EUROPEAN COMMISSION

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**COMMISSION STAFF WORKING PAPER**

**SUMMARY OF THE IMPACT ASSESSMENT**

***Accompanying the document***

**Proposal for a COUNCIL REGULATION**

**establishing a Community system for registration of carriers of radioactive materials**

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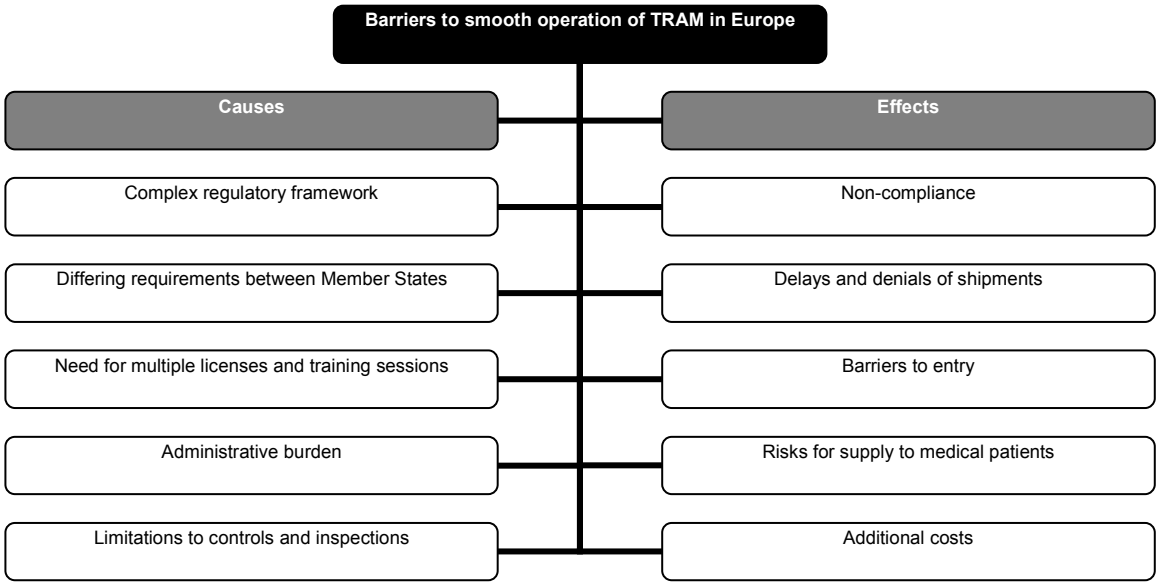
## 1. PROBLEM DEFINITION:

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.

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.




Stakeholders involved in the transport of radioactive materials (TRAM) have repeatedly voiced their concern about **barriers to the smooth functioning of TRAM activities in Europe**. They complain about a complex regulatory framework, differing requirements between Member States, the multitude of licences, approvals and training courses needed for transports involving more than one Member State, the high administrative burden and the lack of controls and inspections. These elements lead to non-compliance, denials and delays of shipments, barriers to entry (in particular for small and medium-sized companies), risks for the supply to medical patients and ultimately higher than necessary costs. These drivers and effects have been summarised in picture above:

Given the nature of RAM, its handling, use and 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 existing legislation, which ranges from non-binding international regulations, binding modal rules and Community law to national law, results in a level of control and supervision that is more intensive than for other classes of dangerous goods. The complete set of rules is multi-layered, which makes it very complex, although the main objective of safety is attained (over the past decades there has never been a transport incident that has caused significant radiological damage to persons or the environment).

In addition, there are major differences between Member States in terms of procedures, assessments, administrative requirements and application formats, which are not related to safety.

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 regulations, this does indeed create barriers to market entry 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.

Radioactive materials are widely used in hospitals, most commonly for the purposes of diagnosis and treatment. 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.

The main issue with TRAM, when compared to other classes of dangerous goods, is the existence of differing administrative requirements when implementing the Basic Safety Standards Directive 96/29/Euratom. By defining transport as one of the "practices which involve a risk from ionizing radiation", the Directive requires Member States to establish a "reporting" system (requirement to submit a document to the competent authority to notify their intention to carry out a practice), while still allowing them to impose prior "authorization" (a permission granted in a document by the competent authority to carry out a practice, on application, or granted by national legislation). This enables the competent authorities to check more closely whether the standards contained in that Directive are being respected.

## 2. ANALYSIS OF SUBSIDIARITY

EU action is justified under Title II Chapter 3 of the Euratom Treaty, which provides the Community with the powers to set basic standards of radiation protection and their implementation. At the same time, this EU action in a growing market for transport services would harmonise and effectively tackle the particular problems relating to trans-boundary shipments which require a multitude of licences and approvals, and thereby create real added value.

Indeed, EU action can successfully help to harmonise and simplify rules in the Community and to increase transparency, while continuing to guarantee a high level of safety.

## 3. OBJECTIVES OF THE EU INITIATIVE

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.

Considering the specificities and relatively low number of transports involving fissile materials, the main problems concern radiopharmaceutical isotopes. 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 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, four options have been 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 registering carriers of radioactive materials.

### 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 the 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 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.

## 5. ASSESSMENT OF IMPACTS

Although the options analysed by ECORYS - the independent experts who carried out a supporting study for the Commission - seem to have a rather modest impact from a global viewpoint, this impact does matter to such a small sector. The impacts are categorised in five groups, namely: Public sector expenses and fees, Regulatory effects, Transport, Safety and environment, and Social impacts.

Small and medium-sized companies are expected to benefit in proportion to the total savings achieved under these options: the higher the savings in total, the higher the savings for these enterprises that nowadays are often effectively blocked out of the market.

### 5.1. Baseline scenario: No policy changes/business as usual

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

### 5.2. Option 1: Commission Recommendation to harmonise implementation of existing law; Website with access to legislation

As a Recommendation on how to interpret rules laid down in Directives is 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.

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

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

### 5.3. Option 2: Regulation with harmonised rules and a 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 mentioned above.

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.

### 5.4. 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. Savings could reach € 13 million annually.

An EU Agency in conjunction with a Regulation will ultimately reduce the complexity of the framework by harmonising it. Furthermore, according to the stakeholders, the number of denials and delays would decrease. The biggest possible reduction is related to the administrative burden because of the simplified regulatory framework. On the other hand, running an EU Agency costs additional money, which is clearly seen in the high costs for this policy option.

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.

## 6. COMPARISON OF OPTIONS

The following comparative table summarises the impact of 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 | + | + | + | - |

With regard 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, such an initiative is unlikely to succeed, due to opposition of the Member States, the lengthy process needed to establish such an agency and concerns about subsidiarity.

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.

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.