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IMPACT ASSESSMENT

Accompanying document to the

Proposal for a COUNCIL REGULATION

establishing a Community system for Registration of carriers of radioactive materials

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1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Agenda Planning

The recast of the Community regulatory framework regarding transport of radioactive material is included in the Commission's Legal and Work Programme as a simplification measure and was registered in the agenda planning by the Directorate-General (DG) for Energy and Transport as item 2008/TREN/005. Tabling the initial proposal in 2011 allowed for more in-depth consultation while following the procedure foreseen in the Euratom Treaty.

1.2. Organisation and timing

The then-Directorate-General for Energy and Transport launched the preparations in late 2006 when a codification study to assess the Community regulatory framework regarding the transport of radioactive material was commissioned.[1]

With a view to preparing this impact assessment report, ECORYS Nederland BV, a team of independent consultants, carried out a supporting study between October 2007 and June 2008[2].

The Impact Assessment Steering Group (IASG) including representatives of DG Environment, the Secretariat General and four different directorates of the lead DG took up its work in October 2007 and met in January and June 2008 to discuss the work progress. Taking onboard the results of the codification study as well as the appropriate remarks received in these discussions and the consultations presented below, the supporting study was completed in October 2008.

The IASG approved the draft report in May 2009; the Impact Assessment Board approved the report in July 2009 (while recommending certain improvements; see 1.4).

1.3. Consultation and expertise

1.3.1. Stakeholder consultation

Four main groups of stakeholders in the transport of radioactive materials were consulted for the supporting study:

- Competent Authorities (depending on the situation in the Member State, for example a ministry of health or transport, a national commission, institute, agency or state office);

- carriers, including standard carriers and those specialised in radioactive materials;

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[1] Riskaudit IRSN/GRS International, Study on the Codification of the European Union Regulatory Framework regarding the Transport of Radioactive Material, July 2007

[2] ECORYS Nederland BV, Impact Assessment of the Proposal for a Council Regulation on the Revision of the Regulatory Framework for TRAM Activities, August 2008

- main producers of radioactive materials in Europe, for example GE Healthcare, Amersham, CISBIO, Advanced Accelerator Applications, Covedien;

- users such as hospitals, clinics and the European Association of Nuclear Medicine (EANM)[3].

The Competent Authorities are by nature authorities of the Member States whereas the users, carriers and producers that have replied to the questionnaire are private organisations.

Of the 556 stakeholders approached, 64 have answered the questionnaire.

Organisation type	Approached	Number of respondents
Competent authorities	27	22
Carriers	351	13
Producers	46	7
Users	132	22
Total	**556**	**64**

Ten of the main stakeholders were interviewed (face-to face or by telephone) to get targeted information as well as specific input for impact evaluations.

From the users of transport, mainly hospitals and medical institutes in different countries have responded. Also the large producers in Europe like Advanced Accelerator Applications and GE Healthcare have replied. Moreover, the main producer of technetium, Covedien, has been interviewed. Airlines, logistic service providers and, of course, road transport companies were among the carriers that replied.

The Member States, via their members of the Standing Working Group for the safe transport of radioactive materials (SWG)[4], were regularly informed and consulted by DG Energy and Transport at each step of the study by electronic communication and in plenary sessions of the SWG in December 2007, June 2008 and 2009.

In addition and until June 2010, a sub-group of the SWG advised the Commission on the administrative procedures of the proposed initiative after the Group of experts referred to in Art. 31 of the Treaty establishing the European Atomic Energy Community (Euratom) had given its green light to the principles of the proposal in their meeting of November 2009.

[3] EANM has further distributed the questionnaire among ca. 100 members)

[4] The Standing Working Group (SWG), established in 1982 following a request of the European Parliament, consists of national experts with specific competence in the field of safe transport of radioactive materials.

1.3.2. Public consultation

As foreseen in the minimum standards for consultation[5], the public was consulted via internet ("Your Voice in Europe") from 10/12/2007 to 28/01/2008. A total of 54 answers were received.

1.3.3. Main results of the consultations

The stakeholder consultation showed a need for harmonisation and simplification of existing rules providing for a level playing field across the European Union. Among others, the following issues were highlighted:

- High legislative burden;
- Administrative complexity;
- Lack of consistency and cooperation between Member States;
- High costs of transport licences and training due to the multitude of Member States;
- Barriers to entry for carriers, in particular small and medium-sized enterprises.

Regarding available policy options, the stakeholders support a codification of existing rules. They are generally in favour of adjusted legislation if it reduces the legislative burden while diverging interests of the different groups lead to less clearer positions on specific questions. The national Competent Authorities, expectedly, refuse setting up a EU agency taking over their work (see Annex 1).

The public consultation via internet, while certainly not of such a high quality as for example the follow-up telephone calls, did not bring very clear results, but included a call for action at EU level, in particular with regards to soft measures and increased transparency of the existing rules (see Annex 2).

1.4. Impact Assessment Board

The Impact Assessment Board reviewed the draft report on 1st July 2009. In their opinion of 6 July 2009 the Board welcomed that the report provides a good overview of the existing legislative framework and a clear problem definition as regards the barriers to smooth transport operations in Europe. In addition, the Board recommended improvements on the description of the scope of initiative, certain aspects of the cost-benefit analysis, and the comparison of the options.

As agreed during the Board meeting, this report has been revised along the lines indicated. In particular, the scope of the initiative and the legal framework affected have been described in more detail in chapter 2.5 and the objectives adapted to this more concrete approach. Secondly, the underlying assumptions have been integrated into the main body of the text and the results of the cost-benefit analysis better

[5] General principles and minimum standards for consultation of interested parties by the Commission, COM(2002)704

explained in chapter 5 and Annex 3. Thirdly, chapter 6 on the comparison of the identified options has been edited to better clarify the criteria used and to identify the coherence with other EU legislation. Due to the social and political concerns, political feasibility and social acceptance have been addressed as well.

2. PROBLEM DEFINITION

2.1. Background

Radioactive materials are used in many applications that help us in our daily lives, ranging from healthcare, research, industrial manufacturing and agriculture to electric power generation. Radioactive material (RAM) is shipped in packages varying from small boxes with tiny amounts of radiopharmaceuticals for healthcare use to heavy steel containers with spent nuclear fuel and vitrified waste from the nuclear fuel cycle, both of which are highly radioactive materials.

According to a study on the transport of radioactive material (TRAM) in Europe[6] over 1 million packages of RAM were transported annually at the beginning of the last decade within, to or from the EU, over land, water and by air. These packages represent about 2% of all dangerous goods packages. Road transport is the most important transport mode for RAM shipments.

It is estimated that 2.5 million RAM packages are shipped annually across the EU, which represents about 2% of all dangerous goods packages. Most (nearly 90%) of these packages contain relatively small quantities of RAM.[7]

The packages for small quantities of RAM are either "Excepted packages" (for low-activity sources and materials; 15-30% of all packages) or "Type A packages" (for medium-activity materials for industrial and medical uses and able to withstand normal transport and handling conditions). The packages used in the nuclear fuel cycle are mostly large and heavy. These are the so-called "Type B packages" (for high activity materials and be certified to withstand severe accident conditions). In France, for instance, a country with a fully developed nuclear programme, about 750 Type B packages containing fuel cycle materials are transported per year, that is a mere quarter percent of all transported radioactive packages.[8]

Based on the registration data available from certain Member States, the Commission estimates that some 1000 to 2000 carriers active in the European Union.

TRAM traffic, both domestic and internationally, varies significantly between countries (see figure below). Whether a country has a national nuclear programme, a major producer or commercial supplier of radioisotopes for medical, scientific and industrial applications influences largely the volume of TRAM.

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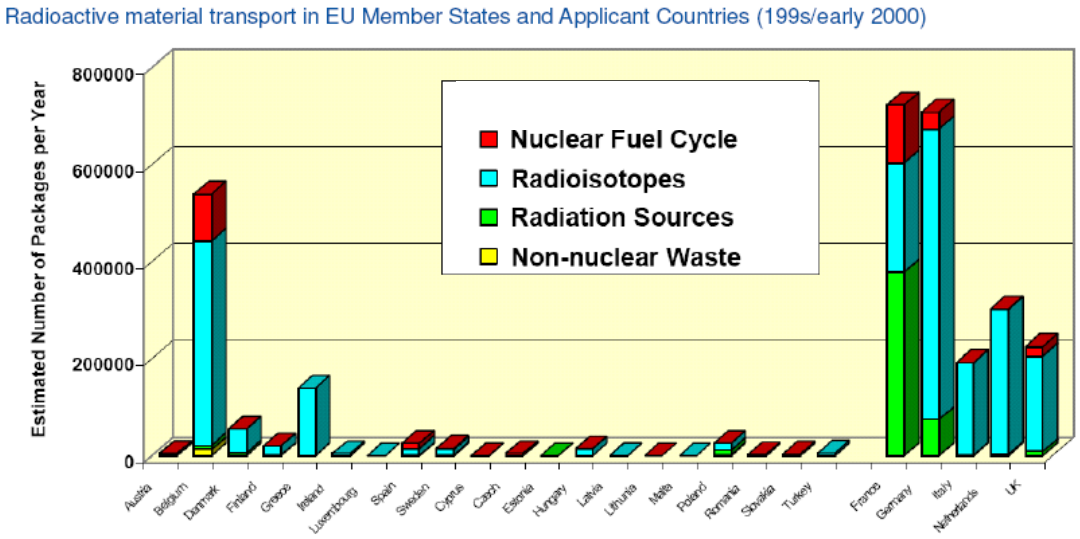
6 NPRB, GRS, ANPA, NRG, IRSN, CEPN, Statistics on the Transport of Radioactive Materials and Statistical Analyses. March 2003

7 Riskaudit IRSN/GRS International, Study on the Codification of the European Union Regulatory Framework regarding the Transport of Radioactive Material, July 2007

8 European Parliament, Commission on Regional Policy, Transport and Tourism, Hearing on Nuclear Transport, 21/06/2000



Source: NRPB et al. (2003)

Given the nature of RAM, its handling, use and its transport in the public domain, adequate attention is required in order to protect the public and workers exposed to RAM and to prevent any releases to the environment. The safety of TRAM is ensured by a large set of binding and non-binding rules. This regulative framework for the transport of radioactive materials comprises international, European and national legislation, which creates a rather complex regulatory framework. Figures indicate that the transport of radioactive materials is the safest category of transport.

As a **general principle**, if you want to transport RAM you may need

- an approval of the package containing the material,
- a licence or registration for the carrier allowing him to transport RAM,
- depending on the quality of the material, an approval for the shipment from or a notification to the relevant Competent Authority.

A major fraction of RAM transports are trans-boundary shipments[9] in which case all or a sub-set of these four administrative steps need to be taken in every Member State. The problem is compounded by the fact that Member States differently interpret international arrangements and EU Directives and/or have additional requirements.

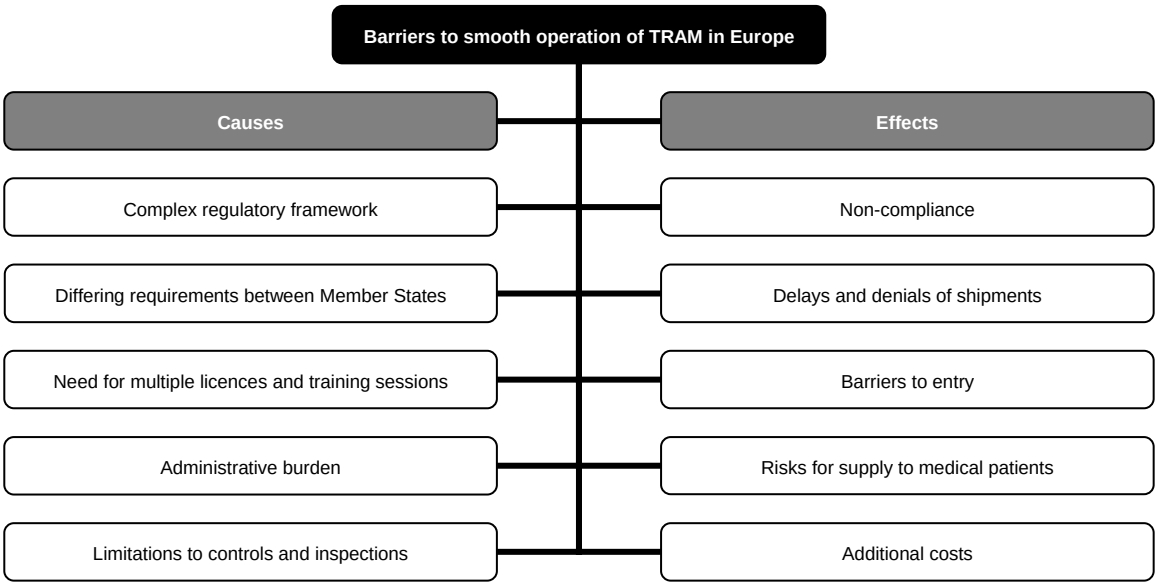
Some of these deviations of, for example, licensing or approval requirements at Member State level interfere with fundamental goals of the EU, such as the internal market.

All in all, TRAM is more expensive and more regulated than other – partially equally hazardous - classes of dangerous goods.

[9] This is particularly true for many radioisotopes used in medicine where only a few production centres exist worldwide.

The objective is, therefore, to examine whether and how Community legislation should be revised in order to assure high safety standards, prevent undue burden on all parties, including the Competent Authorities, and mitigate the barriers to the smooth functioning of TRAM in Europe.

On basis of multiple reports and the interviews already held with experts in the field of TRAM, drivers and effects of these barriers have been summarised in the following figure and are analysed in the two chapters following the overview of the legal framework.



2.2. Overview of the regulatory framework

TRAM Legislation has developed in the past decades leading to a body of existing regulatory instruments and regulations consisting of:

- International rules

– International regulations, like the UN Model Regulations including the IAEA Transport Regulations,

– Modal Regulations of the regional and international transport organisations (International Modal Regulations),

– A variety of international conventions, codes and agreements.

- Community law

- National law

This framework assigns specific responsibilities of compliance with certain duties, requirements and practices to the parties involved in TRAM (e.g. Competent Authorities, transport operators). To reach the primary objective of ensuring safety and security, TRAM is subject to a more stringent regulatory regime than other dangerous goods as it is being covered by, on the one hand, the rules governing the

transport of dangerous goods and, on the other hand, radiation protection requirements.

2.2.1. International rules

2.2.1.1. International regulations

Radioactive materials are classified as Class 7 out of nine classes of dangerous goods whose transport is governed by the United Nations "Recommendations on the Transport of Dangerous Goods".

The International Atomic Energy Agency (IAEA) is tasked to formulate specific recommendations for the transport of Class 7 materials. The standards are defined in the IAEA Safety Requirements No. TS-R-1 "Regulations for the Safe Transport of Radioactive Materials" (latest edition of 2009) and are included in the UN Recommendations.

The IAEA Regulations establish the standards of safety which provide an acceptable level of control of the radiation, criticality and thermal hazards to persons, property and the environment that are associated with the transport of RAM.

These IAEA Transport Regulations are of a recommendatory nature and not legally binding but for the IAEA's own activities. Member States and transport organisations concerned are encouraged, however, to take the Regulations as a basis for corresponding national laws and regulatory activities. Currently, almost all international organisations concerned and more than 60 IAEA Member States are known to have adopted the recommended Regulations directly or indirectly for their own regions.

2.2.1.2. Modal Regulations

The IAEA Regulations have been incorporated into the mode-specific regulations by specialised regional and international organisations, as presented in the following table:

Mode of transport	Organisation	Modal Regulation
Road	UN/ECE	European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)
Inland waterways	UN/ECE	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)
Inland waterways	CCNR	Provisions concerning the Carriage of Dangerous Goods on the Rhine (ADNR)
Rail	OTIF	Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID)
Air	ICAO	Technical Instructions for the Safe Transport of Dangerous Goods by Air (TI)
Air	IATA	Dangerous Goods Regulations (DGR)
Sea	IMO	International Maritime Dangerous Goods Code (IMDG Code)
Post	UPU	Universal Postal Convention and its detailed regulations

These Modal Regulations are binding to those countries that are parties to the agreements. Most EU Member States are party to the Modal Regulations[10].

2.2.1.3. International conventions, codes and agreements

Next to these specific transport rules, there are additional international conventions and agreements on civil nuclear liability, physical protection, early notification, mutual emergency assistance and safeguards control of nuclear material which also affect TRAM.

These rules have found wide acceptance and are only binding to contracting parties. Their number being limited (about 10) this legislation does not greatly increase the complexity of TRAM.

2.2.2. Community regulatory framework

Safety in the transport of radioactive material is a primary concern of the European Union and its Member States.

The legal basis for the actions at European level lies in the Treaty on the Functioning of the European Union (TFEU), which makes transport a shared competence, in particular in Title VI, and in chapter 3 of title II of the Euratom Treaty, which provides the legal frame for setting the basic standards on radiation protection.

Council Directive 94/55/EC with regard to the transport of dangerous goods by road has made the provisions of the Modal Regulation for road transport (ADR) uniformly applicable to road transport by adopting in particular the technical annexes to the ADR agreement. These annexes set standards for the classification, packaging and labelling of dangerous goods and the construction of vehicles used to transport them. A similar Directive was introduced for the transport of dangerous goods by rail (Council Directive 96/49/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail). Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods combined all inland transport modes of dangerous goods, which significantly simplified Community rules.

In addition to the legislation based on the EC Treaty, specific TRAM rules are based on the EURATOM Treaty, whereby Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation is particularly relevant. Article 2 of this Directive defines transport as one of the "practices which involve a risk form ionizing radiation emanating from an artificial source or from a natural radiation source in cases where natural radionuclides are or have been processed in view of their radioactive, fissile or fertile properties". Hence, Articles 3 and 4 apply, under which "reporting" (requirement of submitting a document to the competent authority to notify the intention to carry out a practice) is required by carriers and Member States can impose prior "authorization" (a permission granted in a document by the competent authority, on application, or granted by national legislation, to carry out a practice on carriers). This allows

[10] Except Malta, Cyprus and Estonia for RID

competent authorities to better check if the standards contained in that Directive are being respected.

In addition, two shipment control procedures are in force to supervise the movements of radioactive materials between Member States (Council Regulation (Euratom) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States) and the supervision and control of shipments of radioactive waste and spent fuels (Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel). Finally, Council Directive 89/618/Euratom of 27 November 1989 on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency and Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources also touch upon transport.

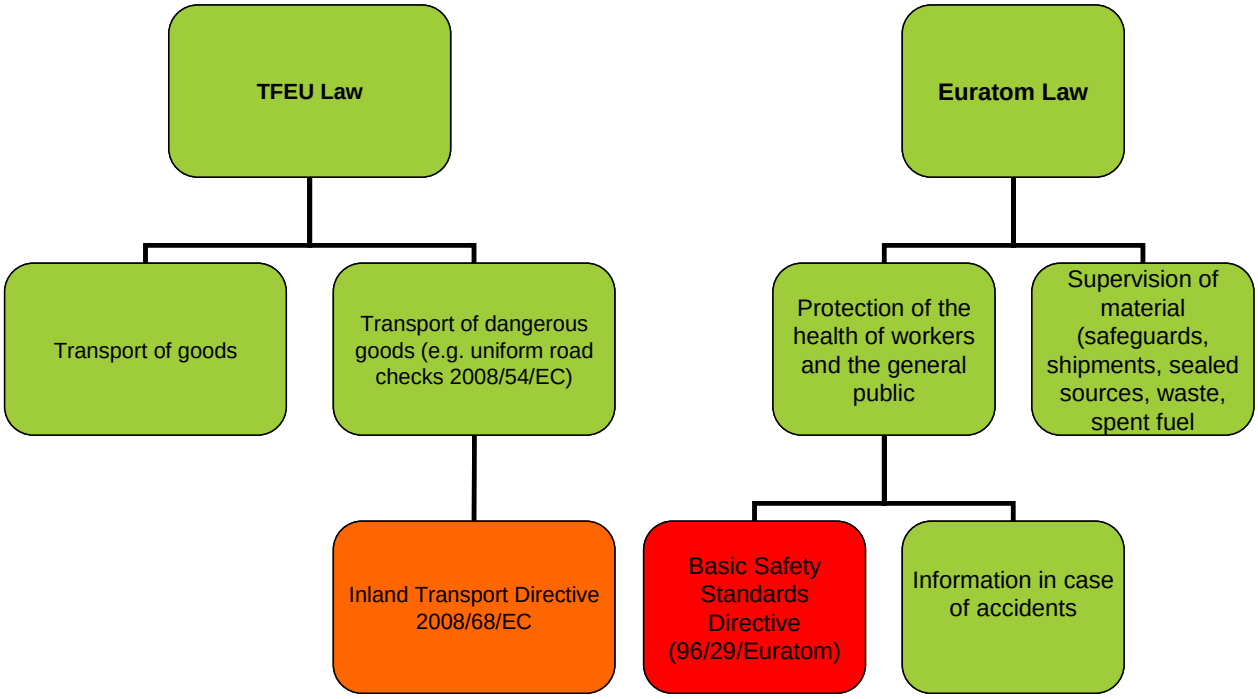
The Directives are complemented by a number of legal instruments and associated EU legislation.

These instruments state many duties, obligations and technical and administrative requirements to both Member States and transport operators as indicated in the following table.

The duties and obligations that have to be established with the transport of RAM in general are for example the following[12]:

- Implementation and application of the EURATOM Basis Safety Standards for radiation protection
- Approval or notification of certain transboundary shipments of radioactive material within and into and out of the Community
- Appointment of safety advisors by hazardous material transport operators and the establishment of minimum examination requirements
- Application of uniform procedures for checks of dangerous goods shipments by road
- Information of the general public in the case of a radiological emergency
- Application of the provisions of the EURATOM safeguards to prevent the spread and misuse of specials nuclear material and explosive nuclear weapons
- Notification of the competent authority of the Community port Member State by vessels carrying dangerous or polluting goods
- Cooperation between the Community and Member States in civil protection assistance interventions in the event of major emergencies, e.g. natural, technological, radiological or environmental accidents.

In a simplified way, the acquis ranging from general to very specific rules can be regrouped in the following way:



2.2.3. National law

National laws of EU Member States related to the transport of dangerous goods, use of nuclear energy, radiation protection, security, waste management, occupational and industrial safety etc. do result in additional requirements for the transport of radioactive materials. By transporting radioactive materials across several Member States, the different sets of national legislation result in a web of differing regulations. Among others this is the result of EU Directives defining minimum levels. This is for example the case of Council Directive 96/29/Euratom on the basic safety standards, where Member States have, if at all, implemented the reporting and authorization requirements of Art. 3 and 4 in different ways.

Some examples of such differences can be found in the following table:

National additional requirements for notification of international; shipments to, through and from (including landing in).

Country	National extra establishment requirements
Belgium	Prior authorisation needed activity and fissile quantities exceeds limits of Belgium Royal Decree
Denmark	Prior authorisation needed when notification according TS-R-1 § 559 is required (additional criteria for fissile materials), also for over flights, see previous table
France	Prior authorisation*) when notification according to TS-R-1, § 559 is required (notification at least 24 hrs in advance of shipment)
Germany	Prior authorisation needed activity > 1000 TBq and fissile quantities exceeds German limits of U-233 + U-235 + Pu-239 + Pu-241 > 15 g and concentration > 15 g/100 kg
Italy	Prior authorisation required when notification according to TS-R-1, § 559 is required and/or materials of fissile class I, II and III are shipped (notification at least 48 hours in advance of shipment).
Netherlands	Notification for all RAM > exemptions table 2.12. Permission is required in case of shipments of fissile materials, see previous table and also in case of shipment to and from the Netherlands of consumer goods and medicinal products with activity > exemptions of table 2.12 and consignments with 0,1% fissile materials (3% in case of Th) and > exemptions from Table 2.12
UK	See France

*) see requirements for B(M) multilateral of TS-R-1, § 820, and requirements as used for special form in case of transport by air , see TS-R-1 § 416.

2.3. Causes for problems related to the transport of radioactive materials

Stakeholders have repeatedly referred to the following causes for problems on TRAM:

2.3.1. Complex regulatory framework

The transport of radioactive substances has been subject to a comprehensive and stringent regulatory regime for many years which has helped to assure safety of the public, the environment and the workers involved. As a matter of fact, there has never been a transport incident that has caused significant radiological damage to persons or the environment over the past decades. This is in large parts due to the implementation in Europe of the IAEA Transport Regulations which, as mentioned above, provide for an acceptable level of control of the radiation, criticality and thermal hazards to persons, property and the environment that are associated with the transport of RAM.

Many rules are, as the codification study concluded, indispensable given the technical complexity in providing an acceptable level of safety and prevention against the hazards arising from radioactivity and proliferation potential.

Nevertheless, TRAM activities are nowadays more heavily regulated than other dangerous goods. The complete set of rules has many layers, making it overly complex. Thus the main objective has been achieved – at the cost of having a very complex system.

2.3.2. Requirements differ between Member States

As seen above, there are major differences between Member States in terms of procedures, assessments, administrative requirements and application formats, which are not relate to safety. There is ample room to decrease the burden, in particular with regards to extra requirements that rather interfere with fundamental goals of the EU, such as the internal market.

2.3.3. Need for multiple licences and training sessions for trans-boundary transports

Unlike for other classes of dangerous goods, carriers of RAM may need particular licences in a majority of Member States. The costs for obtaining these licences and the costs for training, especially of the drivers, are high in comparison to the amount of class 7 goods to be carried. Most licences cost between a few hundred Euros and three thousands Euros.

However, it is the fact that you need several of these 'national' licences, which by the way have to be renewed at differing, but often short intervals, that substantially drive up the costs. A carrier regularly transporting radioisotopes from Belgium to Italy would need the corresponding licences from several Member States involved.

2.3.4. Administrative burden

The administrative burden for transport of medical RAM is comparatively heavy, among others due to shipment notification requirements.

2.3.5. Limitations to controls and inspections

The stakeholder consultation emphasized that there is a shortage of resources with the Competent Authorities to check TRAM activities appropriately - notwithstanding the fact that enforcement is considered as very important.

2.4. Effects

These causes lead among others to the following effects:

2.4.1. Non-compliance

The current complexity of the current legislation has led to a situation where inspections reveal a relatively high number of non-compliant transports. According to data for Belgium, 58% of TRAM vehicles inspected were considered to be non-compliant, compared to 40% of non-compliance for transport of dangerous goods in general. According to information of the French authorities they experience most problems with relatively small carriers and less frequently with the larger specialised carriers.

According to a recent evaluation, frequent reasons for non-compliance in dangerous goods in general appear to be found in incorrect transport documents, missing orange panels and fire extinguishers as well as inappropriate vehicles or packaging.[11]

This certainly calls for more stringent enforcement by the relevant bodies, which in turn requires them to have a better oversight of who the market participants are.

2.4.2. Delays and denials of shipments

National official bodies cannot deny the transport of radioactive material if shipments fulfil the compulsory requirements. Nonetheless, carriers, ports and handling facilities do deny shipments – for two main causes: Negative perceptions of radioactive materials as well as the complexity of regulation and related costs.

Some ferry services and harbours, for example, have refused to transport and handle radioactive material although the risk created by the material is very low; even "excepted packages", which per se do not pose any danger to persons involved in their transport, have been refused.

Delays and denials of shipments are of growing concern. According to information by the IAEA, which has set up a Steering Committee on Denial of Shipments in 2006, there are more and more denials in international shipments. Indeed, data reported to the IAEA over a six-month period between September 2007 and March 2008 indicate 69 reports of delays and denials of shipments. Most of these were delays (42). The majority of the reports concerned air transport (46 reports), while the remaining 23 cases concerned sea, rail and road transport. Most of these reports concerned radioisotopes used for medical purposes (e.g. iodine-131, fluorodeoxyglucose and cobalt-60) with short half-life times. It can be fairly assumed that the majority of denials goes unreported.

2.4.3. Barriers to entry

Increasingly, the transport of radioactive materials is becoming a case for specialised large carriers. As a result of the complexity of the regulatory framework and the high costs that are associated with compliance with the rules, effective barriers to market entry exist for new (and especially small and medium-sized) carriers. Due to their specialisation, the remaining established carriers, in addition to benefitting from the reduced competition, appear to be able to run TRAM without major difficulties.

However, the lack of competition and the dependence on a limited number of specialised carriers do represent inherent risks to the transport of RAM. This is further aggravated in the field of medical isotopes where only very few production centres exist. Therefore, the lack of competition contributes to making the system of transporting RAM vulnerable.

In addition, certain Member States are reported to have national rules which either keep foreign carriers off their markets or put them at a disadvantage to their own carriers.[12]

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[11] European Commission (2005) Evaluation of EU Policy on the Transport of Dangerous Goods since 1994 (TREN/E3/43-2003) – Final Report

2.4.4. Risks for supply to medical patients

Radioactive materials are widely used in hospitals, most commonly for the purposes of diagnosis and treatment. Some of the radioactive materials are transported to hospitals and then dispensed and used on a regular basis, sometimes weekly, to ensure a constant supply. Problems with the transport of radioactive materials might have an impact on the treatment of patients, especially in the case of last-minute shipments of short-lived medical radioactive materials, which by definition have a limited preparation time.

The Council has reviewed the security of supply of radioisotopes and invited the Commission and Member States "to propose measures to ensure efficient transport of radioactive material within the European Union"[13].

2.4.5. Additional costs borne eventually by the society at large

All these four effects contribute to pushing costs up. In general terms, certain experience shows that TRAM can be 15 to 20 % more expensive than the transport of other classes of dangerous goods.

These costs must ultimately be paid for – first by the users. In the case of medical uses they are ultimately borne by the social security systems of Member States, an aspect that has not been considered in detail yet.

2.5. Scope of an EU level initiative

Facing these problems, DG Energy (and Transport, before the recent split) has embarked on a review of the issues involved and the possible solutions. Whereas the initial idea was to recast the complete legislation governing the transport of radioactive materials, it soon emerged that the main issue with TRAM, when compared to other classes of dangerous goods, are the existence of differing administrative requirements when implementing the Basic Safety Standards Directive 96/29.

Acknowledging the work undertaken by the Standing Working Group and the Association of Competent Authorities of a sub-set of Member States, in particular on package design approval, and replying to the request by the SWG "to review the justification of these variations and assess the cost-benefit of harmonisation of these requirements within the EU"[14], the Commission focussed on these administrative procedures for the access to the carrier market.

As seen above, Directive 96/29 defines transport as a so-called "practice" for which Member States have to define reporting requirements and may define authorisation requirements.

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12 There is anecdotal evidence that certain transports have even been cancelled because the Competent Authority was very difficult to reach

13 Council Conclusions on the security of supply of radioisotopes for medical use, 2986th AGRICULTURE and FISHERIES Council meeting, Brussels, 15 December 2009

14 6th Report of the Standing Working Group on the Safe Transport of Radioactive material in the European Union (March 2009), p. 9

Out of the 22 Member States that replied to a questionnaire sent out by the Commission in July 2009, six Member States (Austria, Czech Republic, Finland, Sweden, United Kingdom) require neither a licence, nor a registration for carriers. In Denmark and Spain only a registration is required while six countries (France, Germany, Lithuania, Netherlands, Poland, Slovenia) have introduced a "graded" licence or graded authorisation (with stricter rules for more dangerous materials) and eight others (Belgium, Bulgaria, Greece, Ireland, Italy, Luxembourg, Romania, Slovakia) use a general licence (all packages, all modes).

As the Standing Working Group notes, and as companies involved confirmed, this "could jeopardise the proper functioning of the internal market in this sector" – apart from being one of the causes of denials. "EP and Council are invited to support measures aimed at reducing unjustified administrative and regulatory burdens for the safe transport of RAM"[15] .

It must be noted at this stage that the scope of any new initiative will not and cannot interfere with rules on safety, security, safeguards, control of sources where these rules continue to apply.

Taking into account

- the need to provide for high safety standards for the transport of radioactive materials in all 27 Member States ,

- the need to tackle the problems encountered in trans-boundary transports, in particular, the variety in the implementation of Articles 3 and 4 of the Basic Standards Directive,

it is more than evident that EU action can help to harmonise and simplify rules in the Community and increase transparency while continuing to guarantee a high level of safety.

3. OBJECTIVES

The **general objectives** of TRAM policy are directly linked to the fundamental objectives of EU policy, as applied in this particular field, i.e.,

- to ensure and maintain adequate safety standards in order to protect the public and the environment during transports of radioactive materials and

- to aim at a European single market for services for the transport of radioactive materials.

Both these general objectives are enshrined or at least referred to in the EURATOM Treaty, but can similarly be found in the TFEU. They underscore that actions on TRAM can very well contribute to the Europe 2020 strategy and the simplification of legislation.

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[15] 6th Report of the Standing Working Group on the Safe Transport of Radioactive material in the European Union (March 2009), p. 10

Considering the specificities and relatively low number of transports involving fissile materials, the main problems concern radioisotopes and radiation sources. Hence, the **specific objectives** of the proposed Community action should be:

- to guarantee the safety and health protection of citizens during the transport of radioactive materials in the territory of the EU,
- to help remove obstacles to the internal market in this sector,
- to increase transparency in TRAM legislation allowing carriers and users to easily find the information needed and identify the authorities involved easily,
- to create the appropriate legislative and organisational conditions to ensure delivery in time and in good conditions of the life-saving radioisotopes that are essential for trials and therapy treatments for a large number of diseases.

Finally, **operational objectives** are related to the specific outputs of Community action:

- to apply internationally accepted regulations so as to make repetitive Member States rules obsolete,
- to allow carriers to transport materials in the Community without the need for additional administrative procedures for registration or licences in other Member States,
- to establish national contact points guiding carriers to the relevant information and authorities,
- to abandon notification requirements for individual transports for radioactive materials – apart from fissile and high-consequence radioactive materials.

4. POLICY OPTIONS

In order to maintain the safety of TRAM activities, simplify legislation, increase transparency and eliminate barriers to a functioning internal market and after comparing different experiences in transport sectors as well as the available legal instruments, the following policy options were evaluated:

4.1. Baseline scenario: No policy changes/business as usual

Under this option, the scope and content of the existing EU legislation on TRAM would be kept in its present format. Member States would be in a position to continue setting their own administrative requirements for entry into the transport market.

4.2. Option 1: Commission Recommendation to harmonise implementation of existing law; website with access to legislation

Under this option, the Commission would make available a central website giving access to the different Competent Authorities, the legal framework and the forms

necessary in the different Member States. In addition, a Commission Recommendation would interpret the applicable rules of Directive 96/29 with a view to harmonising implementation and, in particular, to urging Member States to recognise, where necessary, the licences and registrations issued by other Member States.

4.3. Option 2: Regulation with harmonised rules and the Competent Authorities playing a more efficient role

A Regulation would go one step further – by proposing directly applicable harmonised rules such as a common registration system for carriers which does away with the different systems used in the Member States for the reporting and authorization and giving carriers access to the EU27 transport market in one "slimmed-down" procedure while adopting a graded approach. To allow for the necessary exchange of data, the Commission would set up a secure online registration system.

4.4. Option 3: Regulation with a new EU agency as central Competent Authority

Going beyond option 2, while ensuring safe standards and completing the internal market, an EU agency as central Competent Authority would oversee all transport of radioactive materials in the European Union and issue the licences and approvals needed, thereby replacing existing procedures in the Member States, in a manner similar to the European Aviation Safety Agency based in Cologne.

4.5. Excluded option

Currently, the Competent Authorities of certain Member States are cooperating more and more closely together on some of the procedures involved. Such a voluntary formation can be seen as an important first step to addressing some of the detected problems. However, the pace of change that will be initiated by this Association with regards to the different sets of existing national legislation risks to be slow and to remain limited to a subset of Member States. Independent experts having judged this option to be inferior to the alternatives mentioned above, this option was not considered any further.[16]

Nevertheless, the Commission is committed to building upon the results of this initiative and to foster closer cooperation of the authorities involved.

5. ANALYSIS OF IMPACT

The policy options presented above have varying degrees of economic, social and environmental impact. Even though the impact in general appears to be modest from a global viewpoint, the impact would be important enough for such a small sector.

[16] ECORYS Nederland BV, Impact Assessment of the Proposal for a Council Regulation on the Revision of the Regulatory Framework for TRAM Activities, August 2008

The impacts outside the European Union have been left out of the considerations as they are minuscule.[17]

5.1. Types of impact and underlying assumptions

The impacts are categorised in five groups, namely: Public sector expenses and fees, Regulatory effects, Transport operations, Safety and environment, and Social impacts. The following table gives examples of impacts under the different headings:

Public sector expenses, fees	Regulatory frame	Transport operations	Safety and environment	Social impacts
Fewer costs for coordination between Member States	Fewer derogations from the regulative framework	Decrease in delays of trans-boundary shipments	Level of safety in TRAM	Timely arrival of medicines due to less disruptions during shipment
Costs for establishing institutional means	Better and harmonised rules on TRAM at European level	Decrease of denials and non-compliance of shipments	Less fuel consumption and less pollution due to efficient shipments	Decrease of need for human resources as consequence of efficiency impacts
Change of costs for licences	Reduced complexity of regulations	Tear down entry barriers for small and medium-sized enterprises	Less exposure of the general public due to fewer disruptions during shipment	
	Decrease of costs due to less administrative burden			
	Costs of additional requirements in national law			
	Less time needed to approve TRAM			

For the first three groups, the experts of ECORYS have calculated the economic impact. The assessments in their support study were based on desk research, interviews and results of the stakeholder consultation. The nominal figures they came up with should be seen as a rough approximation because data available on the sector is scarce. In addition, only a few Competent Authorities and companies had provided the requested information.

In order to come up with figures, the researchers first estimated the costs under the three headings by focussing on administrative burden for competent authorities, carriers, producers and users, as well as costs for inspection, licence fees and denials of shipments. In doing so, the experts made use of, among others, costs communicated by competent authorities, the administrative burden calculations for dangerous goods of the UK Department of Transport, interviews with isotope producers and expert judgement.

[17] Outside enterprises would benefit of possible administrative savings, but they play a minor role, which is not expected to rise considerably.

To evaluate the impacts of the individual options, ECORYS experts defined coefficients indicating how far an initiative may reduce the different kinds of costs.

As to the transport operations, for example, the researchers proposed evaluating the costs of denials of shipments by splitting them in three parts: costs of waste, administrative costs and operational costs. Per denial these were assumed to set aside 5000, 750 and 1500 €, respectively. Multiplying these unit prices with the number of shipments resulted in the total potential costs to which the researchers applied different coefficients depending on the option evaluated. A Recommendation in their eyes would avoid 10% of denials, which results in savings of 180.000 € for operational costs alone. Adding up all these savings and additional costs under one headline leads to the amounts given in the table below. In the example, a Recommendation would lead to savings in transport operations of 900.000 € per year.

For the public sector expenses, the researchers estimated institutional costs per option, e.g. € 5 million for an EU agency or the costs for additional inspections. Commission services estimated the costs for licences based on the rough information available.

The savings related to the regulatory framework were calculated by using the administrative burden calculations for dangerous goods of the UK Department of Transport, which allows to calculate burdens along the transport chain.

More details on the assumptions underlying the calculations as well as the assessment of the impacts of the options can be found in Annex 3.

The impacts on safety and environment as well as the social impacts are not quantitatively defined, but are presented in a qualitative manner since there is not enough detailed information available to present figures.

The following assessments include, by the way, the expectations that stakeholders voiced during the stakeholder consultation.

5.2. Baseline scenario

The absence of any serious accidents shows that the current legal framework does ensure safe transport operations.

Under the baseline scenario**,** the current inconsistencies in legislation and the high administrative costs are likely to remain – potentially leading to reduced competition, barriers to entry and risks to the supply of radioisotopes in the medical field. The varying legal regimes in the Member States would continue to exist and transporters would continue to suffer the burden described above.

5.3. Option 1: Commission Recommendation to harmonise implementation of existing law; website with access to legislation

A Recommendation on how to interpret existing legislation is largely welcomed by producers and users. The Competent Authorities see the advantages on specific topics, whilst carriers on average do not see the point of a Recommendation. This legal tool is expected to reduce delays and denials and to remove barriers to entry.

Competent Authorities and producers, on the one hand, assume that a Recommendation may contribute to reducing derogations in Member States and increasing harmonisation. Users and carriers, on the other hand, doubt this effect.

As a Recommendation is, however, not binding in nature, differences between Member States are likely to persist. Users, carriers and producers can expect variations between those countries that have implemented the Recommendation and those that have not. ECORYS estimated the savings at € 1.9 million per year over the baseline scenario. The administrative costs would be reduced by € 1.2 million.

Costs		Savings	
Public sector expenses, fees	0,6	Regulatory frame	1,6
		Transport operations	0,9
		Total impact	**1,9**

Safety and environment	+	Social impacts	x

Increasing transparency by making all information available at one central point, in addition to the Recommendation, could increase the impact while only creating a negligible strain on Commission resources.

This option does not guarantee the reduction of the burden on the part of users, carriers and producers. At the same time, the internal market is unlikely to be completed.

5.4. Option 2: Regulation with harmonised rules a and more efficient role for the Competent Authorities

By providing, among others, for the mutual recognition of licences for carriers, a Regulation would lead to savings of € 13.6 million per year over the baseline scenario. Such an approach would reduce the bureaucratic burden on carriers, users and producers while freeing up resources in authorities, which could then be used, at least partially, for compliance checks, the lack of which has been identified as one of the problems above. The administrative costs of enterprises would be reduced by € 7.35 million.

The Commission would have to cover the electronic registration system whose development is estimated to cost € 400.000 while hosting and maintenance is estimated to cost € 50.000 annually; these figures are included in the public sector expenses.

The effects on transport operations considerably higher than under option 1, the security of supply of radioisotopes can be enhanced and the social impacts of this option are therefore positive.

Costs		Savings	
Public sector expenses, fees	1,4	Regulatory frame	9,8
		Transport operations	5,2
		Total impact	**13,6**

Safety and environment	+	Social impacts	+

On average, stakeholders are in favour of such adjusted legislation. They support, in particular, uniform licences and expect considerable impacts of such an approach.

However the adjustments in legislation could result in some regulators losing revenues. All respondents emphasised that such new legislation may not lead to a higher administrative burden for any of the parties active in the transport of radioactive materials in Europe.

Because a Regulation is binding, this option will be effective in helping to attain the objectives – i.e. to simplify the system, introduce transparency and eliminate barriers to a functioning internal market while maintaining a high level of safety.

5.5. Option 3: Regulation with a new EU agency as central Competent Authority

This option combines the advantages of a Regulation with a central and harmonised implementation of rules through a central Competent Authority as EU agency. ECORYS estimated that savings could reach € 13 million annually. The administrative savings would reach € 9.75 million.

Although most stakeholders are against an EU agency, they believe such an agency could generate many positive impacts. An EU agency in conjunction with a Regulation will ultimately reduce the derogations of the regulatory framework to zero and greatly reduce the complexity of the framework by harmonising it. Furthermore, according to the stakeholders, the number of denials and delays would decrease.

The expectations that establishing an EU agency could generate positive impacts are endorsed by the calculations in the table underneath. The biggest possible reduction is related to the regulatory framework. On the other hand, running an EU agency costs additional money, estimated here at € 5 million, driving up the costs for this policy options.

The effects on transport operations are considerably higher than under option 1, the security of supply of radioisotopes can be enhanced and the social impacts of this option are therefore positive.

Costs		Savings	
Public sector expenses, fees	5,2	Regulatory frame	13,0
		Transport operations	5,2
		Total impact	**13,0**

Safety and environment	+	Social impacts	+

Given the nature of the measures included in this option, the objectives are achievable, although a certain doubt may persist as to whether this option complies fully with the subsidiarity principle and with the current restrained approach concerning new agencies.

5.6. Effects on small and medium-sized enterprises

The exact effects on small and medium-sized enterprises are hardly computable given the data available. Taking into account that in particular small ones are often

effectively blocked out of the market today, they tend to reap a major share of the expected savings.

In general terms, small and medium-sized enterprises are expected to benefit in proportion to the total savings achieved under the above options: the higher the savings in total, the higher the savings for these enterprises. Options 2 and 3 would be, therefore, most beneficial for them.

6. COMPARING THE OPTIONS

6.1. Summary of impacts

In general, all options other than the baseline scenario lead to additional costs on the public administration side, either by additional structures that need to be set up or a loss of income. These costs are always outweighed by the savings due to a better regulatory framework and easier transport operations. Safety is estimated to go slightly up once the general rules are harmonised as unclarities about differing rules disappear.

The social impact, that is, mainly the secure supply of radioisotopes as far as it is impaired by transport operations, would be more positive under options 2 and 3.

Whereas transparency for carriers can be increased under all non-baseline options, there are certain doubts with regard to option 3 in the context of subsidiarity.

The following comparative tables summarises the estimated impact for the options.

COMPARATIVE TABLE OF EFFECTS				
	Policy options			
	Baseline	**Recommendation**	**Regulation**	**EU Agency**
Calculated expected total impact (in million € p.a.)		1,9	13,6	13
Safety and environment		+	+	+
Social impacts			+	+
Transparency, access to information improved		+	+	+
Subsidiarity	+	+	+	-

6.2. Preferred option

With regards to the stated objectives, a central European Competent Authority (option 3) appears to be a very effective solution. However, the high costs involved with setting up such an agency completely negate these advantages compared to option 2. In addition, the following aspects have to be factored in:

- The success of such an initiative is highly unlikely: Member States, and the Commission itself, are very critical of setting up additional EU agencies;

- The whole process of setting up such an agency and making it work is time consuming, concrete results can only be expected years after the decisions enter into force;

- The solution is problematic in relation to the subsidiarity principle and proportionality as a similar value added could be reached by measures that leave responsibilities with the Member States.

Against this background, a **Regulation making use of the national Competent Authorities (option 2), which in addition leads to the highest estimated savings of all of the options, is clearly the preferred option**. By simplifying parts of the existing legislation, harmonising its implementation and providing for recognition of licences, this option is **effective, feasible and acceptable**.

Under certain circumstances, this option could be complemented by setting up the website contained in option 1 with information on the different Competent Authorities, the respective national legal framework and the necessary forms.

6.3. Political feasibility and social acceptance

As radioactivity, and in particular nuclear energy, raises tensions, the social acceptance and the political feasibility of any measure to be taken in these areas need to be carefully evaluated.

With regards to this initiative it is important to recall again that the safety concept for the transport of radioactive materials very much depends on the safety of the transport container and that the international rules as implemented in the EU and its Member States provide already for an acceptable level of control of the radiation, criticality and thermal hazards to persons, property and the environment.

A Regulation on the implementation of the reporting and authorization requirements will not change anything about that. The same goes for other rules concerning, for example, security, safety, third party liability or safeguards.

On the contrary, this proposal will contribute to assuring the supply of radioisotopes in the medical sector.

6.4. Proportionality

The preferred option strikes a careful balance between effective protection of workers and the public during TRAM 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 while keeping the costs within reasonable limits.

7. MONITORING AND EVALUATION

Following the preferred option by making use of a Regulation reduces the need for monitoring implementation in the Member States as a Regulation would apply immediately throughout the EU. Nevertheless the proposed change should also be evaluated against the objectives defined above.

DG Energy proposes to follow the expert advice received and to evaluate the effects of this Regulation two years after it has entered into force. This interim evaluation could reveal any difficulties and bottlenecks to be resolved. After this initial evaluation it might be useful to revisit the issue at five-year intervals to monitor what barriers to the smooth operation of the transport of radioactive materials in the European Union may still exist.

Use could be made in this context of the expert group which might be needed in order to advise the Commission on the administrative requirements under the proposed instrument.

Annex 1: Stakeholder consultation during the supporting study

A questionnaire was distributed among a series of stakeholders: competent authorities, carriers, producers and users. Out of 556 stakeholders approached, just 64 respondents answered the questionnaire.

SUMMARY TABLE OF THE FOCUSED CONSULTATION					
Organisation type	**Questions**	**Answers (number)**			
		Fully agree	**Agree**	**Not agree**	**Fully not agree**
Competent authorities *Approached: 27* *Respondents: 22*	Are actual TRAM problems?	2	14	3	2
	TRAM legislation is relevant in your country?	13	8	0	1
	Legislation is easy to understand?	4	13	4	0
	Legislation is not interpretable?	2	9	10	1
	Legislation is effective?	10	11	0	0
	Are important independent external audits?	7	9	5	1
	Clarity of the system can be improved for consignors	1	10	8	2
	The system is not clear for carriers	0	5	11	5
	The system is not clear for consignees	0	3	10	5
	You provided carriers standard sufficient information	5	9	4	3
	Import/export need notification in your country	7	10	1	1
	Licence required in your country	10	4	3	4
	Licence is not free of charges		15	4	
	Transporters of radioisotopes only need 1 licence	6	3	7	1
	Licence should be valid in multiple countries	6	6	5	2
	Administrative burden is high in your country	1	4	9	6
	CA are responsible to control carriers	12	5	1	3
	CA are enough resources to control carriers	5	4	7	3
	CA are aware of other countries requirements for application procedures	7	11	4	0
	Are you in favour to harmonise the procedures	10	10	1	1
	Have you additional requirements to international ones	5	7	5	5
	Harmonisation should be done by the EC	6	10	1	3
	Besides safety, security requirements are needed	7	12	2	1
	Security provision in ADR are adequate	2	11	8	0
	CA collect data of TRAM	4	12	3	0
	Should vehicles be equipped with tracking devices	2	9	9	1
	You have a safety plan in case of accident	11	10	0	0

	Are actual TRAM problems?	6	6	1	0
Carriers	TRAM legislation is relevant in your country?	6	4	2	1
Approached: 351	Legislation is easy to understand?	1	3	5	4
	Legislation is not interpretable?	2	2	5	4
Respondents: 13	Legislation is effective?	7	4	2	0
	Competent Authorities in your country give you the necessary information	7	6	0	0
	Competent Authorities in other countries give you the necessary information	3	7	0	2
	Licence required in your country	9	1	0	3
	High cost of licence		10	1	
	Transporters of radioisotopes only need 1 licence	1	2	3	5
	Administrative burden is high in your country	7	3	2	0
	Not harmonised regulation on EU level causes unfair competition	5	2	4	1
	The use of an uniform transport document would minimise denial and delays	5	5	0	2
	You send on regular basis TRAM data to your CA	7	1	3	2
	Should vehicles be equipped with tracking devices	4	3	5	1
	You have a safety plan in case of accident	10	3	0	0
	Denials are a main problem	1	4	7	1
	Denials are most of the time related to the content of packages	0	3	7	3
	Denials are most of the time related to documentation of packages	0	4	8	1
	Denials are in many cases relative to the negative perception of RAM	3	4	3	1
	Denials are in many cases related to a lack of harmonisation of TRAM legislation	0	7	3	3
	Denials are in many cases related to non compliance with international requirements	0	5	4	4
	Denials are the most common for type B packages	0	4	6	3
	Denials occur only for transboundary shipments	0	1	8	4
	Training is the most expansive indirect cost	2	6	2	3
	Are actual TRAM problems?	2	13	6	0
Users	TRAM legislation is relevant in your country?	6	13	2	0
Approached:	Legislation is easy to understand?	3	7	6	6
132	Legislation is not interpretable?	2	10	6	3
Respondents:	Legislation is effective?	6	8	8	0
22	Competent Authorities in your country give you the necessary information	5	12	3	2
	Administrative burden is high in your country	8	5	7	0

	Are you in favour to harmonise the procedures	13	7	1	1
	Are actual TRAM problems?	4	3	0	0
Producers	TRAM legislation is relevant in your country?	3	4	0	0
Approached:	Legislation is easy to understand?	1	4	2	0
46	Legislation is not interpretable?	0	5	2	0
Respondents:7	Legislation is effective?	1	5	1	0
	Competent Authorities in your country give you the necessary information	3	3	0	0
	Competent Authorities in other countries give you the necessary information	0	2	2	0
	Administrative burden is high in your country	1	2	3	0
	The use of an uniform transport document would minimise denial and delays	0	3	2	0
	Denials are a main problem	2	2	1	0
	Denials are most of the time related to the content of packages	1	1	1	1
	Denials are most of the time related to documentation of packages	0	1	2	1
	Denials are in many cases related to a lack of harmonisation of TRAM legislation	0	0	1	3
	Denials are in many cases related to non compliance with international requirements	0	0	1	3
	Denials are the most common for type B packages	0	1	1	1
	Denials occur only for transboundary shipments	1	2	0	0
	Transport cost is a reasonable part of the total cost	0	2	2	1
	There enough supply of carriers	0	0	4	1

Due to the specificity and complexity of the subject, the following statements should be advanced in the assessment of the results:

The number of inputs (answers) received in the different consultation processes is considered as relatively low to draw significant statistically conclusions in some of the categories of actors.

Some groups of consulted stakeholders have contradictory views due to their different involvement and role in TRAM activities (carriers vs. users or regulators). Therefore, the number of answer coming from each stakeholder's group could strongly bias the results based strictly on statistics.

Annex 2: Public consultation

The questionnaire in the public consultation process by Internet included 36 technical questions, related to Safety (10 questions), Administrative Burden (7 questions), Market (6 questions), Public Opinion (4 questions) and Policy Options (9 questions). 54 replies were received, of which 11 came from citizens and 43 from organisations/stakeholders. The questions and an overview of the distribution of replies are shown in the following table.

SUMMARY TABLE OF PUBLIC CONSULTATION				
Theme	**General question 1: What problems do you perceive in the field of TRAM?**	**Answers (%)**		
		Yes	**No**	**No opinion**
Safety	The certification of containers	33	50	17
	Package approval	30	56	14
	Regulatory labelling / making of containers	17	70	13
	Training of staff	30	63	7
	Conveyance / transport equipment	24	70	6
	Radiation protection programme	20	72	8
	Physical protection	30	63	7
	Quality assurance management	20	74	6
	Track and trace system	24	59	17
	Other	9	48	43
Administrative burden	Complexity for obtaining national permissions	41	50	9
	Complexity of notification procedures	32	59	9
	Cost for preparing / obtaining documentation	33	56	11
	Revalidation of package certificates	44	44	12
	Staffing resources	41	48	11
	Transport documentation	20	69	11
	Other	9	48	43
Market	Import / export requirements	17	59	24
	Delay of shipments	33	50	17
	Denial of shipments	32	48	20
	Additional fees affecting competitiveness	22	52	26
	Insurance	28	46	26
	Others	9	52	40
	Emergency, preparedness and response	30	61	9
Public opinion	Citizens concerns	48	41	11
	Incident notification	24	69	7
	Other	7	57	35

Theme	**General question 2: What proposals you believe could contribute to solve the above mentioned problems?**	**Yes**	**No**	**No opinion**

Business as usual	No need of action	26	44	30
	Other	24	35	41
	Implement harmonised / common information systems	63	24	13
Soft law measures	Common guides for transport preparation	74	18	7
	More efficiency emergency reports	33	62	15
	Others	12	44	44
	Amendment of Council Regulation 1493/93/Euratom	26	31	43
Regulatory measures	New directive superseding current regulatory measures	28	33	39
	Other	17	22	61

Annex 3: Impact calculations[18]

This annex describes, in more detail, how the impacts presented in chapter 5 of this report were calculated. To that effect, the annex presents first the assumptions used for the calculations followed by the assessment of the options themselves.

The assessments take account of expert judgements of researchers of ECORYS and the Nuclear Research Group (NRG), as well as interviews with competent authorities, producers and carriers.

It must be noted, however, that all calculations are based on a limited number of figures. Given the time and the budget for this project, the researchers had to work with the best available sources in order to approach reality for defining assumptions and calculating impacts. In the questionnaire and with help of separate mailing and telephone calls, the researchers have tried to gather as much reliable information as possible. In fact, only a few companies and competent authorities took the time to help with additional information for the calculations of the impacts.

The researchers proposed to look into the impact of the options on

– administrative burden for competent authorities,

– administrative burden for carriers,

– administrative burden for producers,

– administrative burden for users,

– inspection costs,

– fees for licences,

– costs of denials and delays.

Generally speaking, the researchers first estimated unit prices for the different impact categories. These unit prices were then multiplied with the applicable variables. To evaluate the effects of the different options, the researchers proposed to apply coefficients, specific for every option and based on their expert judgement, to these estimated amounts, resulting in the calculated impact per option.

To make this process clearer, let's take a look at how the effects on the administrative burden of competent authorities were estimated: from consulting authorities in five Member States (Belgium, France, Italy, Netherlands, Spain) the costs of procedures and administration (including personnel) were estimated at € 240.000 per country - multiplied by 27 the total cost within the EU amounts to € 6,48 million. Assuming that a Recommendation may reduce this

[18] This annex reflects the corresponding annex of the support study (ECORYS Nederland BV, Impact Assessment of the Proposal for a Council Regulation on the Revision of the Regulatory Framework for TRAM Activities, August 2008) and was adapted to take account of mainly editorial changes and the focus on the administrative options.

burden by 5% and a Regulation by 30% the effective savings would amount to € 324.000 or € 1,94 million, respectively.

This approach is repeated for each of the different cost types.

Adding up the single effects results in the amounts presented in chapter 5.

The next chapter gives additional information on the underlying assumptions and data sources whereas the final chapter gives some background on how the researchers came up with the coefficients for the options evaluated.

Assumptions for the impact assessment

- Administrative burden for competent authorities

A decrease or increase of the administrative burden of the competent authorities is calculated with help of the fixed costs per competent authority. On basis of information of the competent authorities of France, Italy, Spain, Belgium and the Netherlands the average fixed cost per European competent authority was estimated to be € 240.000. This includes, amongst others, cost of personnel, cost for training, and costs for participating in international meetings. For the whole EU, this amounts to € 6,48 million.

- Administrative burden for carriers, producers and users

By using the administrative burden calculator of the UK Department of Transport, that estimates the burden of regulations in the UK government and in particular for dangerous goods, the researchers have allocated costs to the different parties of the transport chain. Furthermore, the researchers assumed that the UK administrative burden is a ninth of the total burden within the EU (which is roughly in line with the UK share in the EU population). Finally a conversion in real terms provided the prices which then served for evaluating the options.

- Inspection

The costs of inspections are calculated on basis of information gathered from interviews. It is assumed that resources freed up in the competent authorities because of reducing the administrative burden would be used for additional inspections. The cost of inspections is estimated with help of the costs per inspector, as being the largest cost driver. Under the hypothesis that every country has 3 inspectors, this results in inspection costs of € 8.1 million.

- Licence

The costs of licences were not easy to estimate because there are large differences between countries in Europe. Commission services have assumed that 1500 carriers are active on the European market with licences for five countries costing 400 € each.

- Denials/delays

An effective initiative will contribute to reducing the number of denials and delays of shipments, e.g. by reducing the needs for (short-notice) notifications of individual shipments. The costs of these are composed of three different parts: the expenses for dealing with waste

as result of denials of shipment, the administrative costs of denials of shipment and the operational costs of denials of shipment. In case of a denial the radioactive materials that the shipment consists of have to be returned to the producer and recycled. The recycling costs are estimated at € 5.000 per shipment. The administrative handling costs are the procedures related to a denial and the resending of the package and are guessed to be € 750. In addition, the carrier may face additional operational costs in case the truck cannot continue, and the driver works additional hours, which is estimated to cost € 1.500. For the purposes of this impact assessment 1.200 cases of denials and delays are assumed to happen per year.

The table on the following page gives an overview of these assumptions:

Assumptions for calculations of impacts

Subject	Part of	Item (costs per year in €)	Unit	Unit price	Price	Source	Variables			
Administrative burden CA	Regulatory frame	Cost of procedures, administration	Cost per CA	240.000,00 €	6.480.000,00 €	Consultation CA FR, BE, NL, ES, IT	27	Number of CA		
Administrative burden carrier	Regulatory frame	Cost of procedures, administration	Cost for carriers	1.045.898,00 €	4.706.541,00 €	UK administrative burden calculations for dangerous goods	9	UK=1/9 of EU	0,5	Convert into real terms
Administrative bruden producer	Regulatory frame	Cost of procedures, administration	Cost for producers	4.740.352,00 €	21.331.582,00 €	UK administrative burden calculations for dangerous goods	9	UK=1/9 of EU	0,5	Convert into real terms
Administrative burden user	Regulatory frame	Cost of procedures, administration	Cost for users	22.083,00 €	99.375,00 €	UK administrative burden calculations for dangerous goods	9	UK=1/9 of EU	0,5	Convert into real terms
Inspection	Public sector	Cost of inspections	Cost per inspector	100.000,00 €	8.100.000,00 €	Interview Isotopes	27	Coutries	3	Inspectors per country
Licence	Public sector	Cost of licence	Cost per licence	400,00 €	3.000.000,00 €	Commission estimation	1500	Number of carriers	5	Licences per carrier
Denials	Transport	Cost of waste	Cost per denial	5.000,00 €	6.000.000,00 €	Expert judgement ECORYS/NRG	1200000	Number of shipments		
Denials	Transport	Administrative costs	Cost per denial	750,00 €	900.000,00 €	Expert judgement ECORYS/NRG	1200000	Number of shipments		
Denials	Transport	Operational costs	Cost per denial	1.500,00 €	1.800.000,00 €	Expert judgement ECORYS/NRG	1200000	Number of shipments		

Assessing the options

In order to assess now the impact of a certain initiative on the costs derived above, the researchers have estimated coefficients for each of the categories mentioned above under every option. In addition, they estimated fixed institutional costs per measure – for example the running costs of an EU agency under option 3.

These coefficients and costs are presented in the following table. Please note that positive values mean savings induced by the measure, negative values additional burden.

		Recommendation	Regulation	EU Agency
Regulatory frame				
Harmonisation	Costs CA	5%	30%	40%
Complexity	Costs Carrier	5%	30%	40%
Administrative burden	Costs Producer	5%	30%	40%
	Costs User	5%	30%	40%
Public sector expenses, fees				
Inspection	Costs Inspections	-5%	-15%	-40%
Licences	Costs Licences	10%	60%	60%
Institutional	Costs Institution	-500.000 €	-2.000.000 €	-5.000.000 €
Transport				
Delays and denials	Costs denials and delays	10%	60%	60%

In defining these values use was made of expert judgements by ECORYS and NRG. In doing so, they assessed many studies on the effects of harmonisation and reduced complexity in regulations in other sectors. The tendency of these reports is in general a positive effect. In the last couple of years, ECORYS has done several impact assessments in other transport sectors where the issue of harmonisation has played an important role. The outcome is that there are in general positive effects as results of harmonisation and less complexity. Therefore, this tendency is continued in this assessment by considering the impacts of the measures for the transport of radioactive materials.

As result of the closer cooperation of the competent authorities of member states, the expectation is that the developments on a multilateral approval of licences will further expand and will result in savings in the future. Also in case of organisational and legislative measures it is therefore expected that the costs of licences will considerably decrease. This expectation is equal for the delays and denials in TRAM. Harmonisation, less complexity, and faster approval of licences will have positive effects on the number of denials and delays.

The institutional costs are estimations about the costs needed for the establishment of a organisation like an EU agency. These costs are roughly assessed and are strongly hypothetical.