# COMMISSION OF THE EUROPEAN COMMUNITIES

COM(92)141 final - SYN 410 Brussels, 15 April 1992

Proposal for a

# COUNCIL DIRECTIVE

on the approximation of the laws, regulations and administrative provisions of the

of the
Member States
relating to
RECREATIONAL CRAFT

(presented by the Commission)

# I. Explanatory memorandum

#### 1. Background and origin of the proposal

Between 1970 and 1982, the Commission attempted to draw up a draft directive (doc. III/308/81) for the approximation of legislation on the hulls of recreational craft. However, this attempt was abandoned owing to divergent views on the construction principles.

The situation in the Member States is characterized by the following:

- regulations: technical rules based on national legislation involving type-approval in France and Italy result in obstacles to trade and higher production costs (only the largest undertakings persisted in trying to overcome these difficulties);
- <u>standards</u>: in other Member States, national standards not backed by national legislation create no obstacles to trade but, since they are not obligatory, they present no guarantee of protection against the production and placing on the market of potentially dangerous products.

In view of the potential benefits of the single market and the advantages of improving the safety of recreational craft and their components, the representatives of the European industry organized in ICOMIA (International Council of Marine Industry Associations) asked the Commission to put to the Council a directive based on Article 100a of the Treaty on the safety of recreational craft.

The background to this request was in particular the work begun in the 1980s on a large number of standards (about 50) in the framework of the  ${\rm ISO}^{(*)}$  (TC 188), in which industry from the Member States, the EFTA countries and the USA in particular was involved.

As the other means of harmonization did not appear suitable, the Commission has prepared a draft directive in close collaboration with industry, particularly in respect of the essential requirements, and has consulted the national administrations and professional circles concerned.

<sup>(\*).</sup> International Organization for Standardization

#### 2. Consultations

National experts, representatives of the industry, the boat users (European Boating Association) and classification societies were consulted in depth.

The proposal was on the whole welcomed by all the experts representing the above groups. It has been supplemented and amended following the three consultation meetings held in 1990. On a general level, the preparatory work produced a consensus on the value of this intitiative.

#### 3. Risks covered and essential requirements

Apart from two essential requirements concerning identification of the craft and the manufacturer, the risks covered and the essential requirements have been grouped as follows:

- risks relating to use, in particular at sea
  - falling overboard
  - \* structure, stability, buoyancy
  - openings, drainage
  - \* capacity
  - \* compartmentalization
  - \* rescue, towing, mooring
- performance
- safety of the propulsion system
- safety of the fuel system
- safety of the electrical system
- safety of the steering system
- fire protection, in particular gas appliances
- lights.

#### 4. Implementation

It is estimated that it will take about two years from adoption of the directive by the Council before all the standards necessary for its application are available; the planned implementation date is therefore 1 July 1995.

Proposal for a

Council Directive

of

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#### RECREATIONAL CRAFT

The Council of the European Communities,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100A thereof,

Having regard to the proposal from the Commission, in cooperation with the European Parliament.

Having regard to the opinion of the Economic and Social Committee,

Having regard to the Council's decision of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in technical harmonization directives<sup>(1)</sup>

Whereas the laws, regulations and administrative provisions in force in the various Members States relating to the safety characteristics of recreational craft differ in scope and content, whereas such disparities are liable to create barriers to trade and unequal conditions of competition within the internal market.

<sup>(1)</sup> OJ L 380, 31.12.1990, p. 13

Whereas the minimum length of recreational craft should be 2.5 m, since craft under this length cannot be considered as recreational craft; whereas the maximum length of 24 m for recreational craft is derived from  $IMO^{(2)}$  conventions and  $ISO^{(3)}$  standards:

Whereas the removal of technical barriers in the field of recreational craft and their components, to the extent that they cannot be removed by mutual recognition of equivalence among all the Member States, should follow the new approach set out in the Council Resolution of 7 May 1985 which calls for the definition of essential requirements on safety and other aspects which are important for the general well-being; whereas paragraph 3 of article 100 A foresees that, in its proposals, concerning health, safety, environmental protection and consumer protection, the Commission will take as a base a high level of protection, whereas the essential requirements constitute the criteria with which recreational craft and their components as referred to in Annex II when separate and when installed must comply:

Whereas, as a basis for the harmonized standards or other technical specification at European level, concrete form must be given to the essential requirements at a technical level;

Whereas these essential requirements provide the basis for the preparation of harmonized standards at European level on recreational craft and their components; whereas, to remove technical barriers to trade and to ensure market transparency, harmonized standards should be established;

Whereas recreational craft and components thereof are presumed to conform to the essential requirements of the Directive if they conform to harmonized standards:

<sup>(2)</sup> International Maritime Organization

<sup>(3)</sup> International Organization for Standardization /u1/gaboh/LG/NO/4002-EN - 18 Morch, 1992.

Whereas recreational craft considered fit for use are easily recognizable by the EC mark; whereas they must be allowed free movement and free taking into use for their intended purpose throughout the Community;

Whereas the responsibility of the Member States for safety, and other matters covered by the essential requirements on their territory should be recognized in a safeguard clause providing for appropriate Community protective measures;

Whereas the Standing Committee set up under Council Directive 83/189 EEC<sup>(4)</sup> of March 1983, as last amended by Directive 88/182 EEC<sup>(5)</sup> constitues an appropriate forum for the delivery of opinions on matters referred to in this directive;

<sup>(4)</sup> OJ L 109, 26.4.1983, p. 8.

<sup>(5)</sup> OJ L 89, 26.3.1988, p. 75.

Whereas compliance with the technical requirements must be monitored in order to ensure adequate user and third-party safety; whereas existing monitoring procedures may differ appreciably from one Member State to another; whereas, in order to avoid numerous checks which merely impede the free movement of boats and of their components, provision should be made for the mutual recognition of the inspections conducted by the Member States; whereas, in order to facilitate such recognition, it is necessary to lay down harmonized Community procedure and to harmonize the criteria to be taken into account in selecting the bodies responsible for examination, monitoring and verification;

Whereas the internal production control (module A) including the written declaration of conformity by the manufacturer, the establishment of the technical documentation and the inspections by the relevant national authorities seems to be adequate for the assesment of conformity of boats under 6 m length of the hull, whereas this procedure should be reinforced by one or two test or equivalent calculation on boat(s) representative of the production of a manufacturer when it reaches a certain number of units during a certain period, whereas the same procedure should apply to boats between 6 and 12 m length of the hull, whereas the assesment of conformity of boats from 12 to 24 m length of the hull and of components should be left open between several given modules;

Whereas the internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

HAS ADOPTED THIS DIRECTIVE :

#### CHAPTER 1

Scope, marketing and free movement

#### Article 1

- 1. This Directive applies to recreational craft of all types, regardless of the means of propulsion, from 2.5 to 24 m length of the hull, measured according to the appropriate harmonized standard. This directive shall also apply to components referred to in Annex II when separate and when installed.
- 2. A recreational craft shall mean any boat intended for recreational purposes, within the scope of this Directive. This include those used for charter or for recreational boating training.
- 3. The following are excluded from the scope of this directive:
  - craft intended solely for racing including rowing racing boats and so labelled by the manufacturer,
  - canoes and kayaks,
  - sailing surfboards,
  - powered surfboards, personal watercraft and other similar craft,
  - individual replicas of historic craft so labelled by the manufacturer,
  - experimental craft,
  - craft with crew and carrying passengers for commercial purposes,
  - submersibles.
  - air cushion vehicles,
  - hydrofoils.

#### Article 2

- 1. Member States shall take all necessary measures to ensure that the products referred to in Article 1 may be placed on the market and put into use only if they do not endanger the safety of persons and property when they are taken into use for their intended purpose.
- 2. The provisions of the present directive do not exclude the possibility that the Council adopts others provisions concerning the navigation on certain waters, provided this does not lead to modifications to the construction of craft, as foreseen by the present directive.

#### Article 3

The products referred to in Article 1 shall meet the essential safety requirements as in Annex 1.

#### Article 4

- 1. Member States shall not prohibit, restrict or impede the placing on the market or puting into use in their territory of the products referred to in Article 1 which meet the provisions of this Directive.
- 2. Member States shall not prohibit, restrict or impede the placing on the market or puting into use of components as referred to in Annex II when separate and when installed which are intended, according to the declaration of the manufacturer or his authorized representative established in the Community referred to in Annex III, to be incorporated in recreational craft referred to in Article 1.

#### Article 5

Member States shall presume that the products referred to in Article 1, which meet the harmonized standards, reference to which has been published in the Official Journal of the European Communities comply with the essential requirements referred to in Article 3.

Member States shall publish the references of the national standards transposing the harmonized standards.

#### Article 6

Where a Member State or the Commission is of the opinion that the harmonized standards referred to in Article 5 do not fully meet the essential requirements referred to in Article 3, the Commission or the Member State shall notify the committee, set up under the Directive 83/189 EEC setting out its reasons. The committee shall deliver an urgent opinion.

In the light of the opinion of the committee, the Commission shall inform Member States if the standards concerned should be withdrawn from the publications referred to in Article 5.

#### Article 7

1. Where a Member State ascertains that recreational craft referred to in Article 1 bearing the CE mark referred to in Annex IV or constituent products thereof and used for their proper use may endanger the safety of persons and property, it shall take all necessary measures to withdraw them from the market, prohibit use thereof and restrict free movement thereof.

The Member State shall immediately inform the Commission of any such measure, indicating the reasons for its decision and, in particular, where the non-conformity is due to:

- (a) failure to comply with the essential requirements referred to in Article 3:
- (b) incorrect application of the standards referred to in Article 5, in so far it is claimed that the standards have been applied;
- (c) shortcomings in the standards referred to in Article 5 themselves

These measures are applicable until the entry into force of the act provided for in paragraph 2.

2. The measures adopted under paragraph 1 shall be confirmed and extended, possibly amended, to the whole Community or repealed by an act of the Commission.

However, where the measures were adopted under paragraph 1 on the ground of a shortcoming in the standards provided for in Article 5, the procedure laid down in Article 6 is applicable.

- 3. Where a non-complying component referred to in Annex II or craft bears the EC mark, the competent Member State shall take appropriate action against whomsoever has affixed the mark and shall inform the Commission and the other Member States thereof.
- 4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

#### CHAPTER II

#### Conformity assesment

#### Article 8

Before producing and placing recreational craft under the scope of this directive or their components on the market, the manufacturer or his authorized representative established in the Community shall fulfill the following procedures:

- for boats of less than 6 m lengh of the hull and a total production by a manufacturer of 20 boats or less per year: the internal production control (module A), referred to in annex V
- for boats of less than 6 m length of the hull and a total production by a manufacturer of more than 20 boats per year,

and for all boats from 6 to 12 m lengh of the hull: the internal production control plus test (module Aa, option 1) referred to in annex VI.

- for all boats from 12 to 24 m lengh of the hull and for components referred to in Annex II when separate and when installed the following modules(s):
- <u>Either</u>: The EC type examination (module B) referred to in annex VII followed by one of the following modules:
  - conformity to type (module C) referred to in annex VIII or
  - production quality assurance (module D) referred to in annex
     IX

or

- product verification (module F) referred to in annex X

 $\underline{Or}$ : one of the modules G or H:

G: unit verification referred to in annex XI

H: full quality assurance referred to in annex

XII

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#### Article 9

- 1. Each Member State shall notify to the Commission, which informs the Member States, the bodies responsible for the execution of the conformity assessment in the conformity assessment procedures referred to in article 8. For information purposes, the Commission shall publish in the Official Journal of the European Communities and keep up to date a list giving the names of these bodies and their distinguishing number.
- Member States shall apply the criteria laid down in Annex XIV in assessing the bodies to be indicated in such notification. Bodies meeting the assessment criteria laid down in the relevant harmonized standards shall be presumed to fulfil those criteria;
- 3. A Member State shall withdraw its approval from such a body if it established that the latter no longer satisfies the criteria referred to in Annex XIV. It shall inform the Commission and the other Member States of its action forthwith.

# CHAPTER III

#### CE Mark

# Article 10

- 1. The CE mark of conformity with the provisions of this Directive and as set out in Annex IV shall be affixed or marked on each component as referred to in Annex II or boat as to be visible, legible and indelible.
- 2. Marks or inscriptions which could be confused with the CE mark as far as its meaning or graphism are concerned may not be affixed to components or boats under this directive.

#### CHAPTER IV

#### Final provisions

#### Article 11

Detailed grounds shall be given for any decision taken pursuant to this Directive leading to a restriction on the marketing and use of recreational craft. The party concerned shall be informed of the decision as soon as possible together with the means of redress available under the laws in force in the Member State concerned and the periods within which appeals must be lodged.

#### Article 12

The Commission shall take the necessary measures to ensure that data affecting all pertinent decisions concerning the management of this Directive are made available.

#### Article 13

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with the provisions of this Directive at the latest on the 31st of December 1994. They shall forthwith inform the Commission thereof.

They shall apply the above mentionned laws, regulations and administrative provisions, on the 1st of July 1995.

In adopting these provisions, the Member States will give reference to the present directive or make such a reference within their official publications. The way this reference is made, is a matter for the Member States.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.

# Article 14

This Directive is addressed to the Member States.

Done at Brussels, For the Council

The President

#### Annex I

# ESSENTIAL SAFETY REQUIREMENTS FOR THE DESIGN AND CONSTRUCTION

#### OF

#### RECREATIONAL CRAFT

#### 1. GENERAL

# 1.1 Boat usage group:

- A. Suitable for extended voyages on craft largely self-sufficient.
- B. Suitable for offshore and coastal voyages;
- C. Suitable for short voyages in coastal waters, bays, estuaries, large rivers and large lakes.
- D. Suitable for voyages on small river, small lakes and canals;

# 1.2 <u>Definitions</u>:

Rowing boat : a rowing boat is a craft whose primary means of propulsion are oars,

Sailboat: a sailboat is a craft whose primary means of propulsion is sail;

Motorboat: a motorboat is a craft whose primary means of propulsion is engine power.

#### 2. GENERAL REQUIREMENTS

#### 2.1. Boat identification

Each craft shall be marked with a Hull Identification Number including the following information:

- manufacturer's code
- country of manufacture
- unique serial number
- month and year of production
- model year.

The detail requirements shall be in accordance with the relevant harmonized standard.

#### 2.2. Builder's plate

Each craft shall carry a permanently affixed plate mounted separately from the boat Hull Identification Number containing at least the following information:

- manufacturer's name
- boat usage group according to sect. 1.1
- maximum load
- number of persons which the boat is designed to carry when underway.

Craft fitted with or intended to be used with outboard engine(s) shall display the additional information:

- maximum rated engine power for which the boat is designed.

#### 2.3. Protection from falling overboard and means of recovery

Depending on the boat usage group

- 2.3.1 Working surfaces, toerails, safety rails and grabrails shall be designed to minimize the risks of falling overboard and
- 2.3.2 the boat shall be designed or equipped to enable reboarding.
- 2.4. Visibility from the main steering position
- 2.4.1 For motor boats, the main steering position shall give the operator, under the normal conditions of speed and load, good direct visibility forward and to the side, whilst operating throttle, gear, and steering controls.
- 2.4.2 Provision shall also be made for reasonable visibility astern.

#### 2.5. Owner's manual

All craft shall be provided with an owner's manual in the language(s) of the country in which it is marketed. This owner's manual should draw particular attention to the risks of fire and flooding.

# 3. INTEGRITY, STRUCTURAL REQUIREMENTS

#### 3.1. <u>Structure</u>

The choice and combinaison of materials and its construction shall ensure that the craft is strong enough in all respects considering boat usage group according to section 1.1., and boat definition according to section 1.2, for its intended purpose and intended loadings.

#### 3.2. Stability

The craft shall have sufficient stability considering its boat usage group according to sect 1.1, boat definition according to section 1.2, and its intended purpose and its intended loadings.

#### 3.3 Buoyancy

The craft shall be constructed to ensure that it has buoyancy characteristics appropriate to its size and considering its boat usage group according to section 1.1, boat definition according to section 1.2, and its intended purpose and its intended loadings.

#### 3.4. Openings in hull, deck and superstructure

Openings in hull, deck(s) and superstructure shall not impair the structural integrity of the craft or its weathertight integrity.

Windows, portlights, doors and hatches shall withstand the water pressure likely to be encountered in their specific position, as well as pointloads applied by the weight of persons moving on deck;

Through hull fittings below its static flotation plane, designed to allow water passage through the hull, shall be fitted with shut-off means which shall be readily accessible, except where a pipe of a strength equivalent to that of the hull is fitted and extends above static flotation plane.

#### 3.5. Cockpits and wells

Depending on boat usage group according to paragraph 1.1, the boat shall either:

- be self-draining or
- have buoyant elements according to paragraph 3.3 or
- have other means of keeping the water out of the boat interior.

#### 3.6. Removal of water

All craft suceptible to flooding shall be fitted with a means of removing water from the craft.

#### 3.7. Carrying capacity

The maximum load for which the boat is designed and the maximum number of persons on board when underway, for which the boat is designed, as marked on the builder's plate, shall be set according to the stability, section 3.2, buoyancy, section 3.3 and shall take into account the boat usage group according to section 1.1 and its definition according to section 1.2.

#### 3.8. Compartmentation

All boats should be compartmented according to their usage group, paying special attention to collision bulkheads.

# 3.9. <u>Liferaft stowage</u>

All boats should be provided with a stowage for a liferaft if the usage group demands it. The stowage shall be easily accessible at all times, including the case of a capsized multihull.

#### 3.10. Escape hatches for multihulls

All habitable multihull craft shall be fitted with escape hatches than can allow escape from a capsized multihull craft.

# 3.11. Mooring and towing

All craft, taking into account their usage group and their characteristics should be provided with arrangements for stowage and usage of mooring ropes or cables.

All craft shall be fitted with a means of towing the craft.

#### 4. PERFORMANCE

The manufacturer shall ensure that the boat is capable of being properly handled with the most powerful engine for which the boat is designed and constructed. The engine power shall be in accordance with the appropriate harmonized standard.

#### 5. INSTALLATION REQUIREMENTS

#### 5.1. <u>Propulsion system</u>

#### 5.1.1 General

All inboard mounted engines shall be placed within an enclosure separated from living quarters. The craft shall be so constructed as to minimise hazard in the living quarters from fumes, heat, noise and vibrations.

Engine parts and accessories that require frequent inspection and/or servicing shall be readily accessible.

The insulating materials inside engine spaces prevent the fire from spreading.

#### 5.1.2 Ventilation

The engine compartment shall be suitably ventilated, depending on the equipment inside and considering both the temperature requirements and the air consumption of the engine(s), as specified by the engine manufacturer.

#### 5.1.3 Exposed parts

Unless the engine(s) is protected by a cover or its own enclosure, exposed moving or hot parts of the engine shall be effectively shielded

# 5.1.4 Outboard starting

All boats with outboard engines shall have a device to prevent starting the engine in gear, except

- a) when the engine produces less than  $\underline{500\ N}$  of static thrust or a power of x kw
- b) when the engine has a throttle limiting device to limit thrust to  $\underline{500 \text{ N}}$  or a power of x kw at the time of starting the engine.

#### 5.2 Fuel systems

#### 5.2.1 General

The filling, storage, venting and fuel supply arrangements and installations shall be designed and installed so as to minimize the risk of fire and explosion.

# 5.2.2 Fuel tanks

Fuel tanks shall be separated or protected from any source of significant heat. The material the tanks are made of and their method of construction shall be according to their capacity and the type of fuel.

Unless fully isolated from the engine compartment and any source of ignition, all tank spaces shall be ventilated.

Liquid fuel with a flash point below 55°C shall be kept in tanks which do not form part of the hull and are

- a) separate from the engine compartment unless all electrical components contained within it are ignition-protected,
- b) separate from living quarters.

Liquid fuel with a flash point equal to or above 55°C may be kept in tanks that are integral with the hull.

### 5.3 <u>Electrical system</u>

#### 5.3.1 General

Electrical systems shall be designed and installed so as to ensure proper operation of the craft under normal conditions of use and shall be such as to minimize risk of fire and electric shock. Attention shall be paid to the provision of overload and short circuit protection of all circuits, except engine starting circuits, supplied from batteries.

Adequate ventilation shall be provided to minimise the accumulation of gas which might be emitted from batteries.

#### 5.4 Steering system

#### 5.4.1 General

Steering systems shall be designed, constructed and installed in order to allow the transmission of steering loads under normal operating conditions.

#### 5.4.2 Emergency arrangements

Single-engined inboard boats with remote-controlled rudder steering systems and sailboats without auxiliary engines shall be provided with emergency means of steering the craft at reduced speed.

#### 5.5 Gas system

Gas systems for domestic use shall be of the vapour withdrawal type and shall be designed and installed so as to avoid leaks and the risk of explosion. Materials and components shall be suitable for the specific gas used and designed to withstand the stresses and exposures found in marine environment.

Each appliance shall be equipped with a flame failure device effective on all burners. Each gas-consuming appliance must be supplied by a separate branch of the distribution system, and each branch must be controlled by a separate closing device.

Gas bottles shall be stored in an enclosure separated from the living quarters, and ventilated to the outside so that the gas drains overboard unless the bottle contains less than 3 kg of liquid gas and is directly attached to the appliance with no weight bearing on the gas connection. The system shall be tested after installation.

#### 5.6 Fire protection

#### 5.6.1 General

The type of equipment installed and the layout of the craft shall take account of the risk and spread of fire.

Attention shall be paid to the surroudings of open flame devices.

#### 5.6.2 Fire-fighting equipment

craft shall be supplied with fire-fighting equipment suitable for their size and boat usage group. Number, size and distribution of extinguishers shall take account of the type and number of the propulsion units, the size of engine spaces, and any equipment which may present a fire risk.

Where fitted, portable fire extinguishers shall be readily accessible and one shall be so positioned that it can easily be reached from the main steering position of the boat.

#### 5.7. Navigation lights

Provisions shall be made for the fitting of navigation lights when required.

#### ANNEX II

#### COMPONENTS

- 1. Ignition protection for inboard and sterndrive engines.
- 2. Start-in-gear protection for outboard engines.
- 3. Steering wheels, steering mechanisms and cable assemblies.
- 4 Fuel tanks and fuel hoses.
- 5. Ignition-protected components sited in engine and fuel spaces when fuel of a flash point less than 55 degrees centigrade is used.
- 6. Prefabricated hatches and portlights.

# DECLARATION OF THE MANUFACTURER OR HIS AUTHORIZED REPRESENTATIVE ESTABLISHED IN THE COMMUNITY (ARTICLE 4(2).

The declaration of the manufacturer referred to in Aticle 4(2) shall contain the following:

- name and address of the manufacturer or his authorized representative established in the Community;
- description of the components as referred to in Annex II;
- statement that the sale of the recreational craft in which the components are to be incorporated is prohibited until the recreational craft has been declared to conform to the provisions of the Directive;
- name and address of the person signing.

#### ANNEX IV

# CE MARK OF CONFORMITY

The CE mark of conformity consists of the initials "CE" as shown below :

# $\mathbf{CE}$

These initials shall consist of a semi-circular letters. The length of the bar inside the "E" shall be at least 80 % of the outer radius of the semicircle.

The thickness of the letters must be at least one fifth of the height of the CE mark.

The various elements of the CE mark must have about the same vertical dimension, which shall not be less than 5 mm.

The CE mark is followed by the identification number of the notified body, if it intervenes in the control of production, as well as by the last two figures of the year that the CE mark is affixed.

Annex V

# INTERNAL PRODUCTION CONTROL (module A )

- 1. The manufacturer or his authorized representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the products concerned satisfy the requirements of the Directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity.
- 2. The manufacturer shall establish the technical documentation described in paragraph 3 and he or his authorized representative established within the Community shall keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities for inspection purposes.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsability of the person who places the product on the Community market.

- 3. Technical documentation shall enable the conformity of the product with the requirements of the Directive to be assessed. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the product. (see annex XIII).
- 4. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity with the technical documentation.
- 5. The manufacturer shall take all measures necessary in order that the manufacturing process shall ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the Directive that apply to them.

# INTERNAL PRODUCTION CONTROL, PLUS TESTS (module Aa,option 1)

1. This module consists of module A, as referred in annex V, plus the following supplementary requirements:

On one or several boats representing the production of the manufacturer one or more of the following tests, equivalent calculation or control shall be carried out by the manufacturer or on his behalf:

- test of stability according to point 3.2 of the Essential Requirements,
- test of buoyancy characteristics according to point 3.3 of the Essential Requirements.

These tests or calculations or control shall be carried out on the responsability of a notified body chosen by the manufacturer. On the responsability of the notified body, the manufacturer shall affix the former's distinguish number during the manufacturing process.

#### Annex VII

#### EC TYPE EXAMINATION (module B)

- A notified body ascertains and attests that a specimen, representative of the production envisaged, meets the provisions of the Directive that apply to it.
- The application for the EC type-examination shall be lodged by the manufacturer or his authorized representative established within the Community with a notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition;
- a written declaration that the same application has not been lodged with any other notified body;
- the technical documentation, as described in point 3.

The applicant shall place at the disposal of the notified body a specimen, representative of the production envisaged and hereinafter called "type" (\*).

The notified body may request further specimens if needed for carrying out the test programme.

<sup>(\*)</sup> A type may cover several versions of the product provided that the differences between the versions do not affect the level of safety and the other requirements concerning the performance of the product.

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3. The technical documentation shall enable the conformity of the product with the requirements of the Directive to be assessed. It shall, as far as relevant for such assessment, cover the design, manufacture and functionning of the product (see annex XIII).

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- 4. The notified body shall:
- 4.1. examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as the components which have been designed without applying the relevant provisions of those standards;
- 4.2. perform or have performed the appropriate examinations and necessary tests to check whether, where the standards referred to in Article 5 have not been applied, the solutions adopted by the manufacturer meet the Essential Requirements of the Directive;
- 4.3. perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;
- 4.4. agree with the applicant the location where the examinations and necessary tests shall be carried out.
- 5. Where the type meets the provisions of the Directive, the notified body shall issue an EC type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination, conditions for its validity and the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

If the manufacturer is denied a type certification, the notified body shall provide detailed reasons for such denial.

- 6. The applicant shall inform the notified body that holds the technical documentation concerning the EC types examination certificate of all modifications to the approved product which must receive additional approval where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC type-examination certificate.
- 7. Each notified body shall communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.
- 8. The other notified bodies may receive copies of the EC type—examination certificates and/or their additions. The annexes to the certificates shall be kept at the disposal of the other notified bodies.
- 9. The manufacturer or his authorized representative shall keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least ten years after the last product has been manufactured.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.

# CONFORMITY TO TYPE (module C)

- 1. The manufacturer or his authorized representative established within the Community ensures and declares that the products concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of the Directive that applies to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity.
- 2. The manufacturer shall take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured products with the type as described in the EC type-examination certificate and with the requirements of the Directive that apply to them;
- 3. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least ten years after the last product has been manufactured.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market (see annex XIII).

#### Annex IX

## PRODUCTION QUALITY ASSURANCE (module D)

- 1. The manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of the Directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity. The CE mark shall be accompanied by the distinguishing number of the notified body responsible for the monitoring as specified in point 4.
- The manufacturer shall operate an approved quality system for production, final product inspection and testing as specified in paragraph 3 and shall be subject to monitoring as specified in point

## 3. Quality system

3.1 The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the products concerned.

The application shall include:

- all relevant information for the product category envisaged;
- the documentation concerning the quality system;
- the technical documentation of the approved type (see annex XIII) and a copy to the EC type-examination certificate.

3.2 The quality system shall ensure compliance of the products with the type as described in the EC type-examination certificate and with the requirements of the Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plan, manuals and records.

It shall contain in particular an adequate description of

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality;
- the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out:
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;
- the means to monitor the achievement of the required product quality and the effective operation of the quality system.

3.3 The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard.

The auditing team shall have at least one member with experience of evaluation in the product technology concerned. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4 The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system;

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in prargraph 3.2 or whether a re-assessment is required.

It shall notify its decisions to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- 4. Surveillance under the responsibility of the notified body
- 4.1 The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2 The manufacturer shall allow the notified body entrance for inspection purposes to the locations of manufacture, inspection and testing, and storage and shall provide it with all necessary information in particular
  - the quality system documentation
  - the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
- 4.3 The notified body shall periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.
- 4.4 Additionally the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may carry out, or cause to be carried out, tests to verify that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.

- 5. The manufacturer shall, for a period ending at least ten years after the last product has been manufactured, keep at the disposal of the national authorities:
  - The documentation referred to in the second indent of point 3.1;
  - the updating referred to in the second paragraph of point 3.4;
  - the decision and reports from the notified body which are referred to in the final paragraph of point 3.4, point 4.3 and point 4.4.
- 6. Each notified body shall give the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

## PRODUCT VERIFICATION (module F)

- 1. This module describes the procedure whereby a manufacturer or his authorized representative established within the Community checks and attests that the products subject to the provisions of point 3 are in conformity with the type as described in the EC-type examination certificate and satisfy the requirements of the Directive that apply to them.
- 2. The manufacturer shall take all measures necessary in order that the manufacturing process ensures conformity of the products with the type as described in the EC- type examination certificate and with the requirements of the Directive that apply to them. He shall affix the CE mark to each product and shall draw up a declaration of conformity.
- 3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the product with the requirements of the Directive either by examination and testing of every product as specified in point 4 or by examination and testing of products on a statistical basis, as specified in point 5, at the choice of the manufacturer.
- 3.a. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least ten years after the last product has been manufactured.
- 4. Verification by examination and testing of every product
- 4.1. All products shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to verify their

conformity with the type as described in the EC-type examination certificate and the requirements of the Directive that apply to them.

- 4.2. The notified body shall affix or cause to be affixed, its distinguishing number to each approved product and draw up a written certificate of conformity relating to the tests carried out.
- 4.3. The manufacturer or his authorized representative shall ensure that

  he is able to supply the notified body's certificates of conformity
  on request.

#### 5. Statistical verification

- 5.1. The manufacturer shall present his products in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.
- 5.2. All products shall be available for verification in the form of homogeneous lots. A random sample shall be drawn from each lot. Products in a sample shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, shall be carried out to ensure their conformity with the requirements of the Directive which apply to them and to determine whether the lot is accepted or rejected.
- 5.3. The statistical procedure shall use the following elements:
  - the statistical method to be applied,
  - the sampling plan with its operational characteristics.
- 5.4. In the case of accepted lots, the notified body shall affix, or cause to be affixed, its distinguishing number to each product and shall draw up a written certificate of conformity relating to the tests carried out. All products in the lot may be put on the market except those products from the sample which were found not to be in conformity.

if a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent the putting on the market of that lot. In the event of frequent rejection of lots the notified body may suspend the statistical verification.

The manufacturer may, under the responsibility of the notified body, affix the latter's distinguishing number during the manufacturing process.

5.5. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

### Annex XI

## UNIT VERIFICATION (module G)

- 1. This module describes the procedure whereby the manufacturer ensures and declares that the product concerned, which has been issued with the certificate referred to in point 2, conforms to the requirements of the Directive that apply to it. The manufacturer shall affix the CE mark to the product and draw up a declaration of conformity.
- 2. The notified body shall examine the individual product and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, to ensure its conformity with the relevant requirements of the Directive.

The notifed body shall affix, or cause to be affixed, its distinguishing number on the approved product and shall draw up a certificate of conformity concerning the tests carried out.

3. The aim of the technical documentation is to enable conformity with the requirements of the Directive to be assessed and the design, manufacture and operation of the product to be understood (see Annex XIII).

## FULL QUALITY ASSURANCE (module H)

- 1. This module describes the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the products concerned satisfy the requirements of the Directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity. The CE mark shall be accompanied by the distinguishing number of the notified body responsible for the surveillance as specified in point 4.
- 2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing as specified in point 3 and shall be subject to surveillance as specified in point 4.
- 3. Quality system
- 3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body.

The application shall include:

- all relevant information for the product category envisaged
- the quality system's documentation.
- 3.2. The quality system shall ensure compliance of the products with the requirements of the Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of

the quality policies and procedures such as quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to design and product quality.
- the technical design specifications, including standards, that will be applied and, where the standards referred to in Article 5 will not be applied in full, the means that will be used to ensure that the essential requirements of the Directive that apply to the products will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc...,
- the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonized standard (EN 29001)

The auditing team shall have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure shall include an assessment visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2. or whether a re-assessment is required.

It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

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## 4. EC surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of design, manufacture, inspection and testing, and storage, and shall provide it with all necessary information, in particular
  - the quality system documentation;
  - the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc...;
  - the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc....
- 4.3. The notified body shall periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.
- 4.4. Additionally the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it shall provide the manufacturer with a visit report and, if a test has been carried out, with a test report.
- 5. The manufacturer shall, for a period ending at least ten years after the last product has been manufactured, keep at the disposal of the national authorities:
  - the documentation referred to in the second indent of the second subparagraph of point 3.1.;
  - the updating referred to in the second subparagraph of point 3.4.;
  - the decisions and reports from the notified body which are referred to in the final subparagraph of point 3.4., point 4.3. and point 4.4.

6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

## ANNEX XIII

## TECHNICAL DOCUMENTATION SUPPLIED BY THE MANUFACTURER

The technical documentation referred to in Annexes, V, VII, VIII, IX, XI, must comprise all relevant data or means used by the manufacturer to ensure that components or craft comply with the essential requirements relating to them.

The technical documentation shall enable understanding of the design, manufacture and operation of the product, and shall enable assessment of conformity with the requirements of this directive.

The documentation shall contain so far as relevant for assessment :

- a general description of the type;
- conceptual design and manufacturing drawings and schemes of components,
   sub-assembiles, circuits; etc
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product;
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to fulfil the essential requirements when the standards referred to in Article 5 have not been applied;
- . results of design calculations made, examinations carried out, etc.
  - test reports, or calculations namely on stability according to point 3.2 of the Essential Requirements and on buoyancy according to point 3.3 of the Essential Requirements.

## MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES

- 1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of boat or components which they inspect, nor the authorized representative of any of these parties. They shall not become either involved directly or as authorized representatives in the design, construction, marketing or maintenance of the said products. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
- 2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the result of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
- 3. The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it shall also have access to the equipment required for special verification.

- 4. The staff responsible for inspection shall have :
  - sound technical and professional training,
  - satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
  - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
- 5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
- 6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member States itself is directly responsible for the tests.
- 7. The staff of the body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under the Directive or any provision of national law giving effect to it.

### RECREATIONAL CRAFT

### FINANCIAL STATEMENT

## Section 1: Financial implications

- 1. Title of operation: Technical harmonization Directive (Article 100a): Recreational craft.
- 2. Budget heading involved: B5-300 "Completing the internal market" (former Item 7750).
- 3. Legal basis: Article 100a of EEC Treaty.
- 4. Description of operation
  - 4.1 Specific objectives of operation: Removal of trade barriers and of technical barriers.
  - 4.2 Duration: Date proposed for the implementation of the Directive: 1 July 1995
  - 4.3 Target population: Member States' authorities, maritime industries, users of recreational craft.
- 5. Classification of expenditure or revenue
  - 5.1 Non-compulsory expenditure
  - 5.2 Differentiated appropriations
  - 5.3 No revenue
- 6. Type of expenditure or revenue
  - 6.1 100% subsidy: No
  - 6.2 Subsidy for joint financing with other sources in the public and/or private sector: Yes
  - 6.3 Interest subsidy: No
  - 6.4 Other: (Possibly) defraying of meeting expenses
  - 6.5 Should the operation prove an economic success, is there provision for all or part of the Community contribution to be reimbursed: No
  - 6.6 Will the proposed operation cause any change in the level of revenue? If so, what sort of change and what type of revenue is involved? No

- 7. Financial impact on appropriations for operations (part B of the budget)
  - 7.1 Provision should be made for the following resources as part of the budgetary procedure concerned.
    - transposition of 5 published  $ISO^{(1)}$  standards as  $CEN^{(2)}$  standards

ECU 10 000 x 5 = 50 000

completion of 13 standards at an advanced stage of preparation as CEN standards

ECU 30 000  $\times$  13 = 390 000

- preparation of 7 standards on subjects not yet covered

ECU 50 000 x 7 -350 000

790 000 # 800 000

- 7.2 Proportion of mini-budget in total cost of operation. Explain method of calculation
- 7.3 Indicative schedule of commitment and payment appropriations: Commitment appropriations 1992: ECU 800 000

Payment appropriations 1992: ECU 300 000

1993: ECU 350 000 1994: ECU 150 000

8. What anti-fraud measures are planned in the proposal for the operation? Possible control and audit provisions are included in framework contract between the Commission and the CEN.

<sup>(1)</sup> International Organization for Standardization

<sup>(2)</sup> European Committee for Standardization

## Section 2: Administrative expenditure (part A of the budget)

- 1. Will the proposed operation involve an increase in the number of Commission staff? If so, how many? It will be incorporated into the tasks of Units III/E/4 and III/B/2.
- 2. Indicate the amount of staff and administrative expenditure involved in the proposed operation. Explain the method of calculation: Directive 83/189 + (possibly) specialized Committee (ECU 20 000 per annum)

## Section 3: Elements of cost-effectiveness analysis

- 1. Objectives and coherence with financial programming
  - 1.1 Specific objective(s) of proposed operation. If possible this should be quantified and must be shown for each of the years concerned in the case of a multiannual operation: Completing the internal market and making the industrial sector concerned more competitive; preparing harmonized standards needed to implement the Directive
  - 1.2 Is the operation incorporated in the financial programming of the DG for the years concerned? Yes
  - 1.3 To which broader objective defined in the DG's financial programming does the objective of the proposed operation correspond?:
    - Removal of technical barriers
    - Harmonization of technical legislation and standardization

## 2. Grounds for the operation

2.1 Reasons for choosing this operation rather than an alternative which would achieve the same objectives. The justification must be based on three criteria:

Mutual recognition is not applicable; as the approval of recreational craft covers numerous systems, a Directive is needed.

- (a) cost: Agreement CEN/Commission
- (b) spin-off effect (impact beyond the specific objective(s):
   Development of the sector
- (c) multiplier effect (ability to mobilize other sources of finance): None

### 3. Monitoring and evaluation of the operation

- 3.1 Performance indicators selected: Compliance with the deadlines for preparing the standards, and follow-up of the target dates in the mandate.
- 3.2 Details and frequency of planned evaluation: Follow-up of the mandate to the CEN on a yearly base.
- 3.3 Main factors of uncertainty which could affect the specific results of the operation: None

## IMPACT ASSESSMENT

### 1. The proposal

The Directive is proposed in order to remove comprehensive barriers to trade in force in two major boating countries with large boating industries, and with the threat of regulations being brought into force in other countries.

## 2. The Impact on Business

a) All sectors of the boating industry will be affected, except a few companies making craft that are excluded from the Directive (boats constructed solely for racing, replicas of historic craft, canoes, kayaks, submersibles, hovercraft etc).

Component manufacturers will be affected just as much as boatbuilders, although component manufacturers will generally not be manufacturing products exclusively for the boating industry.

- b) 98% of boatbuilders have less than 200 employees 80% of boatbuilders have less than 20 employees 45% of boatbuilders have less than 10 employees
- c) Small firms are in general evenly distributed throughout the EEC.
- d) There are 3 companies with between 1000 and 1500 employees (2 in France and 1 in UK).

#### 3. Compliance by Companies

The Directive attempts to minimise the evaluation of conformity load for small builders of small boats, and therefore keep their compliance costs-per-boat to a minimum.

Small business operating under the Internal Production Control procedure will have to keep full records of designs, tests, calculations carried out etc. for a period of 10 years after the last product has been manufactured at the disposal of the relevant national authorities for inspection purposes.

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# **DOCUMENTS**

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