



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 3 December 2008 (04.12)  
(OR. fr)**

**16537/08  
ADD 2**

**Interinstitutional File:  
2008/0231 (CNS)**

**ATO 121**

**COVER NOTE**

---

from: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 1 December 2008

to: Mr Javier SOLANA, Secretary-General/High Representative

---

Subject: Commission Staff Working Document accompanying document to the  
Proposal for a Council Directive (Euratom) setting up a Community  
framework for Nuclear Safety  
– Summary of the impact assessment

---

Delegations will find attached Commission document SEC(2008) 2893.

Encl.: SEC(2008) 2893



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.11.2008  
SEC(2008) 2893

**COMMISSION STAFF WORKING DOCUMENT**

*Accompanying document to the*

Proposal for a

**COUNCIL DIRECTIVE (Euratom)**

**setting up a Community framework for Nuclear Safety**

**SUMMARY OF THE IMPACT ASSESSMENT**

{COM(2008) 790 final}  
{SEC(2008) 2892}

## 1. CONSULTATION AND EXPERTISE

The Impact Assessment relates to the agenda planning item 2008/TREN/003 - *Revised legislative proposal on nuclear safety*. It accompanies the draft revised Directive setting up a Community framework for Nuclear Safety which aims to re-start the process of establishing a common EU framework on nuclear safety, by replacing the proposed Directive setting out basic obligations and general principles on the safety of nuclear installations<sup>1</sup> presented by the Commission in 2003.

This new proposal is the result of an extensive and continuous consultation process, initiated in 2004 during the Irish Presidency of the Council. Subsequently, the Council Working Party on Nuclear Safety (WPNS), the High Level Group on Nuclear Safety and Waste Management (HLG) and the European Nuclear Energy Forum continued work on this issue.

The consultation process that started in 2004 has resulted in a thorough revision of the approach taken in the 2004 proposal for a safety Directive, which at the time faced a blocking minority of Member States. The main arguments were a too detailed prescription of binding legislation, as well as doubts whether the proposal would fully respect the subsidiarity principle.

The revised legislative proposal on nuclear safety builds on: a) the technical work of the Western European Nuclear Regulators Association (WENRA) completed in 2006 for existing nuclear installations, with the participation of all European nuclear safety regulators; b) the principle that only strong and independent regulators can ensure the continued safe operation of nuclear power plants in the EU; c) enshrining in the European legislation the principles of the main international instruments available, namely the Convention on Nuclear Safety<sup>2</sup> and the safety work carried out by the International Atomic Energy Agency (IAEA), particularly its safety fundamental principles<sup>3</sup>. In addition, the technical background supporting the basic principles proposed in the draft revised Directive setting up a Community framework for Nuclear Safety was provided by the outcome of the activity of the different expert groups dealing with nuclear safety matters.

The European Parliament has constantly supported the setting up of European nuclear safety legislation establishing reference levels, as illustrated over the years in its Reports<sup>4</sup>. Additionally, as reflected in the Conclusions of the 2<sup>nd</sup> European Nuclear Energy Forum, the industry is now a firm supporter of EU nuclear safety legislation.

Finally, for the purpose of finalising the Impact Assessment, a Steering Group was set up, involving representatives of all the interested services of the Commission.

The draft Impact Assessment has been submitted to the evaluation of the Impact Assessment Board, which has issued its initial opinion on 9 September 2008, followed by a final opinion on 14 October 2008 on a resubmitted revised document. The final comments of the Impact Assessment Board have been fully taken into account.

---

<sup>1</sup> Initial 2003 Commission proposal (reference doc. COM(2003) 32 final) and revised 2004 version (reference doc. COM (2004)526 final)

<sup>2</sup> IAEA INFCIRC 449 of 5 July 1994

<sup>3</sup> IAEA Safety Fundamentals: Fundamental safety principles, IAEA Safety Standard Series No. SF-1 (2006)

<sup>4</sup> The latest were the Maldeikis report on the occasion of 50 years of the Euratom Treaty (reference doc. A6-0129/2007) and the Reul report on conventional energies (reference doc. A6-0348/2007).

## 2. PROBLEM DEFINITION

The renewed interest in nuclear power expressed by a number of Member States, with the perspective of numerous life extensions and new build, makes the timing of this revised proposal particularly appropriate. It is evident that the effects of radiological incidents do not stop at borders, with potential consequences both for the health of workers, citizens at large, but also wide ranging economic implications for the energy generating industry. As the protection of the EU public is one of the main political objectives of the EU, a legal framework aiming to achieve, maintain and continuously improve nuclear safety and its regulation in the Community, as well as enhance the role of the Member States' regulatory bodies would create an additional level of guarantee for the public in the EU.

Public acceptance is a prerequisite for the further development of nuclear energy and so far the Community has been consistently active in promoting nuclear safety, as yet there is no Community legal framework establishing common safety standards for the new and existing nuclear installations in the EU. However, the European citizens' concerns about the safety of nuclear installations must be properly addressed by the Community. One of the main conclusions of the 2007 nuclear safety-related survey<sup>5</sup> was that even if Europeans on average have a fair level of knowledge of nuclear issues, in particular whether or not there are nuclear power plants (NPPs) in their countries, they feel unfamiliar with the issue of nuclear safety (ranging from 56% to 90%).

## 3. EU RIGHT TO ACT

The Community's competence to set up basic safety standards at EU level is explicitly regulated in the Euratom Treaty. According to Art. 2, letter b) of the Treaty, *"In order to perform its task, the Community shall, as provided in this Treaty:...establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied."* Title Two, Chapter 3 "Health and Safety", sets up a number of detailed provisions intended to establish, give effect and apply the basic standards mentioned in Article 2(b) of the Euratom Treaty. Chapter 3 of the Euratom Treaty has been used mainly for radiation protection purposes until the recognition by the European Court of Justice of the intrinsic link between radiation protection and nuclear safety and of the Community competence in the field of nuclear safety (in its Ruling in Case C-29/99<sup>6</sup>, the Court stated that *"it is not appropriate, in order to define the Community's competencies, to draw an artificial distinction between the protection of the health of the general public and the safety of sources of ionising radiation."*). Therefore, this Ruling acknowledges the fact that the existing safety standards aiming to protect the health of workers and the general public against the dangers arising from ionizing radiations have to be complemented with safety standards for nuclear installations. The technical competence of the national authorities with responsibility for safety does not preclude the Community from legislating in this connection.

## 4. SOURCES OF THE IMPACT ASSESSMENT

The Impact Assessment updates the 2003 Impact Assessment related to the initial nuclear safety proposal<sup>7</sup>, having as technical background the conclusions and recommendations identified in the Final Report of the WPNS<sup>8</sup>, approved by the Council Working Party on

---

<sup>5</sup> Special Eurobarometer no 271 "Europeans and nuclear safety", Fieldwork Oct-Nov 2006, Publication Feb 2007 [http://ec.europa.eu/public\\_opinion/archives/ebs/ebs\\_271\\_en.pdf](http://ec.europa.eu/public_opinion/archives/ebs/ebs_271_en.pdf)

<sup>6</sup> Commission of the European Communities v Council of the European Union (Case C-29/99)

<sup>7</sup> Included in doc. COM(2003) 32 final

<sup>8</sup> doc. 15475/2/06 REV2 (<http://register.consilium.europa.eu/pdf/en/06/st15/st15475-re02.en06.pdf>)

Atomic Questions (WPAQ) on 13 December 2006 and complemented with the findings of the WPNS subgroups' reports<sup>9</sup>.

In this context, a special emphasis should be put on the activity carried out in the framework of WENRA, an organisation comprising the Heads and senior staff members of the Nuclear Regulatory Authorities from 17 European Countries<sup>10</sup>, whose members have defined many common safety reference levels for power reactors with a view to align national requirements by the year 2010.

Secondly, the Impact Assessment is based on the obligations and requirements of the IAEA Convention on Nuclear Safety, which constitutes an internationally recognised platform for nuclear safety development, as well as on the principles of the IAEA Safety Fundamentals. The Convention does not contain detailed technical rules; however, it sets up a precise legal framework aiming to the continuous improvement of safety. Euratom and all the EU Member States are Contracting Parties to the Convention on Nuclear Safety. The IAEA fundamentals constitute a framework of practices on which national safety requirements are based and to the improvement of which Member States have made considerable contributions.

## 5. POLICY OPTIONS

The Impact Assessment considers **four policy options**:

- *Policy option 0* consists in keeping the current situation unchanged;
- *Policy option 1* envisages the elaboration of Community legislation establishing common safety standards for existing nuclear installations;
- *Policy option 2* consists in the elaboration of Community legislation that sets up only a common framework aiming at achieving and maintaining a high uniform level of nuclear safety throughout the Community by recalling widely recognised nuclear safety principles, the subsequent implementing measures will be prepared within the HLG;
- *Policy option 3* is built upon a set of internationally-recognised nuclear safety principles (approach proposed by Policy option 2), supplemented with additional safety requirements for new nuclear power reactors, which Member States are encouraged to develop in line with the principle of continuous improvement of safety, on the basis of the safety levels developed by WENRA and in close collaboration with the HLG<sup>11</sup>, comprising high-level representatives of the regulatory and safety authorities from all the EU Member States.

## 6. COMPARING THE OPTIONS – PROPOSED EU ACTION

The assessment of the options showed that the most efficient solution for setting up a Community nuclear safety framework is the one envisaged by **Policy option 3**. Hence, the basic approach of the current proposed revised Directive is that the Community sets up only a set of common principles in the field of nuclear safety, already included in the IAEA Convention on Nuclear Safety (enhancing the role of national regulators, prime responsibility of the licence holder for safety under the control of the regulatory body, reinforcing the

---

<sup>9</sup> doc. 15475/2/06 REV 2 ADD 1 (<http://register.consilium.europa.eu/pdf/en/06/st15/st15475-re02ad01.en06.pdf>) doc. 15475/2/06 REV 2 ADD 2 (<http://register.consilium.europa.eu/pdf/en/06/st15/st15475-re02ad02.en06.pdf>) doc. 15475/2/06 REV 2 ADD 3 (<http://register.consilium.europa.eu/pdf/en/06/st15/st15475-re02ad03.en06.pdf>)

<sup>10</sup> Belgium, Bulgaria, Czech Republic, Finland, France, Germany, Hungary, Italy, Lithuania, Netherlands, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, and UK.

<sup>11</sup> established by the Commission Decision 2007/530/Euratom of 17 July 2007 (O.J. L 195 , 27/07/2007)

independence of the regulatory body, ensuring a high level of transparency on issues related to the safety of nuclear installations, implementation of management systems, regular safety supervision, availability of nuclear safety expertise, priority to safety), supplemented with additional safety requirements for new nuclear power reactors, which Member States are encouraged to develop in line with the principle of continuous improvement of safety, on the basis of the safety levels developed by WENRA and in close collaboration with the HLG. Based on the ten principles for the regulation of nuclear safety adopted by it, the HLG will become the focal point for cooperation between the regulatory bodies charged with the safety of nuclear installations in the Member States and will contribute to the development of the EU nuclear safety framework.

Member States are bound to respect the IAEA Safety Fundamentals, as well as the obligations and requirements as incorporated in the Convention on Nuclear Safety.

## **7. ADDED VALUE**

With the renewed interest in nuclear energy in Europe and elsewhere, it is important to maintain a high degree of nuclear safety within the EU, to establish a set of binding rules and common EU safety standards. The recent announcement of new build of NPPs in the EU makes convergence rules at EU level even more necessary in order to support the Member States in their efforts to harmonise safety practices. Despite the existence of cross-border risks in the operation of nuclear installations, there has been only limited standardisation between countries in the past.

Within this framework, the fundamental **added value** of the chosen policy option is that an EU binding legislative framework defining basic obligations and general principles on the safety of nuclear installations, would lead to the attainment of the objective of achieving, maintaining and continuously improving nuclear safety in the Community, a result whose fulfillment at purely national level would not be as efficient. This approach also presents the clear advantage of an increased certainty of regulation at Community level. Consequently, under the institutional provisions of the Euratom Treaty, Euratom possesses its own mechanisms to ensure the compliance of the national laws of the Member States with the Directive's provisions, thus exercising its role of safeguarding the correct application of the Community acquis. Moreover, it should be highlighted that EU legislation confers rights and obligations not only for the authorities from each Member State, but as well as for individuals and businesses. The authorities in each Member State are responsible for implementing EU legislation into national law and enforcing it correctly, and they must guarantee citizens' rights under these laws.

In the absence of an EU legal framework, the IAEA Convention on Nuclear Safety would be applicable for Member States. However, the membership to the IAEA Convention on Nuclear Safety has only a voluntary character, as this Convention represents an incentive instrument and thus can not entail any sanctions for non-compliance. The Convention is not designed to ensure the fulfilment of obligations by Parties through control and sanction but is based on their common interest to achieve higher levels of safety, which will be developed and promoted through regular meetings of the Parties. Membership entails two basic commitments for each Contracting Party: to prepare and make available a National Report for review and to subject its National Report to a peer review by the other Contracting Parties.

The elaboration of EU legislation on the basis of the principles of the Convention on Nuclear Safety and taking full advantage of the safety work already carried out by the IAEA in defining Safety Fundamentals recognises the value of the international progress in the nuclear

safety area and offers European civil society a possibility to become more involved in this field.

Finally, the proposal also aims to reinforce the role and the independence of the national regulatory bodies thereby building on their competencies, rather than creating a top-down approach, as in the initial nuclear safety proposal. It also reinforces the role of the national bodies in the implementation of the agreed measures, solution which is in full compliance with the principle of subsidiarity.

## **8. SUBSIDIARITY**

The EU Member States have already implemented measures enabling them to achieve a high level of nuclear safety within the EU. However, because of the different historical backgrounds, legal frameworks, type and number of reactors and different approaches to regulation, common rules in the field of nuclear safety to be applied across the Community have not yet been established, although this would lead to a further improvement of nuclear safety, which could not be achieved exclusively at national level.

The new proposal reverses the top-down approach of the 2003/2004 proposal to a bottom-up one, as, for the safety of new nuclear power reactors, Member States are encouraged to develop additional safety requirements, in line with the continuous improvement of safety on the basis of the safety levels developed by WENRA and in close collaboration with the HLG. In addition, Member States retain the right to impose at national level more stringent safety measures than those provided for in the Community legal framework.

Secondly, at the level of principles proposed, the revised Directive is anchored on the competence existing in the Member States' regulatory authorities, as well as on the internationally accepted principles of the Convention on Nuclear Safety and of the IAEA Safety Fundamentals, thus not imposing any additional burden on the Member States' authorities.

EU binding legislation also provides legal certainty by opening the possibility for citizens to turn to the European institutions in case they feel unsafe about nuclear energy.

Moreover, it should be mentioned that the new proposal takes fully into account the Member States' views expressed during the examination of the 2003/2004 package, by decoupling safety from nuclear waste and financial issues, as well as by removing the idea to create a Community body of safety inspectors and leaving the responsibility of nuclear safety supervision solely to the national regulators.

## **9. MONITORING AND EVALUATION**

The indicators of progress towards meeting the objectives will be set up at the level of the Member States.

## **10. CONCLUSION**

In the framework of the above considerations, the chosen policy option appears to be the preferred approach, as it presents the highest range the technical, economical and security benefits, by going beyond the level of principles and actually encouraging Member States to define additional safety requirements.