48/EC.

Similarly, the Member States' regulations intended to implement the future Directive on electronic signatures (based on the proposal presented by the Commission on 13 May 1998) will not have to be notified under Directive 98/48/EC.

Also excluded (because they come under Article 10 of Directive 98/34/EC) will be national measures implementing the future Directive on the legal protection of services based on, or consisting of, conditional access.

- Examples of measures covered by the Directive

A national law implementing the Distance Selling Directive which imposed

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obstacle to trade or, in the case of rules on services, to the free movement of services or the freedom of establishment of service operators.

2. Article 9 shall not apply to the laws, regulations and administrative provisions of the Member States prohibiting manufacture insofar as they do not impede the free movement of products.

3. Article 9(3) to (6) shall not apply to the voluntary agreements referred to in the second indent of the second subparagraph of Article 1, point 11.

4. Article 9 shall not apply to the technical specifications or other requirements or to the rules on services referred to in the third indent of the second subparagraph of Article 1, point 11."

[34] Directive 97/7/EC, see footnote 28

consumer-protection requirements additional to those in the Directive (e.g. with regard to the identification of on-line operators) would be subject to the obligation of prior notification.

Similarly, a national law which, at some time in the future, amends the distance selling arrangements already introduced by the implementing law by laying down new arrangements specific to on-line transactions (prior information supplied by a website to the consumer, procedures for on-line confirmation, electronic payment systems, etc.) should be notified at the draft stage, since it would not have been adopted at the time compliance with the Distance Selling Directive was ensured.

Does the rule concern matters which are the subject of Community arrangements for telecommunications services?

The second subparagraph of Article 1, new point 5 of Directive 98/48/EC states that "this Directive shall not apply to rules relating to matters which are covered by Community legislation in the field of telecommunications services, as defined by Directive 90/387/EEC".

Directive 90/387/EEC[35] (as amended by Directive 97/51/EC[36]) defines telecommunications services as "services whose provision consists wholly or partly in the transmission and routing of signals on a telecommunications network by means of telecommunications processes, with the exception of radio broadcasting and television".

In substance, therefore, it is laid down that all future national drafts relating to telecommunications matters already harmonised at Community level - i.e. including national measures other than those covered by the general exemption in Article 10 - will not fall within the scope of the Directive and will not therefore be subject to the obligation to notify.

The reason for this specific exemption is that in the field of telecommunications services (as in financial services, see following section) a large number of matters are already harmonised and are part of an already existing and sufficiently defined Community regulatory framework.

There are several Community directives governing a series of questions relating to these services. These include, for instance:

– Directive 90/387/EEC[37] (already cited), as amended by Directive 97/51/EC,[38] which lays down the principles (objectivity, transparency, advertising, non-discrimination, etc.) and the procedural conditions for the supply of an open telecommunications network and the fundamental requirements which may justify restricting access to networks and public services (security and integrity of the network, interoperability, data protection);

– Directive 90/388/EEC,[39] which concerns the conditions for the liberalisation of the supply of certain services (value added, voice, data transmission, etc.), as amended by Directives 94/46/EC[40] (which sets out the conditions for the liberalisation of satellite

[35] See footnote 29.
[36] See footnote 30.
[37] See footnote 29.
[38] See footnote 30.
[39] Commission Directive 90/388/EEC of 28 June 1990 on competition in the markets for telecommunications services (OJ L 192, 24.7.1990, p. 10).
[40] Commission Directive 94/46/EC of 13 October 1994 amending Directives 88/301/EEC and 90/388/EEC in particular with regard to satellite communications (OJ L 268, 19.10.1994, p. 15).

services), 95/51/EC[41] (concerning the use of cable networks), 96/2/EC[42] (on mobile and personal communications) and 96/19/EC[43] (on the achievement of full competition on the telecommunications market);

– Directive 92/44/EEC,[44] which defines the procedures for the supply of a minimum collection of leased lines;

– Directive 97/13/EC,[45] which lays down the conditions and procedures applicable to general authorisations and individual licences in the field of telecommunications services, etc.

– Directive 97/33/EC,[46] which harmonises the conditions for the interconnection of public networks and telecommunications services accessible to the public and the conditions of access to such networks and services with a view to ensuring universal service and interoperability, etc.

As a result of this specific exemption, not only the measures referred to in Article 10 of Directive 98/34/EC but also all other national regulations relating to questions governed by the Telecommunications Services Directives (e.g. laws amending, clarifying, or repealing the scope of a law transposing a Directive) are not subject to the obligation of prior notification in Directive 98/34/EC (given that, for the most part, they will have to be notified under these Directives.

- Example

This exemption would concern, for instance, a law subsequent to a law implementing Directive 97/13/EC (on a common framework for general authorisations and individual licences in the field of telecommunications services) which laid down new general provisions in the field of licences.

Similarly, a future national law, subsequent to the law which transposed Directive 97/13/EC and laying down specific conditions for granting licences to supply electronic mail telecommunications services, will not, as a result of this exemption, be subject to the obligation of prior notification.

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[41] Commission Directive 95/51/EC of 18 October 1995 amending Directive 90/388/EEC with regard to the abolition of the restrictions on the use of cable television networks for the provision of already liberalised telecommunications services (OJ L 256, 26.10.1995, p. 49).

[42] Commission Directive 96/2/EC of 16 January 1996 amending Directive 90/388/EEC with regard to mobile and personal communications (OJ L 20, 26.1.1996, p. 59).

[43] Commission Directive 96/19/EC of 13 March 1996 amending Directive 90/388/EEC with regard to the implementation of full competition in telecommunications markets (OJ L 74, 22.3.1996, p. 13).

[44] Council Directive 92/44/EEC of 5 June 1992 on the application of open network provision to leased lines (OJ L 165, 19.6.1992, p. 27).

[45] Parliament and Council Directive 97/13/EC of 10 April 1997 on a common framework for general authorisations and individual licences in the field of telecommunications services (OJ L 117, 7.5.1997, p. 15).

[46] Parliament and Council Directive 97/33/EC of 30 June 1997 on interconnection in telecommunications with regard to ensuring universal service and interoperability through application of the principles of Open Network Provision (ONP) (OJ L 199, 26.7.1997, p. 32).

Does the rule concern questions which are the subject of Community arrangements for financial services?

As with the exemption provided for in the case of regulations relating to harmonised matters in the field of telecommunications services, the third subparagraph of Article 1, new point 5 states that: "this Directive shall not apply to rules relating to matters which are covered by Community legislation in the field of financial services, as listed non-exhaustively in Annex VI to the Directive".

The reason for such an exemption from the scope of the Directive is identical and is due to the fact that such rules are part of an already sufficiently established Community legal framework.

It follows from this specific exemption that a future national law subsequent to an implementing law and relating to a question of this type, regulated by a Community directive on financial services, should not be notified even if it is aimed specifically at an on-line financial service.

Purely as a guide, a non-exhaustive list of financial services is supplied in Annex VI to Directive 98/48/EC, which gives the three main categories into which, very summarily, such services can be divided: banking, investment and insurance services.

There are many directives in this field, regulating various legal matters, depending on the specific sector concerned.

For instance, the Second Banking Directive (89/646/CEE[47]), after giving a set of basic definitions ("credit institution", "authorisation", "branch", "own funds", "control", "holding", etc.) provides in particular for, inter alia, harmonisation of the conditions of authorisation (minimum capital, shareholders), mutual recognition of authorisations of credit institutions as part of the freedom to provide services or the right of establishment by means of branches, and harmonisation of certain conditions for the pursuit of the activity (evaluation of own funds, qualifying holding, etc.).

Directive 93/22/EC[48] contains rules on the same questions with regard to investment services in the field of securities.

Other directives on financial services deal with different questions: e.g. deposit guarantee systems (94/19/EC[49]), rules on the prevention of money laundering (91/308/EEC[50]), matters of prudential supervision (92/30/EC,[51] 89/647/EEC,[52] 93/6/EC,[53] 89/299/EEC[54]), and

[47] Second Council Directive 89/646/EEC of 15 December 1989 on the coordination of laws, regulations and administrative provisions relating to the taking up and pursuit of the business of credit institutions and amending Directive 77/780/EEC (OJ L 386, 30.12.1989, p. 1).

[48] Council Directive 93/22/EEC of 10 May 1993 on investment services in the securities field (OJ L 141, 11.6.1993, p. 27).

[49] Parliament and Council Directive 94/19/EC of 30 May 1994 on deposit-guarantee schemes (OJ L 135, 31.5.1994, p. 5).

[50] Council Directive 91/308/EEC of 10 June 1991 on prevention of the use of the financial system for the purpose of money laundering (OJ L 166, 28.6.1991, p. 7).

[51] Council Directive 92/30/EEC of 6 April 1992 on the supervision of credit institutions on a consolidated basis (OJ L 280, 24.9.1992, p. 54).

[52] Council Directive 89/647/EEC of 18 December 1989 on a solvency ratio for credit institutions (OJ L 386, 30.12.1989, p. 14).

information to be published by listed companies (82/121/EEC[55]) and in the event of an acquisition or disposal of a major holding (88/627/EEC[56]), etc.

The matters regulated by all the directives in the field of insurance, in particular with regard to the activities covered, the need for and the conditions of granting authorisation, the principles of and procedures for financial supervision, solvency, etc., should be added.

To sum up, as a result of the specific exemption provided for in the third subparagraph of Article 1, new point 5, no future national regulation concerning one of the questions regulated at Community level should be notified: not only would regulations coming under Article 10 of the Directive (in particular implementing measures, see previous point), but also all national regulations supplementing or subsequent to the implementing instruments (laws amending, clarifying or repealing the scope of a law transposing or having transposed a Community directive).

- Examples of non-notifiable regulations:

– a draft law defining "investment services" and "investment enterprises" in respect of operators and financial activities on the Internet;

– a draft regulation on the deposit guarantee system of credit organisations issuing electronic money;

– a draft decree on on-line insurance operators' obligations as regards accounting, prudential and statistical information.

Does the rule relate to regulated financial markets (stock exchanges) or other financial markets or bodies (partial exemption)?

Another specific exemption is provided for with regard to financial services by the fourth subparagraph of Article 1, new point 5, which states that:

"With the exception of Article 8(3), this Directive shall not apply to rules enacted by or for regulated markets within the meaning of Directive 93/22/EEC or by or for other markets or bodies carrying out clearing or settlement functions for those markets."[57]

The reason for this exemption is the need to adopt without delay regulatory instruments which deal with on-line services relating to highly mobile and very fluid financial markets, where situations may change suddenly and unpredictably.

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[53] Council Directive 93/6/EEC of 15 March 1993 on the capital adequacy of investments firms and credit institutions (OJ L 141, 11.6.1993, p. 1).

[54] Council Directive 89/299/EEC of 17 April 1989 on the own funds of credit institutions (OJ L 124, 5.5.1989, p. 16).

[55] Council Directive 82/121/EEC of 15 February 1982 on information to be published on a regular basis by companies the shares of which have been admitted to official stock-exchange listing (OJ L 48, 20.2.1982, p. 26).

[56] Council Directive 88/627/EEC of 12 December 1988 on the information to be published when a major holding in a listed company is acquired or disposed of (OJ L 348, 17.12.1988, p. 62).

[57] Council Directive 93/22/EEC of 10 May 1993 on investment services in the securities field (OJ L 141, 11.6.1993, p. 27) provides basic definitions (e.g. of investment services, investment firms, financial instruments and competent authorities) and lays down the conditions for taking-up and pursuit, relations with third countries and the provisions concerning freedom of establishment and the freedom to provide services in this field.

As a result of this exemption, the *rules drawn up by* or *concerning* regulated markets or other markets or bodies carrying out clearing or settlement operations for such markets are not subject to the obligation of prior notification (nor, of course, to the other provisions of the Directive on, say, "standstill" periods).

The only obligation to which such rules, in the interests of minimal transparency, are subject is that of "ex-post" notification, i.e. after adoption at national level pursuant to Article 8(3), which - as indicated by the fourth subparagraph of Article 1, new point 5 - is the only provision in the Directive which applies to these rules.

- Examples of regulations which specifically concern on-line services relating to regulated markets or other markets and bodies and which are not therefore to be notified at the draft stage but only after they have been definitively adopted at national level:

– a draft regulation on computerised stock-exchange dealing and settlement;

– a draft decree concerning the clearing system used for electronic trades made on the stock exchange;

– a draft regulation relating to the procedures for the supply and conclusion of electronic transactions concerning securities traded on financial markets other than stock exchanges.

Can the rule notified (at the draft stage) be adopted immediately in domestic law?

(Assumption of prior notification but without a "standstill" period)

Directive 98/34/EC basically imposes a twofold obligation on Member States: notification of a national draft technical regulation with the above-mentioned characteristics, and the deferment of the adoption of the instrument at national level for a certain period (the "standstill", see Chapter 2 below).

The second obligation, however, is still not in force.

The Directive provides for certain cases in which, even if a national rule - following the tests described - should be the subject of prior notification, the Member State concerned is not obliged to defer its adoption. This possibility exists for:

(1) rules associated with tax or financial measures;

(2) circumstances where there is particular urgency.

If, therefore, a rule should come within one of these categories, it will indeed have to be notified in advance (at the draft stage) but without a standstill period, in accordance with the following terms.

Is the rule linked to fiscal or financial measures?

Pursuant to Article 10(4) of the Directive, Article 9 does not apply to the technical specifications or other requirements referred to in the third indent of the second subparagraph of point 11 of Article 1, i.e. specifically to "... rules on services which are linked to fiscal or financial measures affecting the consumption of ... services by encouraging compliance with such ... rules on services". Examples of fiscal and financial measures include tax incentives, taxes, and subsidies for the reception of certain services or for supply via certain procedures.

The non-application of the standstill periods to rules linked to fiscal or financial measures does not affect the possibility for the Commission and the Member States, under the last subparagraph of Article 8(1), to issue comments or reasoned opinions on the aspect "which

may hinder trade and not the fiscal or financial aspect of the measure".

In short, a rule linked to a fiscal or financial measure:

– must be notified at the draft stage,

– may be the subject of reasoned opinions or comments,

– but does not trigger a standstill period for the Member State concerned, which may therefore adopt the rule in domestic law immediately after it has been notified.

• Examples:

– draft regulation linked to fiscal measures: a draft decree concerning the tax scales encouraging the use of on-line lawyers' services;

– draft regulation linked to financial measures: a draft decree subsidising setting up as an electronic mail operator in certain island regions in order to promote this activity.

Urgency clause

Without altering the previous urgency clause relating to rules applying to products, Directive 98/48/EC introduces more flexibility as regards recourse to the urgency clause as far as the rules on information society services are concerned.

It should be emphasised that, even where a Member State invokes the urgency clause, it is still obliged to notify the draft national regulation relating specifically to information society services and to state why urgency is justified.

The Commission, which will have to assess whether urgency is justified, will reply to the request as soon as possible.

It may either accept the case for urgency (without prejudice to the assessment of the substance of the national measure) or challenge it. In the latter instance, if the national measure is adopted definitively in the Member State in breach of the standstill periods, the Commission reserves the right to initiate vis-à-vis the Member State concerned the procedure provided for by Article 169 of the Treaty.

To sum up, Article 9(7), as amended, establishes that for rules relating to information society services the urgency clause applies in three types of situation.

(A) Firstly, "for urgent reasons, occasioned by serious and unforeseeable circumstances relating to the protection of public health or safety, the protection of animals or the preservation of plants". These are the same circumstances as those already provided for in the basic Directive 98/34/EC.

(B) Secondly, "for urgent reasons, occasioned by serious and unforeseeable circumstances relating to ... public policy, notably the protection of minors".

Compared to the previous provision in Directive 98/34/EC, this is a novel situation, which is limited to rules relating to information society services.

This new concept reflects the special importance attached by the Community legislator to the protection of minors in the context of the new services - a subject which is also covered by other Community initiatives.[58]

[58] The Council, on 28 May 1998, noted unanimous agreement on the recommendation on the development of the competitiveness of the European audiovisual and information services

The concept of public policy, which figures *inter alia* in Articles 56 and 66 of the EC Treaty, can be clarified in the light of the case-law of the Court of Justice (which has stated its views on this concept on many occasions in cases concerning not only the free movement of services and the right of establishment but also the free movement of goods and workers).

While not giving a precise definition, the case-law recognises this concept as possibly varying from one country to another and from one period to another[59] and as allowing the competent national authorities an area of discretion within the limits imposed by the Treaty.[60]

However, the Court also explains that the concept of public policy must be interpreted strictly[61] and cannot be determined unilaterally by each Member State without being subject to control by the institutions of the Community.[62]

The Court also provides certain additional information of both a positive and a negative nature.

Thus it explains that the invocation of public policy must be justified on general interest grounds,[63] presupposes the existence of a genuine and sufficiently serious threat affecting one of the fundamental interests of society[64] and must be interpreted in the light of (i.e. in conformity with) the general principles of law and in particular of fundamental rights and the general principle of freedom of expression.[65]

Moreover, the Court states that public policy cannot be invoked for:

– objectives of an economic nature,[66]

– considerations of an administrative nature,[67]

– cultural policy objectives,[68]

– considerations of consumer protection.[69]

From a more general point of view, it should be pointed out that urgent reasons, whether under (A) or (B), that can justify recourse to the immediate adoption of a national measure must, in any event, be due to circumstances which are not only serious but unforeseen, linked to all the purposes mentioned.

Accordingly, it is very important to bear in mind the aspects of the general interpretation of the nature and specific purposes of the urgency clause mentioned by recital 22, which, having stressed the exceptional nature of recourse to such a clause, explains that its application is justified in particular in "circumstances of which there was no previous knowledge and the

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industry by promoting national frameworks aimed at achieving a comparable and effective level of protection of minors and human dignity; see also the proposal for a multiannual action plan on promoting safe use of the Internet (COM (97) 582 final, 26.11.1997).

[59] Case 30/77[1977] ECR 1999.

[60] Case 30/77[1977] ECR 1999.

[61] Case C-260/89 [1991] ECR I-2925.

[62] Case 30/77[1977] ECR 1999.

[63] Case C-484/93 [1995] ECR I-3955.

[64] Case 30/77[1977] ECR 1999.

[65] Case C-260/89 [1991] ECR I-2925.

[66] Case C-17/92 [1993] ECR I-2239.

[67] Case 205/84 [1986] ECR 3755.

[68] Case C-17/92 [1993] ECR I-2239.

[69] Case 177/83 [1984] ECR 3651.

origin of which is not attributable to any action on the part of the authorities of the Member State concerned, so as not to jeopardise the objective of prior consultation and administrative cooperation inherent in this Directive".

It is in this rigorous spirit, therefore, that the urgency clause should be interpreted and applied by both national and Community authorities.

(C) Thirdly, in the case of information society services, the urgency clause may also be invoked, where rules relating to financial services are concerned, "for urgent reasons occasioned by serious circumstances relating to the protection of the security and the integrity of the financial system, notably the protection of depositors, investors and insured persons".

This special form of urgency clause is provided for exclusively in the field of financial services on account of certain risks and requirements specific to this sector.

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ANNEX I

Precedents created by Court of Justice judgments for interpretation of Directive 98/34/EC – Overview (prepared by the Commission DG Enterprise and updated by BIS).

The full judgments are available on the TRIS website for case law: http://europa.eu.int/comm/enterprise/tris/case_law/index_en.htm or on the ECJ website: http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en

I. Rulings on failures to fulfil obligations

Judgment of 2 August 1993, Commission v Italy - Pleasure craft - Case C-139/92, ECR 1993, p. I-4707: *example of a technical regulation*.

By failing to communicate, at the draft stage, Ministerial Decree No 514/87 for the definition and verification of the maximum output, the construction and installation of engines for pleasure craft Italy failed to fulfil its obligations under the Directive.

Judgment of 1 June 1994, Commission v Germany - Sterile medical instruments - Case C-317/92, ECR 1994, p. I-2039: *extension of the scope of a technical regulation to other products; measure implementing an enabling provision.*

1. Application to given products of a technical regulation which previously only applied to other products constitutes a technical regulation and must be notified (ground 25).

2. The fact that the enabling provision has already been communicated to the Commission is no dispensation from the obligation to give notification of the provisions implementing it. It is not the enabling provision which contains the technical specification but, possibly, the implementing measures (ground 26).

Judgment of 14 July 1994, Commission v Netherlands - Flower bulbs - Case C-52/93, ECR 1994, p. I-3591: *another example of a measure which must be notified.*

By adopting an amendment to the PVS regulation on quality standards for flower bulbs without notifying it to the Commission at the draft stage, the Netherlands failed to fulfil its obligations under Article 8 of the Directive.

Judgment of 14 July 1994, Commission v Netherlands - Kilowatt-hour meters - Case C-61/93, ECR 1994, p. I-3607: *another example of a measure which must be notified.*

By adopting decrees concerning kilowatt-hour meters, the strength requirements for soft-drinks bottles and the composition, classification, packaging and labelling of pesticides, without notifying them to the Commission at the drafting stage, the Netherlands failed to fulfil its obligations under Article 8 of the Directive.

Judgment of 11 January 1996, Commission v Netherlands - Margarine - Case C-273/94, ECR 1996, p. I-31: *clarification of the concept of "technical regulation": technical regulation offering an alternative to existing arrangements, subject to compliance with the conditions laid down, and measures with the effect of liberalising trade.*

1. A regulation derogating from another technical regulation already in existence constitutes a technical regulation since it establishes alternative technical specifications observance of which is compulsory. Anyone who wishes to derogate from the existing rule is under an obligation to comply with the alternative specifications in order to produce or place on the market the product in question (ground 13).

2. The notification obligation does not depend on the presumed effects of the technical regulation in question on trade between Member States. Instead, the objective of the procedure is to establish whether there is any risk of creating a barrier and whether it could be justified in the light of Community legislation. Consequently, even rules liberalising the arrangements for the products concerned must be notified (grounds 14 and 15).

Judgment of 17 September 1996, Commission v Italy - Molluscs - Case C-289/94, ECR 1996, p. I-4405: *need for link between the specific specification and marketing of the products; extent of the exemption from the notification obligation for implementing measures; production methods and procedures for medicinal products.*

1. There is a very close correlation between rules concerning the quality of the waters for growing molluscs and the marketing of the product concerned: since compliance with them has a direct impact on the marketing of the goods, in that only goods produced in line with these technical rules may be marketed, the rules in question must be regarded as a technical regulation (ground 32).

2. Moreover, there must be a direct link between a binding Community act and a national measure in order to qualify as an implementing measure exempt from the notification requirement under the first indent of Article 10(1). In the case in point the national rules were of much more limited scope than the Community measures and were, therefore, subject to the notification obligation (grounds 36, 43 and 44).

3. The concept of technical specification includes production methods and procedures for medicinal products, as defined in Article 1 of Directive 65/65, since extension of the scope of Directive 83/189/EEC by Directive 88/182 (ground 51).

Judgment of 16 September 1997, Commission v Italy - Asbestos - Case C-279/94, ECR 1997, p. I-4743: *prohibition of marketing of a substance; types of rules which could have consequences as regards the characteristics of the product; concept of new technical regulation and need for distinct legal effects; extent of the notification obligation not on a par with the standstill obligation.*

1. A provision prohibiting the marketing and use of a substance constitutes a technical regulation (ground 30). This held true even before this was clarified by Directive 94/10.

2. A regulation laying down limit values for the concentration of a substance in the air (in this case, asbestos fibres) does not define a characteristic required of a product and, therefore, does not in principle fall within the definition of a technical specification; nevertheless, it could still be possible to demonstrate that the measure does have consequences for the characteristics of the product (ground 34).

3. A new technical regulation must produce distinct legal effects compared with the existing rules; in the event of disputes this burden of proof falls on the plaintiff (ground 36).

4. In view of the objective of Article 8 of the Directive, which is to enable the Commission to have as much information as possible on the content, scope and general context of any draft technical regulation, it is incumbent on the Member States to communicate the full text containing the technical regulations (ground 41); consequently, the full text must be notified, but only the technical regulations which it contains are subject to the standstill obligation (ground 42).

Judgment of 7 May 1998, Commission v Belgium, Case C-145/97, ECR 1998, p. I-2643: *scope of the notification obligation.*
Under Article 8 of the Directive Member States must communicate not only the draft text containing the technical regulations but also the text of the basic legislative or regulatory provisions principally and directly concerned. The aim of that provision is to enable the Commission to have as much information as possible in order to enable it to exercise as effectively as possible the powers conferred on it by the Directive (ground 12).

Judgment of 15 February 2001, Commission v French Republic, Case C-230/99, ECR 2001, p. I-1169: *refusal to regard a detailed opinion as equivalent to a letter of formal notice (confirmation of the Order of 13 September 2000, Commission v Netherlands, Case C-341/97, ECR 2000, p. I-6611)*

It follows from the function assigned to the pre-litigation stage of proceedings for failure of a State to fulfil its obligations that the purpose of the letter of formal notice is, first, to delimit the subject-matter of the dispute and to indicate to the Member State, which is invited to submit its observations, the factors enabling it to prepare its defence and, second, to enable the Member State to comply before proceedings are brought before the Court. Also, in order for a letter of formal notice to be issued, a prior failure by the Member State concerned to fulfil an obligation owed by it must be alleged.

However, it is clear that, at the time when a detailed opinion under Directive 83/189 is delivered, the Member State to which it is addressed cannot have infringed Community law, since the measure exists only in draft form.

The contrary view would result in the detailed opinion constituting a conditional formal notice whose existence would be dependent on the action taken by the Member State concerned in relation to the opinion. The requirements of legal certainty, which are inherent in any procedure capable of becoming contentious, preclude such incertitude (paras 31 to 34).

II. Rulings on references for a preliminary ruling

Judgment of 30 April 1996 - CIA Security International - Case C-194/94, ECR 1996, p. I-2201: *non-application of the notification procedure to rules laying down conditions governing the establishment of firms or serving merely as enabling provisions for the adoption of technical regulations; effectiveness of the control introduced by the Directive by virtue of the notification and standstill obligations; clear, unconditional nature of Articles 8 and 9 of the Directive; inapplicability of technical regulations adopted in breach of the notification obligation.*

1. Rules laying down conditions governing the establishment of firms in a certain sector do not define the characteristics of a product and, therefore, do not have to be notified (ground 25).

2. Detailed rules defining the conditions concerning the quality tests and function tests which must be fulfilled in order for a product to be approved and marketed constitute technical regulations (ground 26).

3. Provisions which serve merely as a basis for enabling adoption of other technical regulations, but have no legal effect on their own on individuals, do not constitute a technical regulation; but this is not the case with provisions which have legal effect on their own, for example require all concerned to apply for prior approval of their products, even if the implementing rules envisaged have not been adopted (grounds 29 and 30).

4. Articles 8 and 9 of the Directive are precise (to the effect that technical regulations must be notified and controlled at Community level before adoption) and unconditional and must therefore be interpreted so that those articles may be relied on by individuals before national courts (grounds 44 and 50).

5. The aim of the Directive is not simply to inform the Commission but, precisely, the more general aim of eliminating or restricting obstacles to trade, to inform other States of technical regulations envisaged by a State, to give the Commission and the other Member States time to react and to propose amendments for lessening restrictions to the free movement of goods arising from the envisaged measure and to afford the Commission time to propose a harmonising directive (grounds 40, 41 and 50).

6. Failure to fulfil the notification obligation, as a procedural defect in the adoption of the technical regulations concerned, renders such technical regulations inapplicable and unenforceable against individuals. Where an individual rightly invokes breach of this obligation before a national court, the national court must decline to apply the national technical regulation which was not notified (grounds 45, 54 and 55).

Judgment of 20 June 1996 - Semeraro Casa - Cases C-418/93 to C-421/93, C-460/93 to C-462/93, C-464/93, C-9/94 to C-11/94, C-14/94, C-15/94, C-23/94, C-24/94 and C-332/94, ECR 1996, p. I-2975: *non-application of the Directive to national rules regulating the closing times of shops.*

The notification obligation laid down by the Directive does not apply to national rules which do not lay down the characteristics required of a product but are confined to regulating the closing times of shops (ground 38).

Judgment of 20 March 1997 - Bic Benelux - Case C-13/96, ECR 1997, p. I-1753: *classification of a national measure as a technical regulation irrespective of the grounds on*

which it was adopted; classification of an obligation for a marking to inform the public that the product is subject to an environmental tax as a technical regulation.

1. The Directive is not limited to national measures capable of harmonisation only on the basis of Article 100a of the Treaty. The aim is, by preventive monitoring, to protect the free movement of goods, which technical regulations could hinder, directly or indirectly, actually or potentially. Such hindrances may arise irrespective of the grounds on which the measures in question were adopted (ground 19). Consequently, the fact that a national measure does not implement a technical standard which may itself constitute a barrier to the free movement of goods or was adopted in order to protect the environment does not mean that the measure in question cannot be a technical regulation (ground 20).

2. The definition of "other requirement" introduced by Directive 94/10 has no relevance as regards the meaning to be given to "technical specification"; they are two distinct concepts (ground 21).

3. A marking intended to inform the public of the effects of a product on the environment is no different, despite the fact that it is accompanied by an environmental tax, from other labels which remind consumers of the harmful effects of the products in question on the environment. Such a marking can in no way be regarded as exclusively a fiscal accompanying measure (ground 24).

Judgment of 16 June 1998 - Lemmens - Case C-226/97: *inclusion in the Directive of regulations within the scope of criminal law; conditions for application of the Directive to rules applicable to a particular group of users; relation between the concept of inapplicability and free movement of goods.*

1. The Directive also applies to regulations within the scope of criminal law; its scope is not limited to products intended to be used otherwise than in connection with the exercise of public authority (ground 20).

2. Certain measures impose, on a product intended for a particular group of users, technical specifications whose content depends on the specific objective pursued by that group. Where these are too remote from production and marketing of the product they can no longer be classified as technical regulations (ground 24). Where the technical specifications must be complied with for sales to a major user on the market in question, they are technical regulations (ground 25).

3. Non-notification of technical regulations renders such regulations inapplicable, inasmuch as they hinder the use or marketing of a product which is not in conformity therewith, but does not have the effect of rendering unlawful any use of a product which is in conformity with regulations which have not been notified (ground 35).

Judgment of 11 May 1999 - Albers - Joined Cases C-425/97 to C-427/97: *production methods and procedures for agricultural products intended for human consumption; scope of the exemption from the notification obligation for implementing measures.*

1. Rules which are intended to prevent the administration of given substances to certain types of cattle constitute technical specifications within the meaning of Article 1(1) of the Directive, in that this concept covers production methods and procedures for agricultural products intended for human consumption (grounds 16 and 17).

2. Moreover, since they are issued by the national administrative authorities, apply to the whole of the national territory and are binding on their addressees, they are technical regulations (ground 18).

3. Prohibitions on administering a given substance to cattle and on holding, having in stock, buying or selling cattle to which that substance has been administered which are adopted in order to honour obligations under a Community Directive constitute technical regulations but the Member State which adopted them is exempt, under Article 10 of Directive 83/189, from the obligation to notify the Commission.

Judgment of 3 June 1999 - Colim - Case C-33/97: *definition of technical regulation: conditions for a measure replacing an existing technical regulation to become notifiable; classification of an obligation to provide labelling, instructions for use and guarantee certificates in one or more specified languages; scope of the Directive and of Article 28 of the EC Treaty respectively.*

1. The aim of the Directive is to protect, by preventive monitoring, the free movement of goods, which is one of the foundations of the Community. That monitoring is designed to eliminate or reduce barriers to the free movement of goods that might result from technical regulations which the Member States propose to adopt. However, a national measure which reproduces or replaces, without adding new or additional specifications, existing technical regulations which, if adopted after the entry into force of Directive 83/189, have been duly notified to the Commission, cannot be regarded as a "draft" technical regulation or, consequently, as subject to the notification obligation (ground 22).

2. Unlike the obligation to convey certain information about a product to the consumer, which is carried out by affixing particulars to the product or adding documents to it such as instructions for use and the guarantee certificate, which concerns the product directly, the obligation to give that information in a specified language does not in itself constitute a "technical regulation" within the meaning of the Directive but an "ancillary rule" necessary in order for the information to be effectively communicated (grounds 29 and 30).

3. While language requirements imposed on labelling, instructions for use or guarantee certificates are not technical regulations within the meaning of the Directive they do constitute a barrier to intra-Community trade in so far as products coming from other Member States have to be given different labelling involving additional packaging costs (ground 36).

III. New Rulings – BIS unofficial summaries

A. Rulings or failures to fulfil obligations i.e. proceedings taken under Article 226 (formerly 169)

Judgment of 13 September 2000, Commission v. Netherlands - **letter of formal notice - Case C-341/97:** *effect of a detailed opinion on infraction proceedings; a detailed opinion from the Commission does not constitute a formal notice for the purpose of infraction proceedings [Case C-230/99 followed this Judgment]*

1. It follows from the function assigned to the pre-litigation stage of proceedings for failure of a State to fulfil its obligations that the purpose of the letter of formal notice is, first, to delimit the subject-matter of the dispute and to indicate to the Member State, which is invited to submit its observations, the factors enabling it to prepare its defence and, second, to enable the Member State to comply before proceedings are brought before the Court.

2. Also, in order for a letter of formal notice to be issued, a prior failure by the Member State concerned to fulfil an obligation owed by it must be alleged. However, it is clear that, at the time when a detailed opinion under Directive 83/189/EEC is delivered, the Member State to which it is addressed cannot have infringed Community law, since the measure exists only in draft form. The contrary view would result in the detailed opinion constituting a conditional formal notice whose existence would be dependent on the action taken by the Member State concerned in relation to the opinion. The requirements of legal certainty, which are inherent in any procedure capable of becoming contentious, preclude such incertitude.

3. In view of the foregoing considerations, the Commission's action for failure to fulfil obligations must be dismissed as inadmissible under Article 92(2) of the Rules of Procedure in the absence of a formal notice meeting the requirements of Article 169.

B. Rulings on references for a preliminary ruling i.e. proceedings taken under Article 234 (formerly 177)

Judgment of 6 November 1998 - Unilever - Case C-443/98: *standstill; consequences of a failure to abide by the standstill period laid down in the Directive*

1. *CIA Security* related to a technical regulation which had not been notified in accordance with Article 8 of Directive 83/189/EEC. In the statement of the grounds on which that finding was based, the Court also examined the obligations deriving from Article 9 of the Directive. The Court's reasoning shows that, having regard to the objective of Directive and to the wording of Article 9 thereof, those obligations must be treated in the same way as those deriving from Article 8 of the same directive.

2. In *CIA Security,* the finding of inapplicability as a legal consequence of breach of the obligation of notification was made in response to a request for a preliminary ruling arising from proceedings between competing undertakings based on national provisions prohibiting unfair trading. It follows from the case-law of the Court that the inapplicability of a technical regulation which has not been notified in accordance with Article 8 of Directive 83/189/EEC can be invoked in proceedings between individuals for the reasons set out in paragraphs 40 to 43 of this judgment. The same applies to non-compliance with the obligations laid down by Article 9 of the same directive, and there is no reason, in that connection, to treat disputes between individuals relating to unfair competition, as in the *CIA Security* case, differently

from disputes between individuals concerning contractual rights and obligations, as in the main proceedings.

3. A national court is required, in civil proceedings between individuals concerning contractual rights and obligations, to refuse to apply a national technical regulation which was adopted during a period of postponement of adoption prescribed in Article 9 of Council Directive 83/189/EEC.

Judgment of 12 October 2000 - Snellers - Case C-314/98: *applicability and coming into force of amendments to Directive 98/34/EC; definition of "technical specification"*

1. For the purposes of determining whether national rules, such as the regulation adopted on 9 December 1994, constitute a technical regulation covered by the obligation to notify the Commission laid down in Directive 83/189/EEC, the subsequent amendments introduced by Directive 94/10/EC should not be taken into consideration.

2. Article 1(1) of Directive 83/189/EEC provides that, as regards products such as those at issue in the main proceedings, a technical specification for the purposes of that directive is "a specification contained in a document which lays down the characteristics required of a product". Technical specifications for the purposes of Directive 83/189 must thus refer to the product as such; that is, moreover, confirmed by the non-exhaustive list of the specifications concerned provided by way of example in Article 1(1) of that directive. The regulation lays down a number of criteria for establishing the date on which a vehicle, for the purposes of the regulation, is deemed to have been first authorised to use the public highway, for the purposes of drawing up a registration certificate. The regulation does not therefore define any characteristic required of the product as such. National rules concerning the determination of the date on which a vehicle was first authorised for use on the public highway, such as the regulation, do not fall within the scope of Directive 83/189/EEC.

Judgment of 16 November 2000 – Donkersteeg - Case C-37/99: *clarification of a technical regulation and technical specification in relation to agricultural products; requirement for proper disinfectant or cleaning facilities does not define the production method or process; precise rules for a requirement for vaccination were linked to the procedure for the production of the product but as there were no restrictions on either the marketing or the use of the products concerned for failure to comply it was not a technical regulation requiring notification*

1. Article 2(1) of the national measure (VMV) states that "the operator is required to ensure that one or more proper disinfectant containers or appropriate cleaning facilities for disinfecting footwear are present on his holding" but does not lay down a rule defining a "characteristic" required of the agricultural products concerned. Nor does it define a production "method" or "procedure" for those products. The Commission argues correctly that that provision of national law, which merely requires disinfectant containers or appropriate cleaning facilities for disinfecting footwear to be provided on pig farms, does not concern production in the strict sense of the agricultural product under consideration. A rule such as that in Article 2(1) is not a technical specification within the meaning of Article 1(1) of Directive 83/189/EEC and that, as a result, that national provision cannot be a technical regulation for the purposes of that directive. A provision such as that in issue, which requires there to be one or more disinfectant containers or appropriate cleaning facilities for

disinfecting footwear on pig farms, is not, for the purposes of the directive, a technical regulation which ought to have been notified to the Commission before being adopted.

2. A rule such as that contained in Article 2(1) of the national measure (VBZA) which states "every operator is required to have pigs present on his holding vaccinated against Aujeszky's disease in accordance with the vaccination scheme set up for the animal species concerned and the individual areas by the Pig Breeding Department on the recommendation of the Veterinary Care Association" is a technical specification within the meaning of Article 1(1) of the Directive. Since the precise and detailed rules concerning vaccination against Aujeszky's disease are linked to the production, in the strict sense, of the agricultural product concerned and must be complied with throughout the production cycle, that rule therefore defines a "procedure" in the production of that product. Nevertheless, in order to be classified as a technical rule within the meaning of the directive, the rule at issue in the main proceedings must, in accordance with Article 1(5) of the Directive, contain technical specifications "the observance of which is compulsory, *de jure* or *de facto*, in the case of marketing or use in a Member State or a major part thereof, except those laid down by local authorities". Article 2(1) of the VBZA imposes no restrictions on either the marketing or the use of the products concerned if, in contravention of that rule, pigs have not been vaccinated against Aujeszky's disease. A provision such as that in issue which requires every farmer to have the pigs on his holding vaccinated against Aujeszky's disease is not, for the purposes of the directive, a technical regulation which ought to have been notified to the Commission before being adopted.

Judgment of 8 March 2001 **- Van der Burg - Case C-278/99:** *definition of technical regulation and technical specifications; advertising*

1. Under Article 1(1) of Directive 83/189/EEC, for the purposes of the directive a "technical specification" is "a specification contained in a document which lays down the characteristics required of a product". Technical specifications for the purposes of Directive 83/189/EEC must thus refer to the product as such (see Case C-314/98 Snellers). However, legislation which merely prohibits a marketing method does not lay down the characteristics required of a product. The fact that there is a direct relationship between an advertising prohibition and the technical requirements which transmitting equipment (in this case) must satisfy is not sufficient for the prohibition in question to be regarded as a "technical specification" within the meaning of Directive 83/189/EEC. National legislation which prohibits commercial advertising for transmitting equipment of a non-approved type, does not constitute, for the purposes of Directive 83/189/EEC, a technical regulation which should have been notified to the Commission prior to its adoption.

Judgment 22 January 2002 - Canal Satelite Digital - Case C-390/99: *clarification of technical regulation and exemption from notification; requirement to enter equipment details on a register and prior certification as a condition of marketing equipment constitutes a*

technical regulation; national legislation that did not comply with a binding Community act was not exempt from notification

1. National legislation which requires operators of conditional-access services to enter the equipment, decoders or systems for the digital transmission and reception of television signals by satellite which they propose to market in a register and to obtain prior certification for those products before being able to market them constitutes a "technical regulation" within the meaning of Article 1(9), of Directive 83/189/EEC.

2. The extent to which national legislation transposes a binding community act, and to that extent only, there is no duty of notification under Directive 83/189. The national legislation in question, in so far as it established a system of prior administrative authorisation that was not contained in a binding community act, could not qualify as legislation where the Member State complies with a binding community measure resulting in the adoption of technical specifications (Article 10 of Directive 83/189).

Judgment 6 June 2002 - Sapod Audic - Case C-159/00: *clarification of technical regulation, unenforceability of non-notified measures and exemption from notification; requirement to mark or label a product may be notifiable even if not specifying the sign but the severity of any sanction, such as nullity or unenforceability of a contract, is governed by national law; exemption from notification if complying with a Community act does not apply where the Community act only establishes a general framework and does not contain provisions imposing specific obligations on Member States*

1. A provision of national law implementing, in respect of packaging waste, a law relating to the disposal of waste and the recovery of materials could constitute a technical regulation within the meaning of Council Directive 83/189/EEC only if the national court were to hold that it had to be interpreted as requiring a mark or label to be applied. It would be sufficient that the law requires a mark or label, although not specifying what sign should be affixed.

2. In the event that a national provision were to be interpreted as requiring a mark or label to be applied, an individual may invoke the failure to make notification of that national provision in accordance with Article 8 of Directive 83/189/EEC. It is then for the national court to refuse to apply that provision, the question of the conclusions to be drawn from the inapplicability of that national provision as regards the severity of the sanction under the applicable national law, such as nullity or unenforceability of the contract, being a question governed by national law. That conclusion is, however, subject to the condition that the applicable rules of national law are not less favourable than those governing similar domestic actions and are not framed in such a way as to render impossible in practice the exercise of rights conferred by Community law.

3. Although the national law refers in its preamble to Directive 75/442/EEC, that directive establishes only a general framework, leaving Member States a significant degree of freedom. Directive 75/442/EEC does not contain provisions imposing specific obligations on Member States which are implemented by the national law. Article 10 ["comply with binding Community acts which result in the adoption of technical specifications"] of Directive 83/189/EEC, as amended by Directive 88/182/EEC, is to be interpreted as meaning that, where a provision of national law must be understood as requiring a mark or label to be

applied, that provision is not exempted from the notification requirement under Article 8 of Directive 83/189/EEC.

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ANNEX J

FEEDBACK

The operational procedure for the notification of regulations is operated by the Central Unit in BIS. BIS policy is to provide the highest possible standard of service and to maintain it; any feedback on any aspect of the procedure would be appreciated.

Please send any comments you may have to:

Ajay Gohil
Department for Business, Innovation and Skills
1 Victoria Street
London SW1H 0ET

Email: ajay.gohil@bis.gsi.gov.uk

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FORM A

Directive 98/34/EC
UNITED KINGDOM NOTIFICATIONS

To the European Commission: Brussels

1. (Leave blank - for Commission use)

2. United Kingdom.

3A. Department for Business, Innovation and Skills
1 Victoria Street, London, SW1H OET.
Email: 9834@bis.gsi.gov.uk.

3B. (Insert name of the Department responsible for drawing up the draft regulation)

4. (Leave blank - for Commission use)

5. (Insert full title of draft regulation)

6. (Indicate in clear language products and/or services covered by the draft technical regulation)

7. (If draft regulation is also notified under another Community Act, indicate the relevant Community legislation. Examples (*list not exhaustive*) are as follows:

- Regulation (EC) 315/93 on contaminants in food;
- Regulations (EC) 852/853/854/2004 relating to the hygiene of foodstuffs;
- Regulation (EC) 1924/2006 concerning nutrition and health claims made on foods;
- Regulation (EC) 1925/2006 concerning the addition of vitamins and minerals and certain other substances to foods;
- Directive 94/62/EC on packaging and packaging waste;
- Directive 2000/13/EC on the labelling and presentation and advertising of foodstuffs;
- Directive 2006/123/EC on services in the internal market*

**For Directive 2006/123/EC, please specify under this point the provisions of the notified draft under services which contain requirements referred to in Article 15 §2 of Directive 2006/123/EC. Also please mention the requirements referred to in the notified draft among those listed below. The grounds for notification under Directive 2006/123/EC should be mentioned under point 9 (notably in terms of necessity, non-discrimination and proportionality). Note: the requirements of Article 15 §2 of Directive 2006/123/EC are as follows:*
(a) quantitative or territorial restrictions, in particular in the form of limits fixed according to population or of a minimum geographical distance between providers;
(b) an obligation on a provider to take a specific legal form;
(c) requirements which relate to the shareholding of a company;
(d) requirements, other than those concerning matters covered by Directive 2005/36/EC or provided for in other Community instruments, which reserve access to the service activity in question to particular providers by virtue of the specific nature of the activity;
(e) a ban on having more than one establishment in the territory of the same State;
(f) requirements fixing a minimum number of employees;
(g) fixed minimum and/or maximum tariffs with which the provider must comply;
(h) the obligation on the provider to supply other specific services jointly with his service.

8. (Describe the main content of draft regulations - summarise the content of the draft technical regulation in not more than 20 lines. The length of the summary should be in keeping with the importance of the draft. It is important to include at least a few keywords to summarise the text in order to facilitate computer retrieval.)

9. (Indicate the reasons and necessity **(i.e. the grounds)** for making the regulation in not more than 10 lines. Do not repeat information already under other points in the notification message.)

10 (The draft measure must be forwarded with the notification, this part relates to other documents necessary for an understanding of the measure (basic texts). Note that consultation documents are not accepted as draft text.)

a) Indicate the references of the Basic Texts required to understand and assess the draft. Mention of this reference implies that the Basic Texts will be communicated to the Commission at the same time as the draft. Note that internet links are not accepted.

b) If the Basic Texts have been forwarded within the framework of a previous notification, its number must be specified.

c) If the Basic Texts have been forwarded with the framework of an earlier notification which has since that time entered into force and for which the final text has been forwarded, its number must be stated.

d) If communicating a draft a second time under Article 8.1(3) of Directive 98/34/EC because significant changes have been made, which have the effect of amending its scope, shortening the timing of implementation initially scheduled, adding stipulations or requirements or rendering the latter stricter, the number of the previous notification must be stated .

e) In the event that no Basic Text exists, indicate "No Basic Text" so that so that unnecessary requests for the forwarding of Basic Texts can be avoided.

f) If the draft aims in particular to limit the marketing or use of a chemical substance, preparation or product for reasons relating to public health, protection of the consumer or of the environment, Member States must also forward, under Article 8.1(4) of Directive 98/34/EC, either a summary or the references of pertinent data relating to the substance, preparation or product referred to and those relating to known and available substitute products, to the extent that such information is available, as well as the expected effects of the measure with regard to public health or protection of the consumer and the environment, with an analysis of the risks incurred, in appropriate cases, pursuant to the general principles of evaluating the risks of chemical products as referred to in Article 10.4 of Regulation (EEC) 793/93 if it concerns an existing substance or to Article 3.2 of Directive 67/548/EEC (as amended by Directive 92/32/EEC) if it concerns a new substance.

11. (is the **emergency procedure** being used?) **YES/NO***

12. (if "yes" a precise and detailed justification of the grounds in support of the emergency of the measures in question, pursuant to Article 9.7 of the Directive, **must** be provided.)

13. (**confidentiality** required?) **YES/NO***
(Not normally required but if "Yes" pursuant to Article 8.4 of the Directive, the reasons in support of your request must be stipulated.

14. (**fiscal measures** - "Yes" if a solely fiscal measure in accordance with Article 1.11 of the Directive, otherwise "No") **YES/NO***

15. Impact Assessment

Please check a box below as appropriate (if no RIA is available, state "RIA not available", note that internet links are not accepted):

a) ☐ Information on the impact assessment can be found on page (insert page number if an RIA is contained within a larger document eg a consultation document).

b) ☐ The impact assessment is attached.
(Check box if the RIA is forwarded as a standalone document.)

16. TBT and SPS Aspects

TBT Aspect

a) **YES/NO** (Indicate YES or NO to show whether the draft will be notified within the framework of the TBT Agreement (Agreement on Technical Barriers to Trade - http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm).

b) (If NO, indicate the reasons by checking below as appropriate)

i) ☐ The draft is not a technical regulation nor a conformity assessment procedure in the sense of Annex 1 of the TBT Agreement.

ii) ☐ The draft is in conformity with an international standard.

iii) ☐ The draft does not have a significant effect on international trade.

SPS Aspect

a) **YES/NO** (Indicate YES or NO to show whether the draft will be notified within the framework of the TBT Agreement on SPS (Agreement on Sanitary and Phytosanitary Measures - http://www.wto.org/english/tratop_e/sps_e/sps_e.htm).

b) (If NO, indicate the reasons by checking below as appropriate)

i) ☐ The draft is not a sanitary or phytosanitary measure in the sense of Annex A of the SPS Agreement.

ii) ☐ The content of the draft is in essence the same as the one of an international standard, guideline or recommendation.

iii) ☐ The draft does not have a significant effect on international trade.

(If you indicate yes to either part, you must separately send an appropriate notification under the TBT or SPS Agreement via the appropriate UK TBT contact point - currently marilyn.swain@bis.gsi.gov.uk - or SPS contact point, currently Katherine.quinteros@defra.gsi.gov.uk)

Points to note:

- **Some notified draft regulations will require a provision for the recognition of equivalent standards and testing in other Member States.**
- **Departments should make their own arrangements to comply with this requirement of the Directive:**

  Article 12 of the Directive states: "When Member States adopt a technical regulation, it shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of its official publication. The method of making such reference should be laid down by Member States".

  Departments are advised that it would be preferable to include a reference to the Directive in the instrument itself (such as the Explanatory Note to the Regulations). The following is an example of a form of words used:

  "These regulations were notified in draft to the European Commission in accordance with Directive 98/34/EC, as amended by Directive 98/48/EC.

  If this is not possible, Departments should include the following words at point 8 of this notification form:

  "The UK will fulfil its obligation under Article 12 of Directive 98/34/EC when these regulations are officially published"

Please provide the following details (department responsible for the draft regulation):

Name:			
Department:			
Address:			
Tel. No:		**Fax No:**	
Email:		**Date:**	

Please keep a copy. Send by email attaching the draft measure and any necessary background documents to:

Email: 9834@bis.gsi.gov.uk Alternatives: Philip.Plumb@bis.gsi.gov.uk Lisa.Rogers@bis.gsi.gov.uk	Address: Department for Business, Innovation and Skills 1 Victoria Street London SW1H 0ET
Tel: 020 7215 5440	

PLEASE make sure you send us the final text when the measure is adopted, or tell us if you have decided not to proceed to make the measure.

Document Configuration History

Version	Date	Details of Changes
URN 02/1434	December 2002	Replaced July 1999 guidance (URN 99/976)
	July 2003	Amended names of contact points
	September 2009	Updated BIS branding and contact points

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