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Regulation (EC) No 725/2004 of the European Parliament and of the Council

of 31 March 2004

on enhancing ship and port facility security

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 80(2) thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Economic and Social Committee,

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) Intentional unlawful acts and especially terrorism are among the greatest threats to the ideals of democracy and freedom and to the values of peace, which are the very essence of the European Union.
- (2) The security of European Community shipping and of citizens using it and of the environment in the face of threats of intentional unlawful acts such as acts of terrorism, acts of piracy or similar, should be ensured at all times.
- (3) In connection with the transport of goods containing especially dangerous substances, such as chemical and radioactive substances, the potential consequences of the threats posed by intentional unlawful acts for Union citizens and the environment are very serious.
- (4) On 12 December 2002 the Diplomatic Conference of the International Maritime Organisation (IMO) adopted amendments to the 1974 International Convention for the Safety of Life at Sea (SOLAS Convention) and an International Ship and Port Facility Security Code (ISPS Code). These instruments are intended to enhance the security of ships used in international trade and associated port facilities; they comprise mandatory provisions, the scope of some of which in the Community should be clarified, and recommendations, some of which should be made mandatory within the Community.
- (5) Without prejudice to the rules of the Member States in the field of national security and measures which might be taken on the basis of Title VI of the Treaty on European Union, the security objective described in recital 2 should be achieved by adopting appropriate measures in the field of maritime transport policy establishing joint standards for the interpretation, implementation and monitoring within the Community of the provisions adopted by the Diplomatic Conference of the IMO on 12 December 2002. Implementing powers should be conferred on the Commission to adopt detailed implementing provisions.
- (6) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union.
- (7) Security should be enhanced not only for ships used in international shipping and the port facilities which serve them, but also for ships operating domestic services within the Community and their port facilities, in particular passenger ships, on account of the number of human lives which such trade puts at risk.
- (8) Part B of the ISPS Code comprises a number of recommendations which should be made mandatory within the Community in order to make uniform progress towards achievement of the security objective described in recital 2.
- (9) In order to contribute to the recognised and necessary objective of promoting intra-Community short-sea traffic, the Member States should be asked to conclude, in the light of regulation 11 of the special measures to enhance maritime security of the SOLAS Convention, the agreements on security arrangements for scheduled maritime traffic within the Community on fixed routes using dedicated port facilities, without this compromising the general standard of security sought.

- (10) Permanently applying all the security rules provided for in this Regulation to port facilities situated in ports which only occasionally serve international shipping might be disproportionate. The Member States should determine, on the basis of the security assessments which they are to conduct, which ports are concerned and which alternative measures provide an adequate level of protection.
- (11) Member States should vigorously monitor compliance with the security rules by ships intending to enter a Community port, whatever their origin. The Member State concerned should appoint a 'competent authority for maritime security' responsible for coordinating, implementing and monitoring the application of the security measures laid down in this Regulation as they apply to ships and port facilities. This authority should require each ship intending to enter the port to provide in advance information concerning its international ship security certificate and the levels of safety at which it operates and has previously operated, and any other practical information concerning security.
- (12) Member States should be permitted to grant exemptions from the systematic requirement to provide the information referred to in recital (11) in the case of intra-Community or domestic scheduled shipping services, provided the companies operating such services are able to provide such information at any time on request by the competent authorities of the Member States.
- (13) Security checks in the port may be carried out by the competent authorities for maritime security of the Member States, but also, as regards the international ship security certificate, by inspectors acting in the framework of port State control, as provided for in Council Directive 95/21/EC of 19 June 1995 concerning the enforcement, in respect of shipping using Community ports and sailing in the waters under the jurisdiction of the Member States, of international standards for ship safety, pollution prevention and shipboard living and working conditions (port State control). Where different authorities are concerned, provision must therefore be made for them to complement each other.
- (14) In view of the number of parties involved in the implementation of security measures, each Member State should appoint a single competent authority responsible for coordinating and monitoring the application of shipping security measures at national level. Member States should put in place the necessary resources and draw up a national plan for the implementation of this Regulation in order to achieve the security objective described in recital 2, in particular by establishing a timetable for the early implementation of certain measures in accordance with the terms of Resolution 6 adopted by the Diplomatic Conference of the IMO on 12 December 2002. The effectiveness of the checks on the implementation of each national system should be the subject of inspections supervised by the Commission.
- (15) The effective and standard application of measures under this policy raises important questions in relation to its funding. Funding certain additional security measures ought not to give rise to distortions of competition. To this end, the Commission should immediately undertake a study (intended to address in particular the way financing is shared between the public authorities and the operators, without prejudice to the distribution of competences between the Member States and the European Community) and to submit the results and, if appropriate, any proposals to the European Parliament and the Council.
- (16) The measures needed to implement this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission. A procedure should be defined for the adaptation of this Regulation in the light of experience, to make mandatory further provisions of Part B of the ISPS Code not initially made mandatory by this Regulation.
- (17) Since the objectives of this Regulation, namely the introduction and implementation of appropriate measures in the field of maritime transport policy, cannot be sufficiently achieved by the Member States and can therefore, by reason of the European scale of this Regulation, be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

Article 1

Objectives

1. The main objective of this Regulation is to introduce and implement Community measures aimed at enhancing the security of ships used in international trade and domestic shipping and associated port facilities in the face of threats of intentional unlawful acts.

2. The Regulation is also intended to provide a basis for the harmonised interpretation and implementation and Community monitoring of the special measures to enhance maritime security adopted by the Diplomatic Conference of the IMO on 12 December 2002, which amended the 1974 International Convention for the Safety of Life at Sea (SOLAS Convention) and established the International Ship and Port Facility Security Code (ISPS Code).

Article 2

Definitions

For the purposes of this Regulation:

1. 'special measures to enhance maritime security of the SOLAS Convention' means the amendments, as attached as Annex I to this Regulation, inserting the new Chapter XI-2 into the Annex to the SOLAS Convention of the IMO, in its up-to-date version,

2. 'ISPS Code' means the International Ship and Port Facility Security Code of the IMO, in its up-to-date version,

3. 'Part A of the ISPS Code' means the Preamble and the mandatory requirements forming Part A of the ISPS Code, as attached as Annex II to this Regulation, concerning the provisions of Chapter XI-2 of the Annex to the SOLAS Convention in its up-to-date version,

4. 'Part B of the ISPS Code' means the guidelines forming Part B of the ISPS Code, as attached as Annex III to this Regulation, regarding the provisions of chapter XI-2 of the Annex to the SOLAS Convention, as amended, and of Part A of the ISPS Code, in its up-to-date version,

5. 'maritime security' means the combination of preventive measures intended to protect shipping and port facilities against threats of intentional unlawful acts,

6. 'focal point for maritime security' means the body designated by each Member State to serve as a contact point for the Commission and other Member States and to facilitate, follow up and inform on the application of the maritime security measures laid down in this Regulation,

7. 'competent authority for maritime security' means an authority designated by a Member State to coordinate, implement and monitor the application of the security measures laid down in this Regulation in respect of ships and/or one or more port facilities. The competences of this authority may differ depending on the tasks assigned to it,

8. 'international shipping' means any maritime transport service by ship from a port facility of a Member State to a port facility outside that Member State, or conversely,

9. 'domestic shipping' means any transport service by ship in sea areas from a port facility of a Member State to the same port facility or another port facility within that Member State,

10. 'scheduled service' means a series of sailings organised in such a way as to provide a service linking two or more port facilities:

- (a) either on the basis of a published timetable;
- (b) or with a regularity or frequency such as to constitute a recognisable systematic service,

11. 'port facility' means a location where the ship/port interface takes place; this includes areas such as anchorages, waiting berths and approaches from seaward, as appropriate,

12. 'ship/port interface' means the interactions that occur when a ship is directly and immediately affected by actions involving the movement of persons or goods or the provision of port services to or from the ship,

13. 'intentional unlawful act' means a deliberate act, which, by its nature or context, could harm the vessels used for international or national maritime traffic, their passengers or their cargoes, or the port facilities connected therewith.

Article 3

Joint measures and scope

1. In respect of international shipping, Member States shall apply in full, by 1 July 2004, the special measures to enhance maritime security of the SOLAS Convention and Part A of the ISPS Code, in accordance with the conditions and with respect to the ships, companies and port facilities referred to therein.

2. In respect of domestic shipping, Member States shall apply, by 1 July 2005, the special measures to enhance maritime security of the SOLAS Convention and Part A of the ISPS Code to Class A passenger ships within the meaning of Article 4 of Council Directive 98/18/EC of 17 March 1998 on safety rules and standards for passenger ships(1) operating domestic services and to their companies, as defined in regulation IX-1 of the SOLAS Convention, and to the port facilities serving them.

3. Member States shall, after a mandatory security risk assessment, decide the extent to which they will apply, by 1 July 2007, the provisions of this Regulation to different categories of ships operating domestic services other than those referred to in paragraph 2, their companies and the port facilities serving them. The overall level of security should not be compromised by such a decision.

Member States shall notify the Commission of such decisions when they are adopted, as well as of the periodic review, which must take place at intervals of no more than five years.

4. When implementing the provisions required pursuant to paragraphs 1, 2 and 3, Member States shall take fully into account the guidelines contained in Part B of the ISPS Code.

5. Member States shall conform to the following paragraphs of Part B of the ISPS Code as if they were mandatory:

- 1.12 (revision of ship security plans),
- 1.16 (port facility security assessment),
- 4.1 (protection of the confidentiality of security plans and assessments),
- 4.4 (recognised security organisations),
- 4.5 (minimum competencies of recognised security organisations),
- 4.8 (setting the security level),
- 4.14, 4.15, 4.16 (contact points and information on port facility security plans),
- 4.18 (identification documents),
- 4.24 (ships' application of the security measures recommended by the State in whose territorial waters they are sailing),
- 4.28 (manning level),
- 4.41 (communication of information when entry into port is denied or the ship is expelled from port),
- 4.45 (ships from a State which is not party to the Convention),
- 6.1 (company's obligation to provide the master with information on the ship's operators),
- 8.3 to 8.10 (minimum standards for the ship security assessment),
- 9.2 (minimum standards for the ship security plan),
- 9.4 (independence of recognised security organisations),
- 13.6 and 13.7 (frequency of security drills and exercises for ships' crews and for company and ship security officers),
- 15.3 to 15.4 (minimum standards for the port facility security assessment),
- 16.3 and 16.8 (minimum standards for the port facility security plan),
- 18.5 and 18.6 (frequency of security drills and exercises in port facilities and for port facility security officers).

6. Notwithstanding the provisions of paragraph 15.4 of Part A of the ISPS Code, the periodic review of the port facility security assessments provided for in paragraph 1.16 of Part B of the ISPS Code shall be carried out at the latest five years after the assessments were carried out or last reviewed.

7. This Regulation shall not apply to ships of war and troopships, cargo ships of less than 500 gross tonnage, ships not propelled by mechanical means, wooden ships of primitive build, fishing vessels or vessels not engaged in commercial activities.

8. Notwithstanding the provisions of paragraphs 2 and 3, Member States shall ensure, when ship security plans and port facility security plans are approved, that such plans contain appropriate provisions to ensure that the security of ships to which this Regulation applies is not compromised by any ship or port interface or ship-to-ship activity with any ships not subject to this Regulation.

Article 4

Communication of information

1. Each Member State shall communicate to the IMO, the Commission and the other Member States the information required pursuant to regulation 13 (Communication of information) of the special measures to enhance maritime security of the SOLAS Convention.

2. Each Member State shall communicate to the Commission and the other Member States the contact details of the contact officials referred to in paragraph 4.16 of Part B of the ISPS Code and the information provided for in paragraph 4.41 of Part B of the ISPS Code when a ship is expelled from or refused entry to a Community port.

3. Each Member State shall draw up the list of port facilities concerned on the basis of the port facility security assessments carried out, and establish the scope of the measures taken to apply the provisions of paragraph 2 of regulation 2 (extent of application to port facilities which occasionally serve international voyages) of the special measures to enhance maritime security of the SOLAS Convention.

Each Member State shall communicate the said list to the other Member States and to the Commission by 1 July 2004 at the latest. The Commission and any Member State concerned shall also be given sufficient details of the measures taken.

Article 5

Alternative security agreements or equivalent security arrangements

1. For the purposes of this Regulation, regulation 11 (Alternative security agreements) of the special measures to enhance maritime security of the SOLAS Convention may also apply to scheduled intra-Community shipping operating on fixed routes and using associated port facilities.

2. To that end, Member States may conclude among themselves, each acting on its own behalf, the bilateral or multilateral agreements provided for in the said SOLAS regulation. Member States may, in particular, consider such agreements in order to promote intra-Community short sea shipping.

The Member States concerned shall notify the agreements to the Commission and provide sufficient details of the measures to allow the Commission to consider whether the agreements compromise the level of security of other ships or port facilities not covered by the agreements. The details of the measures directly linked to national security, if any, may be omitted from the notification to the Commission.

The Commission shall examine whether the agreements guarantee an adequate level of protection, in particular as regards the requirements of paragraph 2 of the abovementioned SOLAS regulation 11, and whether they conform with Community law and are in accordance with the proper functioning of the internal

market. If the agreements do not meet these criteria, the Commission shall within four months adopt a decision in accordance with the procedure referred to in Article 11(3); in such cases, the Member States concerned shall revoke or adapt the agreements accordingly.

3. The periodic review of such agreements provided for in paragraph 4 of regulation 11 of the special measures to enhance maritime security must take place at intervals of no more than five years.

4. Member States may adopt, for domestic shipping and the port facilities as referred to in Articles 3(2) and 3(3) of this Regulation, equivalent security arrangements as provided for in regulation 12 (equivalent security arrangements) of the special measures to enhance maritime security of the SOLAS Convention, provided such security arrangements are at least as effective as those prescribed in Chapter XI-2 of the SOLAS Convention and the relevant mandatory provisions of the ISPS Code.

The Member State concerned shall communicate to the Commission sufficient details of such arrangements when they are adopted, and the outcome of periodic reviews thereof, at the latest five years after they were adopted or last reviewed.

The conditions of application of such arrangements shall be subject to the Commission inspections provided for in Article 9(4), (5) and (6) of this Regulation under the procedures defined therein.

Article 6

Provision of security information prior to entry into a port of a Member State

1. When a ship which is subject to the requirements of the special measures to enhance maritime security of the SOLAS Convention and of the ISPS Code or of Article 3 of this Regulation announces its intention to enter a port of a Member State, the competent authority for maritime security of that Member State shall require that the information referred to in paragraph 2.1 of regulation 9 (Ships intending to enter a port of another Contracting Government) of the special measures to enhance maritime security of the SOLAS Convention be provided. The said authority shall analyse, as far as necessary, the information provided and, where necessary, apply the procedure provided for in paragraph 2 of that SOLAS regulation.

2. The information referred to in paragraph 1 shall be provided:

- (a) at least 24 hours in advance; or
- (b) at the latest, at the time the ship leaves the previous port, if the voyage time is less than 24 hours; or
- (c) if the port of call is not known or if it is changed during the voyage, as soon as the port of call becomes known.

3. A report shall be kept of the procedure followed in respect of each ship subject to a security incident, as defined in paragraph 1.13 of regulation 1 (definitions) of the special measures to enhance maritime security of the SOLAS Convention.

Article 7

Exemptions from the provision of security information prior to entry into a port

1. Member States may exempt scheduled services performed between port facilities located on their territory from the requirement laid down in Article 6 where the following conditions are met:

- (a) the company operating the scheduled services referred to above keeps and updates a list of the ships concerned and sends it to the competent authority for maritime security for the port concerned,
- (b) for each voyage performed, the information referred to in paragraph 2.1 of regulation 9 of the special measures to enhance maritime security of the SOLAS Convention is kept available for the competent

authority for maritime security upon request. The company must establish an internal system to ensure that, upon request 24 hours a day and without delay, the said information can be sent to the competent authority for maritime security.

2. When an international scheduled service is operated between two or more Member States, any of the Member States involved may request of the other Member States that an exemption be granted to that service, in accordance with the conditions laid down in paragraph 1.

3. Member States shall periodically check that the conditions laid down in paragraphs 1 and 2 are being met. Where at least one of these conditions is no longer being met, Member States shall immediately withdraw the privilege of the exemption from the company concerned.

4. Member States shall draw up a list of companies and ships granted exemption under this Article, and shall update that list. They shall communicate the list and updates thereof to the Commission and any Member State concerned.

5. Notwithstanding the provisions of paragraphs 1 and 2, a Member State may, on security grounds and on a case-by-case basis, request the provision of the information referred to in paragraph 2.1 of regulation 9 of the special measures to enhance maritime security of the SOLAS Convention prior to entry into a port.

Article 8

Security checks in Member State ports

1. Certificate verification, as defined in paragraph 1.1 of regulation 9 (Control of ships in port) of the special measures to enhance maritime security of the SOLAS Convention, shall be carried out in the port either by the competent authority for maritime security defined in Article 2(7) of this Regulation or by the inspectors defined in Article 2(5) of Directive 95/21/EC.

2. Where the officer conducting the certificate verification referred to in paragraph 1 has clear grounds for believing that the ship is not in compliance with the requirements of the special measures to enhance maritime security of the SOLAS Convention and of the ISPS Code, but does not belong to an authority which in that Member State is responsible for carrying out the measures provided for in paragraphs 1.2 and 1.3 of regulation 9 of the special measures to enhance maritime security of the SOLAS Convention, s/he shall immediately refer the matter to the said authority.

Article 9

Implementation and conformity checking

1. Member States shall carry out the administrative and control tasks required pursuant to the provisions of the special measures to enhance maritime security of the SOLAS Convention and of the ISPS Code. They shall ensure that all necessary means are allocated and effectively provided for the implementation of the provisions of this Regulation.

2. Member States shall designate a focal point for maritime security by 1 July 2004.

3. Each Member State shall adopt a national programme for the implementation of this Regulation.

4. Six months after the date of application of the relevant measures referred to in Article 3, the Commission, in cooperation with the focal point referred to in paragraph 2, shall start a series of inspections, including inspections of a suitable sample of port facilities and relevant companies, to monitor the application by Member States of this Regulation. These inspections shall take account of the data supplied by the focal point referred to in paragraph 2, including monitoring reports. The procedures for conducting such inspections shall be adopted in accordance with the procedure referred to in Article 11(2).

5. The officials mandated by the Commission to conduct such inspections in accordance with paragraph 4 shall exercise their powers upon production of an authorisation in writing issued by the Commission and specifying the subject-matter, the purpose of the inspection and the date on which it is to begin. The Commission shall in good time before inspections inform the Member States concerned by the inspections.

The Member State concerned shall submit to such inspections and shall ensure that bodies or persons concerned also submit to those inspections.

6. The Commission shall communicate the inspection reports to the Member State concerned, which shall indicate sufficient details of the measures taken to remedy any shortcomings within three months of receipt of the report. The report and the list of measures taken shall be communicated to the Committee referred to in Article 11(1).

Article 10

Integration of amendments to international instruments

1. The applicable international instruments referred to in Article 2, which are applied in accordance with Article 3(1), shall be those which have entered into force, including the most recent amendments thereto, with the exception of the amendments excluded from the scope of this Regulation resulting from the conformity checking procedure established by paragraph 5.

2. The Commission shall decide on the integration of amendments to the international instruments referred to in Article 2 in respect of ships operating domestic services and the port facilities serving them to which this Regulation applies, in so far as they constitute a technical update of the provisions of the SOLAS Convention and the ISPS Code. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(4); on imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 11(5). The procedure for checking conformity established in paragraph 5 of this Article shall not apply in these cases.

3. The Commission may adopt provisions in order to define harmonised procedures for the application of the mandatory provisions of the ISPS Code, without broadening the scope of this Regulation. Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(4).

On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 11(5).

4. For the purposes of this Regulation and with a view to reducing the risks of conflict between Community maritime legislation and international instruments, Member States and the Commission shall cooperate, through coordination meetings and/or any other appropriate means, in order to define, as appropriate, a common position or approach in the competent international fora.

5. A procedure for checking conformity is hereby established in order to exclude from the scope of this Regulation any amendment to an international instrument only if, on the basis of an evaluation by the Commission, there is a manifest risk that such an amendment will lower the standard of maritime security or be incompatible with Community legislation.

The procedure for checking conformity may be used solely to make amendments to this Regulation in the fields expressly covered by the procedure referred to in Article 11(2) and strictly within the framework of exercise of implementing powers conferred on the Commission.

6. In the circumstances referred to in paragraph 5, the procedure for checking conformity shall be initiated by the Commission, which, where appropriate, may act at the request of a Member State.

The Commission shall submit to the Committee set up in Article 11(1), without delay, after the adoption of an amendment to an international instrument, a proposal for measures with the aim of excluding the

amendment in question from this Regulation.

The procedure for checking conformity, including, if applicable, the procedures set up in Article 5(6) of Decision 1999/468/EC, shall be completed at least one month before the expiration of the period established internationally for the tacit acceptance of the amendment concerned or the envisaged date for the entry into force of said amendment.

7. In the event of a risk as referred to in the first subparagraph of paragraph 5, Member States shall refrain, during the course of the procedure for checking conformity, from taking any initiative intended to integrate the amendment in national legislation or to apply the amendment to the international instrument concerned.

8. All relevant amendments to international instruments that are integrated in Community maritime legislation, in accordance with paragraphs 5 and 6, shall be published, for information purposes, in the *Official Journal of the European Union*.

Article 11

Committee procedure

1. The Commission shall be assisted by a committee.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at one month.

3. Where reference is made to this paragraph, Articles 6 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The periods laid down in Article 6(b) and (c) respectively of Decision 1999/468/EC shall be set at one month.

4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 12

Confidentiality

In applying this Regulation, the Commission shall take, in accordance with the provisions of Commission Decision 2001/844/EC, ECSC, Euratom of 29 November 2001 amending its internal Rules of Procedure(2), appropriate measures to protect information subject to the requirement of confidentiality to which it has access or which is communicated to it by Member States.

The Member States shall take equivalent measures in accordance with relevant national legislation.

Any personnel carrying out security inspections, or handling confidential information related to this Regulation, must have an appropriate level of security vetting by the Member State of the nationality of the personnel concerned.

Article 13

Dissemination of information

1. Without prejudice to the public right of access to documents as laid down in Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents⁽³⁾, the inspection reports and the answers of the Member States referred to in Articles 4(3), 5(2), 5(4) and 9(6) shall be secret and shall not be published. They shall only be available to the relevant authorities, which shall communicate them only to interested parties on a need-to-know basis, in accordance with applicable national rules for dissemination of sensitive information.

2. Member States shall, as far as possible and in accordance with applicable national law, treat as confidential information arising from inspection reports and answers of Member States when it relates to other Member States

3. Unless it is clear that the inspection reports and answers shall or shall not be disclosed, Member States or the Commission shall consult with the Member State concerned.

Article 14

Sanctions

Member States shall ensure that effective, proportionate and dissuasive sanctions for breaching the provisions of this Regulation are introduced.

Article 15

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2004, apart from the provisions of Articles 3(2) and (3), and 9(4), which shall enter into force on and apply from the dates specified therein.

This Regulation shall be binding in its entirety and directly applicable in all Member States.