EUROPEAN COMMISSION



Brussels, 30.8.2011 COM(2011) 518 final

2011/0225 (NLE)

Proposal for a

COUNCIL REGULATION

establishing a Community system for registration of carriers of radioactive materials

{SEC(2011) 1005 final} {SEC(2011) 1006 final}

EN EN

EXPLANATORY MEMORANDUM

1. JUSTIFICATION AND OBJECTIVE

At European level, carriers of radioactive materials are covered by transport legislation under the Treaty on the Functioning of the European Union (TFEU) and legislation of the radiation-specific aspects including the health protection of workers and the general public under the Treaty establishing the European Atomic Energy Community (Euratom).

TFEU legislation has been simplified by Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods by combining all inland transport modes.

Council Directive 96/29/Euratom of 13 May 1996 lays down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. According to Article 30 of the Treaty, these basic standards mean:

- (a) maximum permissible doses compatible with adequate safety;
- (b) maximum permissible levels of exposure and contamination;
- (c) the fundamental principles governing the health surveillance of workers.

Member States, according to Article 33, shall lay down appropriate provisions to ensure compliance with the basic standards.

For the sake of protecting the health of workers and the general public and to better focus their work, Member states authorities need to know which persons, organizations or undertakings to check on. To that effect, Art. 3 and 4 of the Directive require Member States to submit certain practices involving a hazard from ionizing radiation to a system of reporting (notification) and prior authorization or prohibition of certain practices.

Directive 96/29/Euratom applies to all practices which involve a risk from ionizing radiation emanating from an artificial source or from a natural radiation source, including transport.

As transport is the only "mobile" practice, and given the often cross-border nature of transport operations, a carrier may have to follow these reporting and authorization procedures in several Member States. In addition, Member States have implemented these procedures in differing systems, thereby adding to the complexity of transport operations as such.

Replacing these national reporting and authorization procedures by a unique registration system for the practice of transport will therefore contribute to simplify the procedure, reduce administrative burden, do away with barriers to entry, while the high radiation protection levels reached will be maintained.

This Regulation replaces the reporting and authorization systems in the Member States in implementing Council Directive 96/29/Euratom by a single registration. The Regulation establishes a European System for Carrier Registration. Carriers should apply through a central web interface. These applications will be screened by the respective national competent authority which issues the registration if the applicant fulfils the basic safety standards. At the same time, the system allows the competent authorities a better overview of

the carriers that are active in their country. The system must be available, tested and functional when this Regulation enters into force.

The Regulation adopts a graded approach by excluding from the registration procedure carriers who transport exclusively "excepted packages". On the other hand, the Regulation leaves it up to the Member States to add additional registration requirements for carriers of fissile and highly-radioactive materials.

Other Community law and international rules regarding physical protection, safeguards, and third-party liability continue to apply. This is true, in particular, for Directive 2008/68/EC.

2. LEGAL BASIS

The provisions of this Regulation are related to the basic standards for the protection of the health of workers and the general public. Consequently, the legal base chosen is the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof.

3. SUBSIDIARITY AND PROPORTIONALITY

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Community. As the Community's legislative powers under Title II Chapter 3 of the EURATOM Treaty are exclusive in nature, they are not subject to the principle of subsidiarity.

Proportionality is also assured. The proposed mechanism, according to the impact assessment carried out in the preparation, strikes a careful balance between effective protection of workers and the public during transport operations, the legitimate interests of the stakeholders involved and the interests of Member States. Above all, the preferred option is the minimum necessary to effectively achieve the objectives set while keeping the costs within reasonable limits.

Proposal for a

COUNCIL REGULATION

establishing a Community system for registration of carriers of radioactive materials

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular the second paragraph of Article 31 and Article 32 thereof.

Having regard to the proposal from the Commission, drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the European Parliament²,

Whereas:

- Article 33 of the Treaty requires Member States to lay down the appropriate (1) provisions to ensure compliance with the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.
- The basic safety standards are established by Council Directive 96/29/Euratom of 13 (2) May 1996³. That Directive applies to all practices which involve a risk of ionizing radiation emanating from an artificial or a natural radiation source, including transport.
- (3) In order to ensure compliance with the basic standards, it is necessary to lay down which persons, organizations or undertakings should be checked on by the authorities of Member States. To this effect Directive 96/29/Euratom requires Member States to submit certain practices involving a hazard from ionizing radiation to a system of reporting and prior authorization or to prohibit certain practices.
- **(4)** Transport being the only practice having a cross-border nature, carriers of radioactive materials may be required to follow requirements related to reporting and authorization systems in several Member States. This Regulation replaces these reporting and authorization systems in the Member States by a single registration

¹ OJ C, , p. .

²

OJ C , , p. . OJ L 159, 29.6.1996, p. 1.

- system valid across the European Atomic Energy Community (hereinafter the 'Community').
- (5) For carriers by air and sea, such registration and certification systems already exist. Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonization of technical requirements and administrative procedures in the field of civil aviation⁴ lays down that air carriers need a specific air operator certificate for transportation of dangerous goods. For transports by sea, Directive 2002/59/EC of the European Parliament and of the Council of 27 June 2002 establishes a Community vessel traffic monitoring and information system⁵. The certificates issued by the civil aviation authorities and the reporting system for maritime vessels are deemed to satisfactorily implement the reporting and authorization requirements of Directive 96/29/Euratom. A registration of air and see carriers under this Regulation is therefore not necessary to enable Member States to ensure compliance with the basic standards in these transport modes.
- (6) Carriers of radioactive material are subject to a number of requirements of Union and Euratom legislation as well as international legal instruments. The International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material (TS-R-1) and the Modal Regulations for the Transport of Dangerous Goods continue to apply directly or are implemented by Member States under Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods⁶ for road, rail and inland waterway transport. The provisions of this Directive are, however, without prejudice to the application of other provisions in the fields of occupational safety and health and environmental protection.

HAS ADOPTED THIS REGULATION

Article 1 Subject matter and scope

- (1) This Regulation establishes a Community system for registration of carriers of radioactive materials which facilitates the Member States' task to ensure that the basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiations laid down in Directive 96/29/Euratom are complied with.
- (2) This Regulation shall apply to any carrier transporting radioactive materials within the Community, from third countries into the Community and from the Community into third countries. It shall not apply to carriers transporting radioactive materials by air and sea.

⁴ OJ L 373, 31.12.1991, p. 4.

⁵ OJ L 208, 5.8.2002, p. 10.

⁶ OJ L 260, 30.9.2008, p. 13.

Article 2 Definitions

For the purposes of this Regulation

- (1) "carrier" means any person, organization or public undertaking carrying out the practice of transport of radioactive material by any means of transport in the Community including carriers carrying out activities on the basis of hire or reward arrangements;
- (2) "competent authority" means any authority designated by the Member State to carry out tasks in accordance with this Regulation;
- (3) "transport" means all transport operations from the place of origin to the place of destination, including loading, storage in transit and unloading of radioactive material;
- (4) "radioactive material" means any material containing radionuclides where both the activity concentration and the total activity in the consignment exceed the values specified in paragraphs 402–407 of the IAEA Regulations for the Safe Transport of Radioactive Material, Safety Requirements No. TS-R-1, 2009, Vienna;
- (5) "high consequence dangerous goods radioactive material" means radioactive materials which have the potential for misuse in a terrorist incident and which may, as a result, produce serious consequences such as mass casualties or mass destruction as defined in Appendix A.9. of the IAEA Nuclear Security Series No.9 "Security in the Transport of Radioactive Material", Vienna, 2008;
- (6) "excepted package" means any package in which the allowed radioactive content does not exceed the activity levels laid down in Table V of Section IV of Regulations for the Safe Transport of Radioactive Material No. TS-R-1 or one tenth of these limits for the transport by post and which are labelled as UN No. 2908, 2909, 2910 or 2911;
- (7) "fissile material" means uranium-233, uranium-235, plutonium-239 and plutonium-241 or any combination of these radionuclides.

Article 3 General provisions

- (1) Carriers of radioactive materials shall have a valid registration obtained in accordance with Article 5. The registration shall allow the carrier to carry out the practice of transport throughout the whole European Union.
- (2) Individual transport operations shall be accompanied by a copy of the carrier's registration certificate or by the licence or registration obtained in accordance with the applicable national procedure in the case of transport referred to in paragraph (3).
- (3) A holder of valid licences or registrations issued in accordance with Directive 96/29/Euratom for the handling of radioactive material or for the use of equipment containing radioactive material or sources may transport these materials or sources

- without registration under this Regulation if transportation is included in the licences or registrations for all Member States where the transport takes place.
- (4) National reporting and authorization requirements that are additional to the requirements laid down by this Regulation may only apply to the carriers of the following materials:
 - fissile material, except for natural uranium or depleted uranium which has been irradiated in a thermal reactor only;
 - high consequence dangerous goods radioactive materials.

Article 4 Electronic System for Carrier Registration (ESCReg)

- (1) For the supervision and control of the transport of radioactive material, an Electronic System for Carrier Registration (ESCReg) shall be established and maintained by the Commission. The Commission shall define additional information, as well as technical specifications and requirements of the ESCReg.
- (2) The ESCReg shall grant restricted and secure access to the competent authorities of the Member States, to the registered carriers and to the applicants, subject to the relevant provisions on personal data protection, as laid down in particular by Directive 95/46/EC of the European Parliament and of the Council⁷. The competent authorities shall have access to all data available.
- (3) The Commission shall not be responsible for the content and the accuracy of the information submitted through the ESCReg.

Article 5 Registration procedure

- (1) A carrier shall apply for registration through the ESCReg.
- (2) The applicant carrier shall submit the completed electronic application form set out in Annex I.
- (3) Upon completion and submission of the application form, the applicant shall receive an automatic acknowledgement of receipt, together with an application number.
- (4) If the applicant is established in one or more Member States, the competent authority of the Member State where the head office of the applicant is established shall process the application.
- (5) If the applicant is established in a third country, the competent authority of the Member State where the carrier intends to first enter the territory of the Union shall process the application.

⁷ OJ L 281, 23.11.1995, p. 31.

- (6) The competent authority of the Member State which issues the first certificate of carrier registration shall issue also the new certificate in the event of modification of data in accordance with Article 6.
- (7) Within eight weeks of issuing of the acknowledgement of receipt the competent authority shall issue a certificate of carrier registration if it considers the submitted information to be complete and in compliance with the applicable requirements of this Regulation, and with Directive 96/29/Euratom and Directive 2008/68/EC.
- (8) The certificate of carrier registration shall contain the information set out in Annex II and shall be issued in the form of the standardized registration certificate through the ESCReg.
- (9) A copy of the certificate of carrier registration shall be provided automatically through the ESCReg to all the competent authorities of the Member States where the carriers intend to operate.
- (10) If the competent authority refuses to issue the certificate of carrier registration on the grounds that the application is not complete or not in compliance with the applicable requirements, it shall respond in writing to the applicant within eight weeks after issuing of the acknowledgement of receipt. The competent authority shall provide a statement of the reasons for the refusal.
- (11) A copy of the refusal and statement of the reasons shall be provided automatically through the ESCReg to all the competent authorities of the Member States where the carriers intend to operate.
- (12) In case of refusal to issue the certificate of carrier registration, the applicant may lodge an appeal in accordance with the applicable national legal requirements.
- (13) A valid certificate of registration shall be recognized by all Member States.
- (14) The certificate of carrier registration is valid for a period of five years and may be renewed upon application by the carrier.

Article 6 Modification of data

- (1) The carrier shall be responsible for ensuring the continued accuracy of the data provided for in the application form for Community carrier registration submitted to the ESCReg.
- (2) The carrier shall apply for a new certificate in the event of modification of the data contained in part A of the application form for Community carrier registration.

Article 7 Compliance assurance

(1) If a carrier does not comply with the requirements of this Regulation the competent authority of the Member State where the non-compliance was discovered shall apply

enforcement measures within the legal framework of that Member State, such as written notices, training and education measures, suspension, revocation or modification of the registration or prosecution, depending on the safety significance of the non-compliance and the record of compliance of the carrier.

- (2) This competent authority shall communicate to the carrier and to the competent authorities of the Member States concerned where the carrier was planning to transport radioactive materials, the information on applied enforcement action and a statement of reasons for application of that action. If the carrier does not comply with the enforcement action applied pursuant to paragraph 1, the competent authority of the Member State of establishment of the head office of the carrier or, if the carrier is established in a third country, the competent authority of the Member State, where the carrier intended to first enter the territory of the Community shall revoke the registration.
- (3) The competent authority shall communicate to the carrier and to the other competent authorities concerned the revocation together with a statement of reasons.

Article 8 Competent authorities and national contact point

- (1) Member States shall designate a competent authority and a national contact point for the transport of radioactive materials.
- (2) Member States shall forward to the Commission not later than one month after the entry into force of this Regulation the name(s), address(es) and all necessary information for rapid communication with the competent authorities and with the national contact point for the transport of radioactive materials, as well as any subsequent change to such data.
- (3) The Commission shall communicate this information and any changes thereto to all competent authorities in the Community through the ESCReg.

Article 9 Cooperation between competent authorities

Competent authorities of Member States shall cooperate with a view to harmonising their requirements for issuing a registration and to ensuring the harmonised application and enforcement of this Regulation.

Where there are several competent authorities within a Member State, they shall liaise and cooperate closely on the basis of legal or formal agreements between them covering the responsibilities of each authority. They should communicate with and provide information to each other, to the national contact point, and to other governmental and non-governmental organizations that have related responsibilities.

Article 10 Expert group

The Commission shall establish an expert group by a Commission Decision on the basis of Article 135 of the Euratom Treaty.

The group shall advise and assist the Commission in the performance of its tasks provided for in this Regulation.

The group shall be composed of experts nominated by the Member States and of experts nominated by the Commission and shall be chaired by a representative of the Commission.

Article 11 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 six months following its entry into force.

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

Done at Brussels, [...]

For the Council
The President
[...]

ANNEX I APPLICATION FORM FOR COMMUNITY CARRIER REGISTRATION

PLEASE SEND THIS APPLICATION ONLY USING THE SECURE ELECTRONIC SYSTEM FOR CARRIER REGISTRATION (ESCReg) WEB SITE OF THE EUROPEAN COMMISSION

THE INFORMATION IN PART A IS SUBJECT TO A NEW REGISTRATION IF A MODIFICATION IS REQUESTED.

The information provided in the present application form will be processed by the European Commission in compliance of the Euratom Regulation xxxxx

NEW CERTIFICATE OF REGISTRATION
MODIFICATION OF AN EXISTING REGISTRATION
RENEWAL OF AN EXISTING REGISTRATION

Registration Certificate number/s:

Please give details of why a variation of an existing registration is being sought?

1. IDENTIFICATION OF THE APPLICANT:

PART A	PART B			
COMPANY NAME: FULL ADDRESS: NATIONAL REGISTRATION NUMBER:	1. Name, position, full address, telephone number and the e-mail-address of the responsible representative of the carrier's organisation (person empowered to commit the carriers organisation):			
	2. Name, position, full address, telephone number and the e-mail-address of the contact person for the authorities on technical/administrative issues (which has the responsibility for compliance with the regulations for the activities deployed by the carrier company):			
	 3. Name, position and full address of the safety adviser (only for inland transport modes and if different from 1 or 2): 4. Name, position and full address of the responsible for the 			

	Protection Programme if different from 1 or 2 or 3			
2. NATURE OF TRANSPORT:				
PART A	PART B			
ROAD RAIL INLAND WATERWAYS	1 Staff involved and trained for transport (information) 1 to 5 5 to 10 10 to 20 20 2 Transport activity sector: general description of the nature of transport activities to be undertaken (information) medical use industrial use, non destructive testing use, research nuclear fuel cycle use waste high consequence dangerous goods - radioactive material			
3. GEOGRAPHICAL COVERAGE				
Please tick from the list below those planned to be transported and select the	Member States in which radioactive material is ne nature of activity			
If activities are also deployed in Member States other than the Member State whe the application for registration is made, more specific details for every country; transit only, or major loading/unloading places within the particular counfrequency:				
PART A	PART B			
□Austria	☐ transit☐ unloading			
□Belgium				
□Bulgaria	major loading places:			
□Cyprus	major unloading places:			
□Czech Republic				

□Denmark	frequency:
□Estonia	□ daily
□Finland	□ weekly
□France	☐ monthly ☐ less frequent
□Germany	
□Greece	
□Hungary	
□Ireland	
□Italy	
□Latvia	
□Lithuania	
□Luxembourg	
□Malta	
□Netherlands	
□Poland	
□Portugal	
□Romania	
□Slovakia	
□Slovenia	
□Spain	
□Sweden	
□United Kingdom	
4. TYPE OF CONSIGNMENTS	
Registration is requested for:	
PART A	PART B: Estimated number of
PACKAGE TYPE - Classification following TS-R-1	packages /year

UN 2908 RADIOACTIVE MATERIAL, EXCEPTED PACKAGE — EMPTY PACKAGING

UN 2909 RADIOACTIVE MATERIAL, EXCEPTED PACKAGE — ARTICLES MANUFACTURED FROM NATURAL URANIUM or DEPLETED URANIUM or NATURAL THORIUM

UN 2910 RADIOACTIVE MATERIAL, EXCEPTED PACKAGE — LIMITED QUANTITY OF MATERIAL

UN 2911 RADIOACTIVE MATERIAL, EXCEPTED PACKAGE — INSTRUMENTS or ARTICLES

UN 2912 RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-I), non-fissile or fissile excepted

UN 2913 RADIOACTIVE MATERIAL, SURFACE CONTAMINATED OBJECTS (SCO-I or SCO-II), non-fissile or fissile excepted

UN 2915 RADIOACTIVE MATERIAL, TYPE A PACKAGE, non-special form, non-fissile or fissile excepted

UN 2916 RADIOACTIVE MATERIAL, TYPE B(U) PACKAGE, non-fissile or fissile excepted

UN 2917 RADIOACTIVE MATERIAL, TYPE B(M) PACKAGE, non-fissile or fissile excepted

UN 2919 RADIOACTIVE MATERIAL, TRANSPORTED UNDER SPECIAL ARRANGEMENT, non-fissile or fissile excepted

UN 2977 RADIOACTIVE MATERIAL, URANIUM HEXAFLUORIDE, FISSILE

UN 2978 RADIOACTIVE MATERIAL, URANIUM HEXAFLUORIDE, non-fissile or fissile excepted

UN 3321 RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-II), non-fissile or fissile excepted

UN 3322 RADIOACTIVE MATERIAL,

LOW SPECIFIC ACTIVITY (LSA-III), non-fissile or fissile excepted UN 3323 RADIOACTIVE MATERIAL, TYPE C PACKAGE, non-fissile or fissile excepted UN 3324 RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-II), **FISSILE** UN 3325 RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-III), **FISSILE** UN 3326 RADIOACTIVE MATERIAL. SURFACE CONTAMINATED OBJECTS (SCO-I or SCO-II), FISSILE UN 3327 RADIOACTIVE MATERIAL, TYPE A PACKAGE, FISSILE, non-special form UN 3328 RADIOACTIVE MATERIAL, TYPE B(U) PACKAGE, FISSILE UN 3329 RADIOACTIVE MATERIAL. TYPE B(M) PACKAGE, FISSILE UN 3330 RADIOACTIVE MATERIAL, TYPE C PACKAGE, FISSILE UN 3331 RADIOACTIVE MATERIAL, TRANSPORTED UNDER SPECIAL ARRANGEMENT, FISSILE UN 3332 RADIOACTIVE MATERIAL, TYPE A PACKAGE, SPECIAL FORM, non-fissile or fissile excepted UN 3333 RADIOACTIVE MATERIAL, TYPE A PACKAGE, SPECIAL FORM,

5. RADIATION PROTECTION PROGRAMME (RPP)

FISSILE

PART A:	PART B:
☐ By ticking this box:	reference and date of the document describing the RPP
I declare that we have a RPP that is fully implemented and strictly applied	describing the Ref

	Upload of the RPP				
6. QUALITY ASSURANCE PROGR	AMME (QAP)				
This QAP shall be available for inspearticle 1.7.3 of ADR)	ection by the competent authority (according to				
PART A:	PART B:				
□By ticking this box:	Reference and date of the document				
I declare that we have a QAP that is fully implemented and strictly applied	□ ISO 9002				
7. DECLARATION					
	☐ I, the carrier, hereby certify that I comply with all the relevant international Community and national regulations relating to the transport of radioactive materials				
\Box I, the carrier, hereby certify that the	information contained in this form is correct.				
Date Name	Date Signature				

ANNEX II ELECTRONIC CERTIFICATE OF CARRIER REGISTRATION FOR THE TRANSPORT OF RADIOACTIVE MATERIAL

NOTE:

A COPY OF THIS CERTIFICATE OF REGISTRATION SHALL ACCOMPANY EACH TRANSPORT FALLING UNDER THE SCOPE OF THIS REGULATION.

This certificate of registration is issued in compliance with Council Regulation (Euratom) xxxxx

This certificate does not relieve the carrier from compliance with the other applicable transport regulations.

- 1) REGISTRATION REFERENCE NUMBER: BE/ xxxx / dd-mm-yyyy
- 2) NAME OF THE AUTHORITY / COUNTRY:
- 3) COMPANY NAME & ADDRESS
- 4) MODE OF TRANSPORT:
- \square ROAD
- □ RAIL
- ☐ INLAND WATERWAYS
- 7) MEMBER STATES where the certificate is applicable
- 8) PACKAGE TYPE UN NUMBER (see annex 1- same format)
- 9) DATE

ELECTRONIC SIGNATURE

VALIDITY PERIOD: DATE + 5 years

LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS HAVING A BUDGETARY IMPACT EXCLUSIVELY LIMITED TO THE REVENUE SIDE

1. NAME OF THE PROPOSAL:

Council Regulation establishing a Community system for Registration of carriers of radioactive materials

2. BUDGET LINES:

Chapter and Article: 320102110005 - (E)-Développement système IT

Amount budgeted for the year concerned: € 350000

3. FINANCIAL IMPACT

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	Dronogol	hog no	tinonoiol	ımn	11001	1010
	Proposal	11/45 110	тинанклан		1111/411	10115

Proposal has no financial impact on expenditure but has a financial impact on revenue – the effect is as follows:

(€ million to one decimal place)

Budget line	Revenue	12 month period, starting dd/mm/yyyy	[Year n]
Article 4			0.35

Situation following action					
	[n+1]	[n+2]	[n+3]	[n+4]	[n+5]
Article 4	0.05	0.05	0.05	0.05	0.05

4. ANTI-FRAUD MEASURES

5. OTHER REMARKS