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An instrument of market openness
and good regulatory practice

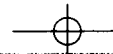
The notification procedure created by the Agreement on Technical Barriers to Trade



European Commission

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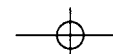
European Commission

An instrument of market openness and good regulatory practice

The notification procedure created
by the **Agreement**
on Technical Barriers to Trade

"ENTERPRISE" DIRECTORATE-GENERAL
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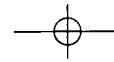
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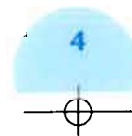
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Preface

Enterprises are the driving force in international trade. So that they can fully benefit from the growth in international trade, the tariff liberalisation undertaken must be accompanied by the removal of unjustified technical barriers.

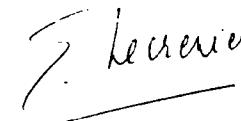
Differences between the technical regulations and conformity assessment procedures adopted by various countries can result in the creation of obstacles to international trade. Such measures may be adopted to pursue legitimate objectives, for example in order to guarantee consumer protection, to ensure that products placed on the market do not harm the environment or public health or even to ensure national security. However, these may also conceal protectionist intentions on the part of national authorities.

Due to the prior notification system established by the Agreement on Technical Barriers to Trade (*TBT Agreement*), Members of the World Trade Organization inform each other about these measures prior to their adoption. On the one hand, this allows the creation of unnecessary technical obstacles to international trade to be prevented and, on the other, allows the process of global harmonisation to be encouraged.

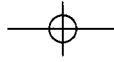
The European Community's participation in the system, through notification and enquiry points, is extremely useful as it specifically allows the EC to be informed about proposals of third countries which may have an impact on exports of Community enterprises. It also allows a dialogue to be initiated with our trading partners before the adoption of such measures.

For enterprises, it is essential that all the possibilities offered by this procedure are developed. They therefore have an interest in making themselves heard and in using the system established by the TBT Agreement to aid their integration into the world economy and reinforce their competitiveness. Their participation in this system must therefore be encouraged.

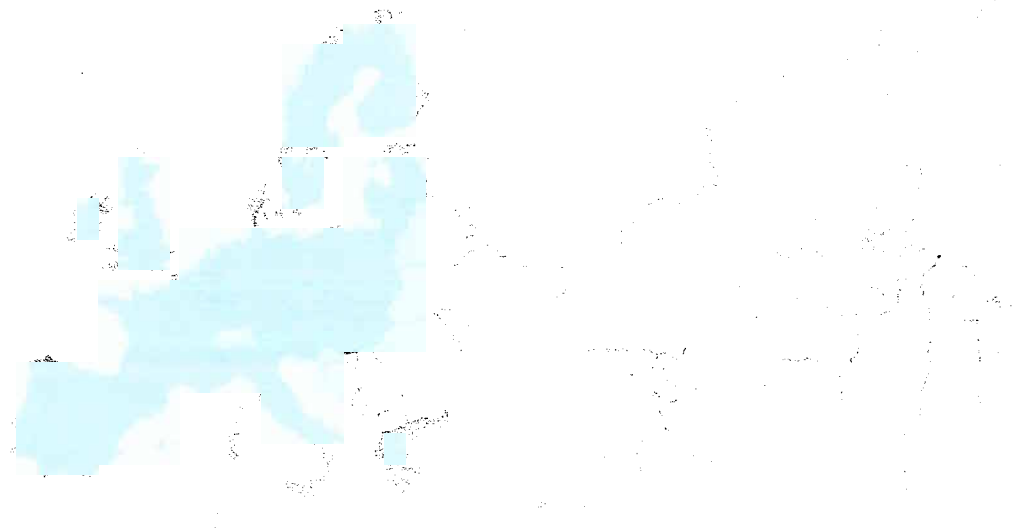
As a result, the Commission has begun a series of actions aimed at providing economic operators and national authorities with information on the notification procedure established by the TBT Agreement. The publication of this brochure together with the development of a website which contains all the documents on notifications are part of this communication effort. I hope that these initiatives will be successful in terms of increasing the participation of all those affected in this valuable instrument of transparency, dialogue and cooperation at international level.



Sabine Leclercq
Head of Unit
Enterprise Directorate-General



I. Introduction





I. Introduction

The TBT Agreement is the main international instrument adopted to date in the area of technical regulations.

The impact of technical regulations on trade in goods is being increasingly recognised. The gradual reduction of tariff barriers to trade has been accompanied by an increase in the number of measures creating technical obstacles to trade, such as regulations on packaging and labelling or conformity assessment procedures. These regulations may be intended to pursue a legitimate objective, such as the protection of human health or safety. However, they are also sometimes wrongfully used in order to erect protectionist barriers around the domestic market.

The Agreement on Technical Barriers to Trade (*TBT Agreement*) is the main international instrument adopted to date in the field of technical regulations. This Agreement aims to ensure that regulations, standards and testing and certification procedures do not create unnecessary obstacles to international trade.

The Agreement provides for a notification procedure which requires all Members of the World Trade Organization (WTO) to inform other Members, through the WTO Secretariat, of their proposed technical regulations and conformity assessment procedures. This procedure is a formidable instrument of transparency allowing all parties to the Agreement and economic operators to become acquainted with the technical regulations and conformity assessment procedures envisaged by other parties before these are adopted.

The existence of divergent technical regulations and different conformity assessment procedures can create a cost for enterprises, particularly for small and medium-sized enterprises, which, in order to export their products, must adapt their production to the requirements established in the recipient country. As a result, enterprises

see their opportunities for making economies of scale limited, incur additional costs as a result of submitting their products to the various conformity assessment procedures and, finally, must support the costs linked to obtaining the necessary information.

The notification system established by the TBT Agreement forms an important source of information as it allows Community enterprises to find out about the conditions of access to markets of third countries, in particular so that they can make preparations to comply with these. It is also an important instrument of dialogue as it allows the various laws of third countries to be examined before these are adopted and, if necessary, to be discussed with the notifying country in order to get the latter to change its mind, particularly when the proposed measure does not respect the obligations of the TBT Agreement. This specifically ensures that measures going against the interests of Community enterprises can be stopped from being adopted. The notification system also represents a useful source of information in the development of regulatory initiatives by the European Commission and Member States.

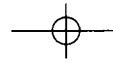
It is therefore essential that all those involved, particularly the national authorities and economic operators in the European Union, have a precise knowledge of the notification procedure established by the Agreement and are aware of its potential. The publication of this brochure is a response to this need for information. Its aim is to inform all those involved – and particularly European manufacturers – about the objectives, content and scope of this important instrument of international law which aims to prevent the establishment of technical obstacles to world trade.

The notification procedure established by the Agreement allows Community enterprises to find out about the conditions of access to markets of third countries and prevents unjustified obstacles to trade.



II. Presentation of the TBT Agreement





II. Presentation of the TBT agreement

II.1. Objectives

Before presenting the notification procedure in detail, the objectives and scope of the Agreement should be briefly set out.

Negotiated during the Uruguay Round, the TBT Agreement, which entered into force on 1 January 1995, increases the precision and binding force of the provisions of the plurilateral agreement on technical barriers to trade, known as the "Standards Code", negotiated during the Tokyo Round (1973-1979) and signed by thirty-two contracting parties to GATT.

The TBT Agreement aims to prevent the creation of unnecessary technical obstacles to international trade and encourages mutual recognition and harmonisation.

Unlike the Standards Code which, as a plurilateral agreement, applied only to the thirty-two countries having signed this, the TBT Agreement is a multilateral agreement which forms an integral part of the Agreement Establishing the WTO and therefore applies to all Members of this organisation. In addition, it is more binding than the Standards Code as, under Article 14.1 thereof, "*Consultations and the settlement of disputes with respect to any matter affecting the operation of this Agreement shall take place under the auspices of the Dispute Settlement Body and shall follow, mutatis mutandis, the provisions of Articles XXII and XXIII of GATT 1994, as elaborated and applied by the Dispute Settlement Understanding.*" This means that a Member to the Agreement may be penalised by the Dispute Settlement Body for infringing the rules laid down by this text.

The Agreement was incorporated into Community law through Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994)⁽¹⁾.

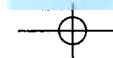
The notification procedure established by the Agreement is an instrument of transparency and dialogue.

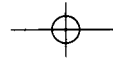
The TBT Agreement stipulates the rules to be followed by governmental and non-governmental bodies when developing technical regulations, standards and conformity assessment procedures. It lays down that technical regulations and conformity assessment procedures must not be more trade-restrictive than necessary to fulfil a legitimate objective and that they must be transparent and non-discriminatory. In addition, by stipulating that Members must use international standards as the basis for their technical regulations, it constitutes an instrument of harmonisation at international level. Finally, it encourages the mutual recognition of technical regulations and conformity assessment procedures and includes a number of obligations with regard to assistance for developing countries.

The Agreement aims to protect the right of Members to establish regulations in order to pursue a legitimate objective while preventing the adoption of protectionist measures. To this end it has established a notification procedure which essentially aims to:

- ensure *transparency*: the procedure allows all WTO Members to become acquainted with the technical regulations and conformity assessment procedures proposed by other Members;
- establish a *dialogue* between the WTO Members: the notification procedure is an instrument of reaction and discussion. It gives all WTO Members the opportunity to comment on the various laws of other Members containing technical regulations or conformity assessment procedures before these are adopted and to engage in a discussion so that, if necessary, their content can be amended. At Community level, the procedure allows enterprises to find out about the conditions of access to markets of third countries and it prevents measures going against their interests from being adopted.

⁽¹⁾ Decision of 22 December 1994, OJ L 336, 23.12.1994, p. 1.





II.2. Scope

The TBT Agreement applies to technical regulations, standards and conformity assessment procedures. These concepts are defined in Annex 1 to the Agreement (see below, point III.1).

Article 1 specifies that the Agreement covers "all products, including industrial and agricultural products".

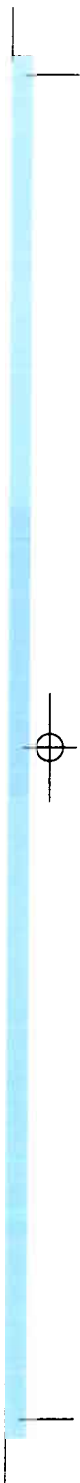
However, there are two exceptions:

Firstly, according to paragraph 4 of Article 1, the Agreement does not apply to purchasing specifications prepared by governmental bodies for production or consumption requirements of governmental bodies. These provisions are covered by the Agreement on Government Procurement, according to its coverage.

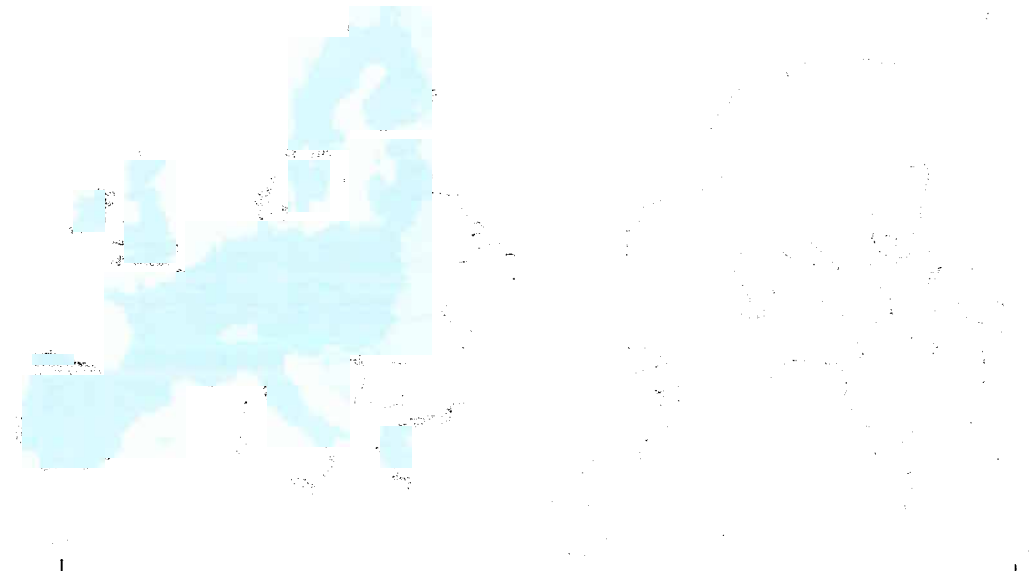
Secondly, according to paragraph 5 of Article 1, the Agreement does not apply to sanitary and phytosanitary measures which are covered by the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

The Agreement covers all products, including industrial and agricultural products.





III. The notification procedure





III. The notification procedure

III.1. Concepts: technical regulation, conformity assessment procedure

Members to the TBT Agreement must announce their proposed technical regulations and conformity assessment procedures. Members must also ensure that the technical regulations and conformity assessment procedures of local governments on the level directly below that of central government are announced, except where their technical content is substantially the same as that of texts previously announced by the central government bodies (Articles 3.2 and 7.2 of the Agreement).

The Agreement requires WTO Members to notify their proposed technical regulations and conformity assessment procedures.

Local governments are defined in Annex 1 to the Agreement as "Government other than a central government (e.g. states, provinces, Länder, cantons, municipalities, etc.), its ministries or departments or any body subject to the control of such a government in respect of the activity in question." During the first triennial review of the Agreement, Members were asked to indicate which local governments, in each of their territories, were authorised to adopt technical regulations or conformity assessment procedures. Following communication of this information by certain Members, the Agreement's Secretariat prepared a list of local governments subject to the notification obligation (?).

The technical regulation and conformity assessment procedure concepts are defined in Annex 1 to the Agreement.

A "technical regulation" is a "document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."

Technical regulations must be mandatory. This is the element differentiating them from standards, the application of which is voluntary.

The Appellate Body in the "European Communities – Measures Affecting Asbestos and Asbestos-Containing Products" (?) and "European

Communities – Trade Description of Sardines" (?) cases indicated three criteria that a document must meet in order to fall within the definition of "technical regulation" in the TBT Agreement:

"First, the document must apply to an identifiable product or group of products ... Second, the document must lay down one or more characteristics of the product ... Third, compliance with the product characteristics must be mandatory."

The concept of "conformity assessment procedure" covers "any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled."

The explanatory note specifies that "Conformity assessment procedures include, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations."

III.2. Conditions for notification

Members to the TBT Agreement must announce their proposed technical regulations and conformity assessment procedures when the following two conditions are met:

There are *no relevant international standards* (for technical regulations) or *no relevant guides or recommendations* issued by international standardising bodies (for conformity assessment procedures) or the technical content of a proposed technical regulation or proposed conformity assessment procedure is *not in accordance* with relevant international standards or relevant guides or recommendations issued by international standardising bodies.

This condition results from the presumption that a technical regulation in accordance with an international standard will not create unnecessary obstacles to international trade.

(?) G/TBT/W/76 and its Addendum.

(?) Appellate Body Report, WT/DS135/AB/R, adopted on 5 April 2001.

(?) Appellate Body Report, WT/DS231/AB/R, adopted on 23 October 2002.



The technical regulation or conformity assessment procedure may have a significant effect on trade of other Members.

There is no precise definition of the concept of a significant effect on international trade. According to a recommendation of the TBT Committee ^(*), in order to assess the significance of the effect on trade of technical regulations, the Members concerned should take into consideration such elements as the value or other importance of imports in respect of the importing and/or exporting Members concerned, the potential growth of such imports and difficulties for producers in other Members to comply with the proposed technical regulations. The effects in question may include both import-enhancing and import-reducing effects.

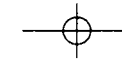
In addition, it is not only the effect on trade of a single proposed technical regulation or single conformity assessment procedure which should be considered as the combined impact of notified texts with other pre-existing technical regulations and conformity assessment procedures should be assessed.

Finally, the effect on trade may involve one or more products or groups of products and may affect the relations between two or more Members.

III.3. Timing of notification

Technical regulations and conformity assessment procedures must be notified to the WTO Secretariat at the proposal stage, namely at an early enough stage, when amendments can still be made and when comments can still be taken into account. The aim of the notification procedure would not actually be achieved if the communication occurred after the adoption of the text as it would no longer be possible to take account of the comments of other Members to the Agreement.

^(*) See document G/TBT/1/Rev. 8.
^(*) <http://www.wto.org>



Under Articles 2.10 and 5.7, Members are not required to announce, at the proposal stage, technical regulations and conformity assessment procedures adopted following *urgent problems* of security, health, environmental protection or national security. However, they are required to inform other Members of the adoption of these texts, to provide these on request and to take account of any comments from other Members.

The TBT Committee has noted that it would be useful for Members to share information, on a voluntary basis, with regard to the future preparation of proposed technical regulations and conformity assessment procedures, before the corresponding notifications are submitted, in order to increase transparency and improve the possibilities for making comments. This procedure could occur electronically and the TBT Committee encourages Members to draw the Committee's attention to such information.

III.4. Notification form

A proposed technical regulation or conformity assessment procedure is announced by sending the WTO Secretariat a standard notification form. It is very important that the form is filled in accurately and completely as this is the only document sent by the notifying Member and provided to the public on the WTO's site ^(*).

Document G/TBT/1/Rev. 8 of 23 May 2002 containing all the decisions and recommendations adopted by the TBT Committee since 1 January 1995 includes detailed explanations regarding the data to be entered in the form.

Firstly, the following must be indicated: the notifying Member and, where applicable, the local government involved, the body responsible for elaborating the proposal or for managing the notification procedure, the legal basis in the TBT Agreement under which the notification is made, allowing the nature of the announced measure to be identified, particularly whether this involves a technical regu-

Conditions for notification:

- non-existence of international standards on the subject or non-conformity with relevant international standards
- significant effect on trade.

Proposals must be notified at an early stage so that the comments of other WTO Members can be taken into account.



III. The notification procedure

lation or conformity assessment procedure, and the stage at which the text is being announced, particularly as to whether this involves a proposal or a text already adopted due to urgent problems.

Secondly, the notifying Member must provide information on the content of the announced text to allow other Members to the Agreement to make an initial assessment of this and to determine whether, if applicable, the notifying Member should be asked for a copy of the text. It is therefore recommended that not only the scope of the proposal is indicated, namely the products covered, but also that the content, objectives and rationale should be specified. With regard to texts announced under the urgency procedure, the reasons invoked for the urgency should also be indicated.

It is recommended that no sections are left blank. Where necessary, "not known" or "not stated" should be indicated.

Finally, the following should be indicated: the documents relevant to the notification, for example the basic documents to which the proposal refers, the proposed date of adoption and entry into force of the text, the final date for comments by other Members and the body from which the text can be obtained.

To encourage the electronic transmission of documents, it is recommended that the standard notification form is downloaded from the WTO's site ^(?) and then filled out and returned by e-mail to the Secretariat.

III.5. Renotification

Article 1.6 of the Agreement stipulates that "All references in this Agreement to technical regulations, standards and conformity assessment procedures shall be construed to include any amendments thereto and any additions to the rules or the product coverage thereof, except amendments and additions of an insignificant nature." In terms of the notification procedure, this means that any substantial amendment to a

previously announced proposed technical regulation or conformity assessment procedure should in turn be announced.

III.6. Reactions

In accordance with Articles 2.9.4 and 5.6.4 to the Agreement, Members shall "without discrimination, allow reasonable time for other Members to make comments in writing ..."

The TBT Committee has recommended allowing a minimum of 60 days for comments and has encouraged the extension of this period to 90 days to give other Members the opportunity to analyse the announced text.

As previously indicated, the announced text is not transmitted at the time of notification but the notification form indicates where the text can be found (for example on a website) or who can be contacted to obtain this. A Member interested in the notification of another Member must therefore firstly obtain the text. The possibility is not excluded of the notifying Member being able to request, for the supply of the text, reimbursement of the administrative costs linked to its transmission. It should be noted that "developed" countries must, on request, provide a translation in one of the three official languages of the WTO (French, English and Spanish) of documents covered by a specific notification or, in the case of voluminous documents, of summaries of these (Article 10.5 of the Agreement).

The TBT Committee has established that "any request for documentation should be processed if possible within five working days." ^(?) In addition, "if a delay in supplying the documentation requested is foreseen, this should be acknowledged to the requester, along with an estimate of when the documents can be provided" ^(?).

Once the text has been received, a translation of this may need to be requested. To aid access to translations and therefore save time in analysing the text, it is recommended that the notifying Member is asked which other Members have requested the same text so that

To announce a text to the WTO Secretariat, a standard notification form must be filled in with the main information on the announced proposal.

Other WTO Members must be given a minimum of 60 days to make comments on announced texts.

^(?) See Annex II.
^(?) See document G/TBT/1/Rev. 8.
^(?) *Ibidem*.

any translations which may be available can be shared on mutually agreed terms. It is also recommended that Members automatically send, on receipt of a request for documents, any summary translated in the requester's language or in a working language of the WTO.

Comments on announced texts are generally sent directly by the Member making these to the notifying Member. Moreover, following the third triennial review a tendency is becoming apparent whereby comments sent and replies received in their regard are being made public. Besides, comments on more sensitive notifications which are the subject of reactions from several Members are often discussed during meetings of the TBT Committee in Geneva.

In accordance with Articles 2.9.4 and 5.6.4 of the Agreement, Members shall *"discuss these comments (the comments from other Members) upon request, and take these written comments and the results of these discussions into account."* Compliance with these provisions is essential for the proper functioning of the system. The aim of the notification procedure is basically to establish a productive dialogue between Members in order to prevent the creation of unnecessary technical obstacles to international trade. Sending comments may give rise to bilateral and even multilateral discussions within the TBT Committee and the notifying Member may decide, following the receipt of comments on the announced text, to change its content. To ensure the proper functioning of the system, at the very least it would be necessary to systematically provide a response to all comments sent by other Members.

The TBT Committee has recommended that the Member receiving comments should *"explain within a reasonable time to any Member from which it has received comments, how it will proceed in order to take these comments into account"* and should *"provide to any Member from which it has received comments, a copy of the corresponding technical regulations or procedures for assessment of conformity as adopted or information that no corresponding technical regulations or procedures for assessment of conformity will be adopted for the time being"*⁽¹⁰⁾.

⁽¹⁰⁾ *Ibidem.*

⁽¹¹⁾ *Ibidem*, Chapter 10.

⁽¹²⁾ See document G/TBT/11.

⁽¹³⁾ See document G/TBT/12.

⁽¹⁴⁾ See document G/TBT/14.

III.7. Adoption of an announced text

Under Article 2.11 of the Agreement, *"Members shall ensure that all technical regulations which have been adopted are published promptly or otherwise made available in such a manner as to enable interested parties in other Members to become acquainted with them."* Members shall therefore be required to publish the definitive texts or otherwise make them available but they shall not be obliged to send them to the Agreement Secretariat.

In addition, under Article 2.12 of the Agreement *"... Members shall allow a reasonable interval between the publication of technical regulations and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products or methods of production to the requirements of the importing Member."* This provision is of particular importance to enterprises as it gives them time to adapt their production to the new requirements. It has been recommended that the period between the publication of a text and its entry into force should be six months ⁽¹¹⁾.

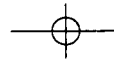
III.8. Some statistics

Every month the TBT Secretariat draws up a list of notifications received. The annual reviews contain information about the notifications received in the year in question and also a summary of notifications received since January 1995, the date when the Agreement entered into force.

In total, from January 1995 to December 2003, 5 459 notifications were submitted. In 2001, Members sent 538 notifications⁽¹²⁾, in 2002 581 notifications⁽¹³⁾ and in 2003 794 notifications⁽¹⁴⁾. The European Communities, for their part, sent 7 notifications in 2001, 17 in 2002 and 21 in 2003, from a total of 229 notifications since 1 January 1995.

Each WTO Member must take account of comments made by other Members.

Once adopted, texts must be published or made available to the public. In addition, they must provide for a reasonable interval before their entry into force.



III. The notification procedure

In 2003, 794 notifications were sent to the WTO Secretariat.

The number of notifications submitted in recent years has been very high which shows that the procedure is constantly increasing in scale.

To give an idea of the breakdown of notifications by objective and rationale indicated, nearly half of the notifications issued in 2003 concerned the protection of human health or safety ⁽¹⁵⁾.



⁽¹⁵⁾ The classification of objectives and rationales is based on criteria indicated in document G/TBT/W/18. In 2003, 196 of the 794 notifications submitted indicated at least two objectives and rationales (see document G/TBT/14, page 22).

IV. Management of the procedure at Community level



IV. Management of the procedure at Community level

The EC-TBT Enquiry Point manages, at Community level, the notification procedure established by the TBT Agreement.

EC TBT Enquiry Point
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 Belgium
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 E-mail: ec-tbt@cec.eu.int
 Website:
<http://europa.eu.int/comm/enterprise/tbt/>

The EC-TBT Enquiry Point notifies the WTO Secretariat of proposals prepared at Community level.

A European Communities' enquiry point has been set up within the Commission to manage the notification procedure. This is known as the EC-TBT Enquiry Point ⁽¹⁶⁾. There is also a service responsible for the TBT notification procedure in each Member State ⁽¹⁷⁾.

The EC-TBT Enquiry Point ensures the European Communities' participation in the information and notification system for technical regulations and conformity assessment procedures established by the Agreement.

In particular it is responsible for sending the WTO Secretariat notifications of proposed Community acts falling within the scope of the Agreement, for following up comments received by the European Communities and for responding to requests for information made by the enquiry points of third countries on announced proposals. In liaison with enterprises, it also analyses proposals announced by third countries and coordinates the comments of the European Communities on these texts.

The Community enquiry point also exchanges information with its counterparts in Member States. To this end, a group bringing together the national services responsible for notifications has been created. Chaired by the Community enquiry point, it meets regularly to discuss issues linked to the Agreement's application. This group has recently been enlarged to include the services responsible for notifications in the new Member States of the European Union.

The activities of the Community enquiry point are mainly aimed at increasing the participation of Member States and European enterprises in the notification procedure established by the Agreement and at encouraging, by monitoring the measures announced by third countries, the integration of European enterprises within the world economy.

In order to understand the practical operation of the notification procedure at Community level, the following three scenarios should be analysed: notification of *proposed Community acts*, notifications of

proposals elaborated by Member States of the European Union and notifications of third countries.

IV.1. Community texts

Texts are announced by the Commission on behalf of the European Communities at a stage which allows any comments from other WTO Members to be taken into account. In general, proposed acts which must be adopted by the Council or by the Council and Parliament are announced at the stage of the Commission's final proposal. Proposals to be adopted by the Commission are announced as soon as there is a sufficiently stable proposal which can be made available to the public.

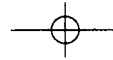
When a third country asks for an extension to the deadline in order to analyse a text announced by the European Communities, the latter tries, as far as possible, to grant this extension.

Where a Community text is subject to comments, the European Communities takes account of these and tries not to adopt the text before having replied to them. It generally responds to comments made on Community texts and on proposals of its Member States. In particular this ensures that it is in the best position when it asks third countries to respond to its own comments.

IV.2. Texts of Member States

According to current practice, Member States are responsible for notification, with the Commission not being involved at this stage. However, the European Communities do intervene where one of its Member States receives a comment from a third country. In fact, where the exercise of Community competence is involved, Member States cannot themselves react; they must send the Commission a proposed reply via the EC-TBT Enquiry Point. The Commission then

⁽¹⁶⁾ This enquiry point is also responsible for providing information on technical regulations and conformity assessment procedures, under Articles 10.1 and 10.3 of the TBT Agreement.
⁽¹⁷⁾ In some Member States, the service responsible for the notification procedure is also responsible for providing information on technical regulations and conformity assessment procedures, under Articles 10.1 and 10.3 of the TBT Agreement.



prepares the definitive reply in close liaison with the Member State in question and sends this on behalf of the European Communities.

The national authorities responsible for notification may, however, contact the Commission if they have any doubts about the obligation to announce a proposal.

The notification procedure established by the TBT Agreement has similarities with the *notification procedure for technical regulations established at Community level by Directive 98/34/EC* ⁽¹⁸⁾ and the two procedures can influence each other ⁽¹⁹⁾. In particular, with regard to a text which must be announced under both procedures, this raises an issue as regards the timing of the two notifications.

Member States of the European Union are free to choose the most appropriate time. Accordingly, they may decide to announce a proposal at the same time to the Commission and to the WTO or, on the other hand, they may announce a text to the WTO only after completing the procedure established by Directive 98/34/EC. At the moment, most Member States simultaneously announce their proposals to the Commission and to the WTO.

IV.3. Texts of third countries

Notifications from third countries allow texts envisaged by them, which risk harming the economic interests of European enterprises, to be identified.

For Community enterprises, the main advantages of the notification procedure are being informed about proposed regulations of third countries, being able to adapt their production in time to the new requirements and having the opportunity to make their opinion known on the announced texts.

Enterprises can send their comments on the proposals of third countries either to the enquiry points of Member States of the European Union or to the enquiry point of the European Communities.

The Commission, based on the reactions of enterprises, Member States of the European Union and its own departments, prepares the definitive text of the comments which is then sent to the enquiry point of the notifying Member on behalf of the European Communities. These reactions are mainly aimed at preventing the adoption of measures creating unnecessary obstacles to trade and going against the interests of Community enterprises or at obtaining a delay in the entry into force of the foreseen measures in order to allow Community exporters to adapt and use up their stocks.

The existence of Commission delegations in third countries is also very important in terms of monitoring the regulatory activity of these countries. On the one hand, these delegations can conduct parallel negotiations with the notifying Member and, on the other, they can be easily contacted by Community enterprises exporting to the Member which are able to evaluate the negative consequences, if any, which may arise from the adoption of the announced measures.

Member States directly notify their proposals. However, the EC-TBT Enquiry Point replies to comments from third countries on texts announced by Member States.

Notifications from third countries allow proposals likely to have an impact on exports of Community enterprises to be identified.

⁽¹⁸⁾ Directive laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services. Directive 98/34/EC was published in OJ L 204, p. 37, of 21 July 1998 and amended by Directive 98/48/EC of 20 July 1998, published in OJ L 217, p. 18, of 5 August 1998.

⁽¹⁹⁾ See Annex I.







V. TBT Committee and notification and information points



V. TBT Committee and notification and information points

V.1. TBT Committee

The Committee on Technical Barriers to Trade, an important arena for the exchange of information on notifications, meets three to four times a year in Geneva.

Article 13 of the TBT Agreement provides for the establishment of a Committee on Technical Barriers to Trade. This Committee affords Members the opportunity of consulting on any matters relating to the operation of the Agreement or the furtherance of its objectives.

The Committee meets three to four times a year in Geneva. It is composed of representatives of Members to the Agreement and of observers from other governments and international organisations.

The Committee forms an important arena for the exchange of information on notifications. Members do take the opportunity of Committee meetings to discuss the most sensitive notifications and to ask the notifying Member how it envisages taking into account the comments received.

For the European Communities, Committee meetings particularly provide an opportunity to ask for the notification of texts being

Each WTO Member designates an authority responsible for the notification procedure and an enquiry point.

prepared in other Members, of which they have become aware and to ask them to respond to comments which they have made.

V.2. Notification and information points

In accordance with Article 10.10 of the Agreement, Members are required to designate a single central government authority that is responsible for the implementation on the national level of the provisions concerning notification procedures. In addition, under Articles 10.1 and 10.3 of the Agreement, Members must ensure that there are enquiry points which are able to respond to requests for information made by other Members and to provide the documents which they need ⁽²⁰⁾.

It was decided, during the last triennial review, to regularly hold meetings, at the rate of one every two years, of the persons responsible for information exchange, including persons responsible for information points and notifications ⁽²¹⁾.

⁽²⁰⁾ The list of the national notification points and information points of Member States of the Community can be found on the Internet site with the following address <http://europa.eu.int/comm/enterprise/tbt>; the list of all enquiry points of Members to the Agreement is given in document G/TBT/ENQ/24 of 9 March 2004.

⁽²¹⁾ See document G/TBT/9 of 13 November 2000, p. 23.

VI. Annual and triennial reviews





VI. Annual and triennial reviews

In accordance with Article 15.3 of the TBT Agreement, the Committee must annually review the implementation and operation of the Agreement.

This annual review is intended to give an overview of the number of notifications per country and to gather together all the documents relating to the notification procedure adopted during the period in question.

To improve the operation of the TBT Agreement, the Committee carries out triennial reviews.

Under Article 15.4 of the Agreement, *“Not later than the end of the third year from the date of entry into force of the WTO Agreement and at the end of each three-year period thereafter, the Committee shall review the operation and implementation of this Agreement, including the provisions relating to transparency, with a view to recommending an adjustment of the rights and obligations of this Agreement where necessary to ensure mutual economic advantage and balance of rights and obligations ...”*

To date, three triennial reviews have taken place, in 1997, 2000 and 2003 ⁽²²⁾. During these reviews, important decisions and recommendations aimed at improving the implementation of the notification procedure were adopted.

During the initial review, it was decided, for example, to establish a list of local governments obliged to announce their proposed technical regulations and conformity assessment procedures.

During the second review, the standard format of notification forms and the guidelines for correctly completing these were established. It was recommended that a standard period of 60 days should be allowed for comments and that, if possible, an extension should be granted bringing the period to a total of 90 days. It was also decided that the Secretariat should prepare a monthly table of notifications issued, and it was planned to hold regular meetings of persons responsible for the exchange of information, including persons responsible for enquiry points and notifications. Finally, steps needed to develop the electronic transmission of information were agreed.

During the third review, to reinforce the dialogue on notifications and make this more transparent, Members were particularly invited to publish their comments and responses on their websites and to make their requests to the enquiry points in one of the three official languages of the WTO. Developed country Members were encouraged to provide more than a 60-day comment period.

⁽²²⁾ See documents G/TBT/5 of 19 November 1997, G/TBT/9 of 13 November 2000 and G/TBT/13 of 11 November 2003.



VII. Access for the public to information





VII. Access for the public to information

Information on the TBT Agreement can be found:

*on the WTO's website:
www.wto.org*

*on the EU's site:
<http://europa.eu.int/comm/enterprise/tbt/>*

on the Member States' sites.

So that the public, and enterprises in particular, can fully benefit from the possibilities offered by the notification procedure, it is firstly essential to ensure that the information exchanged in this context is widely disseminated.

The WTO's website contains all the notification messages. A search engine is available to the public and allows searches to be made using different criteria: notifying country, keyword, document number, etc ⁽²³⁾

In addition, the WTO's site provides general information on the TBT Agreement and, in particular, on the operation of the notification procedure ⁽²⁴⁾.

Several enquiry points of WTO Members, including those of several Member States of the European Union, have established websites for the notification procedure ⁽²⁵⁾.

The European Communities' enquiry point has set up a website which offers a range of information on the notification procedure and on the texts covered by this procedure.

⁽²³⁾ http://docsonline.wto.org/gen_search.asp?searchmode=simple

⁽²⁴⁾ http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

⁽²⁵⁾ <http://europa.eu.int/comm/enterprise/tbt>

VIII. Conclusion





VIII. Conclusion

Although the system could be improved, since its entry into force the notification procedure has played an important role as an instrument of transparency and prevention of obstacles to international trade.

In the nine years since 1 January 1995 that it has been in operation, the notification procedure established by the TBT Agreement has played an important role as an instrument of transparency and prevention of obstacles to international trade. A system for structured dialogue between the regulatory authorities of WTO Members has been established and this has contributed, on the one hand, to the process of international harmonisation and, on the other, to the removal of unnecessary obstacles to trade.

Thanks to improvements made following the triennial reviews, the notification procedure is also becoming increasingly efficient.

However, the system is still open to improvement. Firstly, experience has shown that the WTO Members do not announce all their proposed technical regulations or conformity assessment procedures, including proposals established by bodies at sub-state level, namely local governments.

Secondly, due to the fact that comments on notifications and the responses to these comments are generally exchanged bilaterally between the notifying Member and the commenting Member, the system is not entirely transparent. Additionally, the monitoring of notifications could be assisted by the communication of definitive texts once adopted.

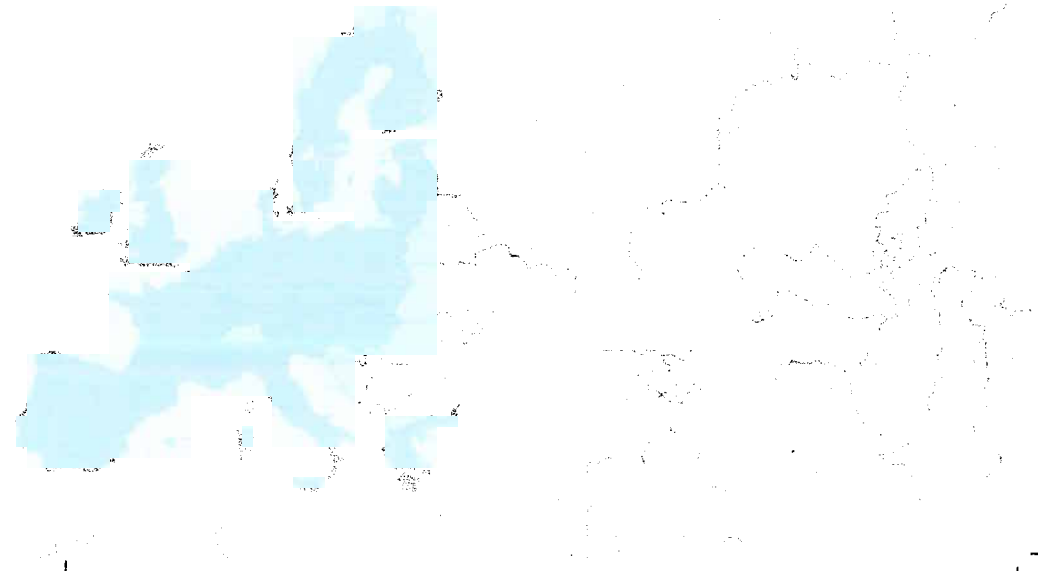
As regards the practical aspects, the difficulty of obtaining, within the period specified for comments, the announced texts or their summaries and the translation of these texts should be noted.

The European Commission has undertaken several actions aimed at ensuring the wider involvement of the EU's Member States and enterprises in the procedure. Publication of this brochure and the development of the website form part of this communication strategy which aims to allow full advantage to be taken of the opportunities offered by the notification procedure, to the benefit of the competitiveness of Community industries.



Annex I

Comparison of the notification
procedures established
by Directive 98/34/EC
and the TBT Agreement





1. Introduction

Within the Community legal system, Directive 98/34/EC (the Directive) represents a priority instrument at the service of the Internal Market. It provides for a notification system allowing Member States and the Commission to become acquainted with proposed national regulations and to check these to ensure that they are compatible with Community law, in particular with the EC Treaty principles on the free movement of goods, the free provision of services and the freedom of establishment (the last two aspects in relation to the notification of measures on Information Society services). As an instrument of transparency and control, the Directive is also valuable for identifying the harmonisation needs at Community level.

The Agreement on Technical Barriers to Trade (the Agreement) is the main international instrument adopted to date in the field of technical regulations. It aims to ensure that regulations, standards and testing and certification procedures do not create unnecessary obstacles to international trade. It provides for a notification procedure intended to allow all WTO Members to become acquainted with the technical regulations and conformity assessment procedures envisaged by other Members.

Even though these stem from the *same philosophy* (prevention of obstacles to trade), given the totally different legal contexts in which they sit the two notification procedures have *major differences*, particularly in terms of the efficiency of the control established and

the consequences of non-compliance with the obligations arising from these.

2. Definitions

• Technical regulations and conformity assessment procedures

The Directive provides for a notification system which requires Member States to immediately communicate to the Commission any draft *technical regulation* (Article 8). The Agreement provides for a notification system which requires Members to the Agreement to announce proposed *technical regulations* (Article 2.9) and proposed *conformity assessment procedures* (Article 5.6).

The definitions of “technical regulation” in the Directive ⁽²⁶⁾ and of “technical regulation” and “conformity assessment procedure” in the Agreement ⁽²⁷⁾ are, at first sight, very similar. However, the “technical regulation” concept in the Directive is generally wider than that in the Agreement.

• Scope

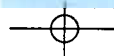
The Directive includes, in the “technical regulation” definition, rules on *Information Society services*, the observance of which is compulsory. The TBT Agreement, by contrast, applies only to technical regulations and conformity assessment procedures on products.

⁽²⁶⁾ According to Article 1(11) of Directive 98/34/EC, amended by Directive 98/48/EC, a “technical regulation” is “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...”

According to the same article, in paragraphs 3 and 4, a “technical specification” is “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, as well as production methods and processes relating to other products, where these have an effect on their characteristics”; “other requirements” are “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”.

⁽²⁷⁾ According to Annex 1 to the Agreement, a “technical regulation” is a “document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method”.

According to the same Annex, a “conformity assessment procedure” is “any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled”.



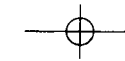
In addition, according to Article 1.5 of the Agreement, this does not apply to *sanitary and phytosanitary* measures as defined in Annex A to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). By contrast, the Directive applies to all technical regulations on all types of product, including the sanitary and phytosanitary measures excluded from the scope of the Agreement.

• Production methods and processes

The “technical regulation” concept in both the Directive and Agreement covers production methods and processes for products.

However, the Directive makes a distinction between production methods and processes for agricultural products and products intended for human and animal consumption, and also medicinal products, and those applicable to other products. As regards the first category of products, the production methods and processes fall, *per se*, within the “technical specification” concept. However, as regards the other products, only production methods and processes which have an effect on the characteristics of the products fall within the definition of “technical specification” within the Directive.

The “technical regulation” concept in the Agreement covers any document which lays down product characteristics or their *related* processes and production methods. The question of whether this covers only production methods and processes which have an effect on product characteristics or all production methods and processes, regardless of their effect on the characteristics of the end product, is, however, much debated.



• Conformity assessment procedures

The “technical regulation” concept in the Directive covers conformity assessment procedures. The Directive does not contain a definition of “conformity assessment procedure”. The “Vademecum” to the Directive specifies that these must be understood as procedures implemented to assure the conformity of a product with the requirements established.

The “technical regulation” concept in the Agreement does not cover conformity assessment procedures. However, these procedures must also be announced under Article 5.6 of the Agreement. The definition of a conformity assessment procedure given by the Agreement is equivalent to that given in practice to the same concept in the Directive.

• Prohibition on manufacture, importation, marketing or use

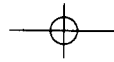
According to the Directive, “laws, regulations or administrative provisions of Member States ... prohibiting the *manufacture, importation, marketing or use of a product*” also constitute technical regulations.

The Agreement does not contain any explicit reference to measures prohibiting manufacture, importation, marketing or use. However, in the context of a case before the Dispute Settlement Body of the WTO involving French Decree No 96-1133 on the prohibition of asbestos, the Appellate Body concluded that a prohibition on a substance *as such* did not prescribe or impose any characteristics and therefore could not be regarded as a technical regulation⁽²⁸⁾. By contrast, still according to the Appellate Body, if a measure specifies that a certain substance must not be contained in an identifiable product, this measure may be regarded as a technical regulation⁽²⁹⁾.

⁽²⁸⁾ Appellate Body Report, *European Communities – measures affecting asbestos and asbestos-containing products*, WT/DS135/AB/R, adopted on 5 April 2001, para. 71.

⁽²⁹⁾ *Ibidem*, para. 75.





3. Criteria for notification

According to the Directive, any technical regulation on products must be announced. The only exceptions to the notification obligation are those set out in Article 10 ⁽²⁹⁾.

The Directive does not contain any “*de minimis*” rule. Accordingly, each technical regulation is notifiable, whatever its impact on intra-Community trade.

The Directive also considers that even a measure which *complies with relevant international standards*, where observance of this is compulsory, is liable to create obstacles to trade. According to Article 10, only provisions by means of which Member States fulfil the obligations arising out of an international agreement, which result in the adoption of common technical specifications within the Community, need not be announced.

On the other hand, the Agreement lays down the obligation to announce a technical regulation or conformity assessment procedure only if the following *two conditions* are met:

- there are *no relevant international standards* (for technical regulations) or *no relevant guides and recommendations* issued by an international standardising body (for conformity assessment procedures) or the technical content of a proposed technical regulation or proposed conformity assessment procedure is *not in accordance* with relevant international standards or relevant guides and recommendations issued by an international standardising body;

- the technical regulation or conformity assessment procedure may have a *significant effect on trade of other Members*.

4. Regulations issued by regional authorities

A technical regulation adopted by a regional authority must be announced under the Directive. According to the latter, to be qualified as a technical regulation, a regulation must be compulsory in nature for the marketing or use of a product in a Member State or *in a major part of this State*. A list of authorities subject to the notification obligation has been established ⁽³¹⁾.

The Agreement also provides for, in Articles 3 and 7, the announcement of technical regulations and conformity assessment procedures of local governments on the level *directly below that of central government*.

5. Procedures

• Intervals

The Directive lays down, in Article 9, *very strict intervals* between the communication of a draft technical regulation and its adoption. The initial 3-month interval may be extended to 6 months if a Member State or the Commission issues a detailed opinion. The interval is extended to 12 months if the Commission announces its intention to propose or adopt a directive, regulation or decision or announces its finding that the draft technical regulation concerns a matter which is covered by a proposal for a directive, regulation or decision, and to 18 months if the Council adopts a common position.

⁽²⁹⁾ Under Article 10(1) of the Directive: “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 ..., - fulfil the obligations arising out of international agreements which result in the adoption of common technical specifications ..., - make use of safeguard clauses provided for in binding Community acts, - apply Article 8(1) of Directive 92/59/EEC, - 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 1.1 of Article 1, in accordance with a Commission request, with a view to removing an obstacle to trade ...”

⁽³¹⁾ OJ N° C 23, 27.1.2000, p. 3.



The Directive does not stipulate *any interval between the adoption of a technical regulation and its entry into force*. The only provision in this respect is contained in the third subparagraph of Article 8(1) of the Directive which lays down the obligation for renotification when the draft technical regulation undergoes substantial changes, such as a shortening of the timetable originally envisaged for implementation.

The Agreement lays down, in Articles 2.9.4 and 5.6.4, that a *reasonable time* must be allowed for other Members to make comments and, in Articles 2.12 and 5.9, that Members shall allow a *reasonable interval* between the publication of technical regulations or requirements concerning conformity assessment procedures and their entry into force.

The TBT Committee has recommended allowing a minimum period of 60 days for comments and has encouraged the extension of this period to 90 days. The interval between the publication of a text and its entry into force should be 6 months.

• Reactions

Under the Directive, Member States and the Commission may issue reactions to announced drafts in the form of *comments* and *detailed opinions*. Comments are sent when the announced draft, although in accordance with Community law, raises interpretation issues or needs to be clarified in terms of its methods of implementation.

Detailed opinions are sent when the draft is incompatible with the principles of the EC Treaty on the free movement of goods (or services) or when it infringes a Community harmonisation directive, regulation or decision. The issuing of a detailed opinion leads to an extension of the standstill period and also imposes an obligation on the Member State in question to report to the Commission on the follow-up it intends to give to this opinion.

The Directive also imposes the obligation on Member States to *communicate the definitive texts*. This allows the Commission and other



Member States to check whether the notifying State has taken into account the reactions received during the procedure.

Under the Agreement, Members may only issue *comments* on notified drafts and request a discussion on these comments. The notifying Member must *take account* of the comments received and the results of discussions.

The Agreement does *not lay down an obligation to communicate the definitive texts*. However, it does stipulate that Members shall publish or otherwise make available technical regulations and conformity assessment procedures adopted.

• Urgency

The Directive and Agreement both lay down special procedures for urgent situations.

The Directive (Article 9.7) allows a technical regulation to be adopted only after notification of the draft and invocation of the urgency procedure. The Commission must give an opinion on this. In a case of urgency, the standstill periods fixed in Article 9 of the Directive do not apply.

Depending on the urgency, the Agreement allows, in Articles 2.10 and 5.7, whichever steps of the notification procedure listed in Articles 2.9 and 5.6 to be omitted as necessary.

The grounds for invoking the urgency procedure are similar. However, the Directive seems stricter as it specifies that Member States may invoke the urgency procedure only in the event of *serious and unforeseeable* circumstances.

6. Consequence of non-compliance with obligations

In accordance with the case-law of the Court of Justice ⁽¹²⁾, non-compliance with the notification obligation and also non-compliance with the obligation to respect the standstill periods laid down

⁽¹²⁾ Case C-194/94 *CIA Security International SA v Signalson SA and Securitel SPRL* [1996] ECR I-2201 and Case C-443/98 *Unilever Italia SpA v Central Food SpA* [2000] ECR I-7535.



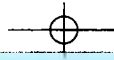
Annex I — Comparison of the notification procedures established by Directive 98/34/EC and the TBT Agreement

by the Directive lead to *the unenforceability* of the technical regulation in question.

Non-compliance with the notification obligation in the Agreement comes under the international responsibility of the WTO Member. How-

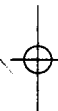
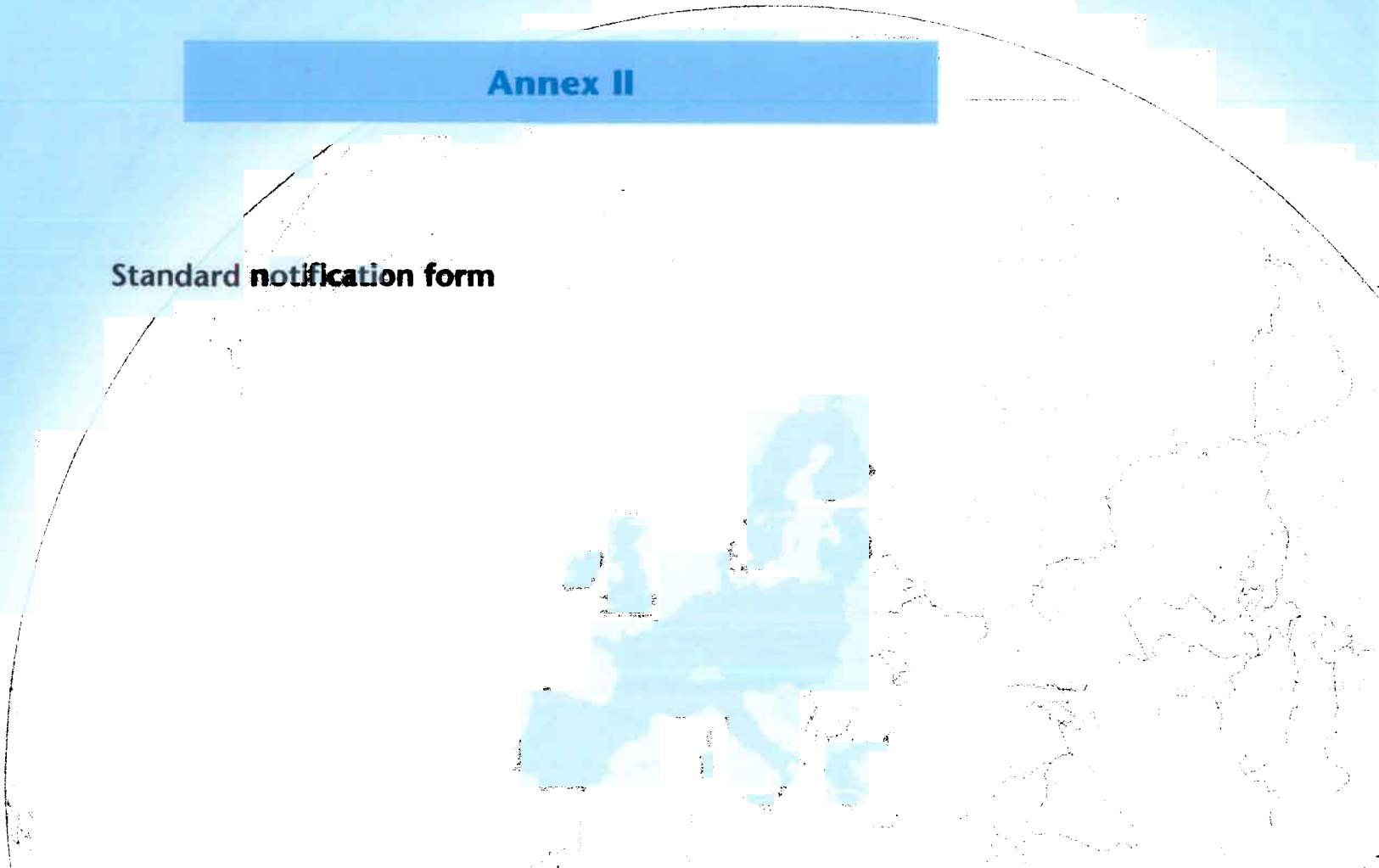
ever, no panel has been requested to form to date solely on the grounds of non-compliance with the notification obligation under the Agreement. Nevertheless, notification procedures allow the comments of WTO Members to be taken into account, and thus disputes over the content of technical regulations may be avoided.





Annex II

Standard notification form





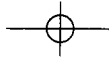
Annex II — Standard notification form

**World Trade
Organization**
**G/TBT/N/
(00-0000)**
Committee on Technical Barriers to Trade
Notification ⁽³⁾

The following notification is being circulated in accordance with Article 10.6.

1. Member to Agreement notifying: If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:
3. Notified under Article 2.9.2 [], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):
5. Title, number of pages and language(s) of the notified document:
6. Description of content:
7. Objective and rationale, including the nature of urgent problems where applicable:
8. Relevant documents:
9. Proposed date of adoption: Proposed date of entry into force:
10. Final date for comments:
11. Texts available from: National enquiry point [] or address, telephone and fax numbers, e-mail and web-site addresses, if available, of the other body:

⁽³⁾ Forms must be completed in English, Spanish or French.

European Commission

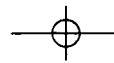
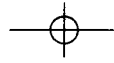
**An instrument of market openness and good regulatory practice
The notification procedure created by the Agreement on Technical Barriers to Trade**

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The notification procedure for proposed technical regulations and conformity assessment procedures established by the Agreement on Technical Barriers to Trade aims to prevent the creation of unnecessary technical obstacles to international trade.

By detailing the objectives, content and scope of this procedure, this publication highlights the importance of the participation of all interested parties and particularly Community enterprises in this instrument of transparency, dialogue and cooperation at international level.

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