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COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

Proposal for a

COUNCIL DIRECTIVE (Euratom)

setting up a Community framework for Nuclear Safety

IMPACT ASSESSMENT

{COM(2008) 790 final}
{SEC(2008) 2893}

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EXECUTIVE SUMMARY

This 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. This revised initiative in the area of nuclear safety aims to re-launch 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[1] presented by the Commission in 2003 (the chronology of the procedural steps undertaken in the framework of the initial nuclear safety legislative package is presented under Section 2.5.5.). This new proposal is the result of an extensive and continuous consultation process, initiated in 2004 during the Irish Presidency. The Council Working Party on Nuclear Safety (WPNS), the European High Level Group on Nuclear Safety and Waste Management (HLG) and the European Nuclear Energy Forum continued work on this issue.

The HLG, created by the Commission in 2007, as well as the European Nuclear Energy Forum, have already contributed to enhancing a better understanding on common approaches that are required in the further development of the safety of nuclear installations. This will lead to an improved transparency to review and communicate nuclear issues, involving market participants, European institutions, Member States' representatives and other stakeholders of the civil society (e.g. NGOs).

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 present revised proposal 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 the 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[2] and the safety work carried out by the International Atomic Energy Agency (IAEA), particularly its safety fundamental principles[3]. In relation to the Member States' support for re-launching a revised nuclear safety legislative proposal, it should be noted that this new proposal benefits from the solid support of the current Council Presidency. A number of Member States which were initially opposed to the 2004 initiative, due to their concerns on enacting Community rules in this area, have now openly changed their position. 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[4]. Additionally, as reflected in the Conclusions of the 2nd European Nuclear Energy Forum, the industry is now a firm supporter of EU nuclear safety legislation.

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1 Initial 2003 Commission proposal (COM 2003/32 final) and revised 2004 version (COM (2004)526 final)

2 IAEA INFCIRC 449 of 5 July 1994

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

4 See Section 2.5.4. for details. The latest were the Maldeikis report on the occasion of 50 years of the Euratom Treaty and the Reul report on conventional energies.

This revised proposal creates a legislative framework for nuclear safety without being prescriptive as regards details. Within this framework, which recognises their sovereign right to use nuclear energy or not, Member States are free to fully exploit the subsidiarity principle.

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.

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 governing the safety of nuclear installations. However, the European citizens' concerns about the safety of nuclear installations must be properly addressed by the Community, based on its recognised competencies in the field, as one of the main conclusions of the 2007 nuclear safety-related survey[5] 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%). As the protection of the EU public is one of the main political objectives of the EU, a legal framework aiming to the achievement of a high level of nuclear safety in the Community, as well as to its permanent development, would create an additional level of guarantee for the public in the EU, by providing legal certainty.

The Impact Assessment updates the 2003 Impact Assessment related to the initial nuclear safety proposal[6], having as technical background the conclusions and recommendations identified in the Final Report of the WPNS[7], approved by the Council Working Party on Atomic Questions (WPAQ) on 13 December 2006 and complemented with the findings of the WPNS subgroups' reports[8]. The WPNS comprised 70 experts from the EU Member States and from the Commission.

In this context, a special emphasis should be put on the activity carried on in the framework of WENRA, an organisation comprising the Heads and senior staff members of the Nuclear Regulatory Authorities from 17 European Countries, whose members have defined many common safety reference levels for power reactors with a view to align national requirements by the year 2010. Any Community initiative in this field should take advantage of the technical progresses achieved within WENRA.

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

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5 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

6 COM 2003/32 final

7 15475/2/06 REV2 (http://register.consilium.europa.eu/pdf/en/06/st15/st15475-re02.en06.pdf)

8 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)

constitute a framework of practices on which national safety requirements are based and to the improvement of which Member States have made considerable contributions.

The above-mentioned documents have already confirmed and provided an in-depth technical background for the basic principles included in the proposed revised Directive, whose **general objective** is to set up a framework aiming to achieve, maintain and continuously improve nuclear safety and its regulation in the Community, as well as to enhance the role of the Member States' regulatory bodies.

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, comprising high-level representatives of the regulatory and safety authorities from all the EU Member States.

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 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 obligations and requirements as incorporated in the Convention on Nuclear Safety and the principles of the IAEA Safety Fundamentals.

This approach marks a complete reversal of the line put forward in the initial Nuclear Safety draft Directive, as it aims to reinforce the role and the independence of the national regulatory bodies thereby building on their competencies, as well as to strengthen the role of the national bodies in the implementation of the agreed measures.

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, establishing a set of binding rules. Despite the existence of cross-border risks in the operation of nuclear installations, there has been only limited harmonization between countries in the past. Within this framework, the fundamental **added value** of this 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. The Membership to this Convention 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. Being a Contracting Party to this Convention implies including in the National Report a self-assessment of the steps and measures already taken and in progress to implement the Convention's obligations, taking an active part in the review of its National Report and the Reports of other Contracting Parties and a commitment to a continuous improvement process.

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 and the role of the national bodies in the implementation of the agreed measures, solution which is in full compliance with the principle of subsidiarity.

SECTION 1: PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Organisation and timing

The elaboration of a *revised legislative proposal on nuclear safety* is included in the Commission's agenda planning 2008 – Commission actions expected to be adopted in the period 01/02/2008 - 31/12/2008 (item 2008/TREN/003). For the purpose of finalising the current accompanying Impact Assessment, a Steering Group was set up, composed of representatives of all the interested services (DG ENV, DG ECFIN, DG RTD, JRC, SJ, SG).

The Impact Assessment Board has assessed the draft Impact Assessment submitted to their attention in August 2008 and issued an initial opinion on 9 September 2008, which included the following general recommendations:

– The report should strengthen the rationale for this initiative by better explaining its European dimension and added value. This should be done, on the one hand, by assessing more clearly how this initiative could contribute to the implementation of the Member States' commitments under the Convention on Nuclear Safety; on the other hand, by

presenting the potentially negative effects of the current differences between the national safety standards of the Member States on the overall level of nuclear safety in the EU and on the smooth functioning of the internal market.

- Secondly, the report should explain the division of regulatory competences in the field of nuclear safety between the EU, HLG and Member States. The role of the HLG as regards the adoption of implementing measures in future should be clarified.
- Thirdly, the overall coherence of the report should be strengthened by providing stronger links between problems, objectives, options and monitoring.
- Finally, the political context of this initiative should be better explained. The report should clarify how the current initiative differs from the nuclear safety proposals that were put forward in 2003/2004. In that context, the report should explain why a public consultation on this initiative was not considered necessary.

Based on these main remarks, the Board requested to receive a revised draft of the Report, on which it will then issue another opinion.

As a follow-up, the Impact Assessment has been revised accordingly, in order to respond to the aspects raised by the Board. In relation to the previous version, additional information was included in the Executive Summary, as well as in the Sections 2, 3, 4 and 5 of the document. The added information strengthens mainly the following aspects:

- the political context of the current revised proposal;
- the description of the consultation with the stakeholders on a legislative framework on nuclear safety, in line with the Commission minimum standards for consultation;
- the main differences of the current revised approach in relation to the previous draft Directive dealing with the safety of nuclear installations included in the Nuclear Safety Package;
- the added value of the proposed revised Directive and its relation with the IAEA Convention on Nuclear Safety;
- the envisaged division of regulatory competencies between the EU institutions, the HLG and the Member States;
- the definition of the concept "nuclear safety";
- the update of the estimations with the results of the latest 2007 DGTREN forecasts;
- the coverage of the proposed European safety reference levels.

After the re-submission of the revised draft Impact Assessment, the Impact Assessment Board has issued its final opinion on 14 October 2008, which included the following general recommendations for improvement:

- The report should, as a general comment, better explain the added value of the initiative and provide greater clarity on the procedure envisaged for adopting new safety reference levels. Specifically for explaining the added value, the report should be more explicit on whether the varying standards have an impact on the functioning of the internal market or raise safety concerns.
- The links between problems, objectives, options and monitoring should be more coherent.
- The definition of regulatory competences between the EU, the HLG and Member states should be explained better.

– The executive summary should be more concise and the report should refrain from concluding on the actions needed in the problem definition section.

In the light of these recommendations, the draft Impact Assessment has been revised accordingly, in order to respond to the issues raised by the Board. In relation to the first version, the Executive Summary was shortened and changes were made mainly in Section 2 of the document. The added information strengthens especially the following aspects:

– the added value of the initiative;

– the analysis of the compliance with the subsidiarity principle;

– the procedural aspects related with the future implementing measures.

As a result of the comments received from the Commission services on the text of the draft Nuclear Safety Directive and on the accompanying Impact Assessment within the Inter-Service consultation, the text of the present document has been further amended accordingly.

1.2. Consultation and expertise

The current draft Directive setting up a Community framework for Nuclear Safety aims to re-launch the Commission's initiative of enacting binding legislation in the field, by updating and replacing the corresponding proposal from the Nuclear Safety Package.

Throughout the elaboration process of the initial Nuclear Safety Package in 2003 and 2004, a wide consultation with the stakeholders on the opportunity of setting up a nuclear safety legislative framework was carried out at the initiative of the Commission, supplementing the consultations resulting from the legislative procedure provided for in the Euratom Treaty (the opinions of the Group of experts set up by Article 31 of the Euratom Treaty and of the European and Social Committee).

The Commission proposal to have an exchange of views on the contribution of nuclear energy in meeting the growing concerns about security of energy supply, reduction of CO2 emissions and competitiveness, while taking fully into account nuclear safety and security aspects was endorsed by the Heads of State and Government reunited in the European Summit of 8 and 9 March 2007[9]. As a concrete follow-up, the European Nuclear Energy Forum was established, to which high representatives from Governments, several Members of the European Parliament representing different political groups and the European Economic and Social Committee participated actively, as well as the Presidents and CEOs of major companies, representatives from energy intensive consumers, NGOs and Trade Unions, and other key decision makers and organisations at national and EU level. The Conclusions of the 2nd Prague Forum emphasised the Forum's strong support for the adoption of EU legislation on nuclear safety based on *"common fundamental safety principles for nuclear installations"* stating furthermore that *"if it succeeds in adopting such a legal framework, Europe can become a real model also for possible nuclear newcomers, ensuring that they take all necessary measures for ensuring the highest safety and security levels before developing nuclear infrastructure".*

In addition, the technical background supporting the basic principles proposed in the current 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. Several different levels and types of activities have been developed at EU level, with the involvement of expert groups. These groups, comprising representatives of the safety

[9] Presidency conclusions (7224/1/07 REV 1)

authorities of the Member States, have actively contributed to the harmonisation of nuclear safety practices.

A detailed report on the consultations undertaken in the framework of the previous Nuclear Safety Package, as well as on the work of the various expert working groups in the field of harmonization of nuclear safety approaches within the EU is presented in the Annex of the Impact Assessment. These extensive consultations are in line with the Commission minimum standards for consultation, allowing the public to be informed and actively involved in the preparation of the legislative initiative.

SECTION 2: PROBLEM DEFINITION

2.1. The problem that requires action

The main purpose of the Euratom Treaty was to supervise the secure management of nuclear installations, including a high standard of health protection. A broad set of specific measures, distinct from those which had evolved under the auspices of the IAEA, has been developed in the field of radiation protection.

Nuclear Safety can be defined as the achievement of proper operating conditions through measures taken with a view to the prevention of accidents or mitigation of accident consequences, resulting in the protection of workers, the public and in the air, water and soil from undue radiation hazards arising from nuclear installations. Paradoxically, the safety of nuclear installations has not developed in the same way as radiation protection, although it is supposed to provide concrete guarantees for protecting population against ionising radiation, an area in which the Commission has, for a number of years, had undeniable technological expertise through the Joint Research Centre (JRC) and the Framework Programme for research and technological development. However, the Community has actively intervened in connection with the harmonisation of nuclear safety practices for over 25 years, in particular under the Council Resolutions of 22 July 1975[10] and 18 June 1992[11] on the technological problems of nuclear safety. Although the established system of radiation protection ensures a high level of protection for the health of the population, it should be further supplemented to ensure that a high level of safety of nuclear installations is maintained, developed and continuously improved. However, binding Community legislation in the area of nuclear safety has not been adopted until present.

At present, the interest in nuclear energy is undergoing a revival phase, due to a number of driving factors.

Energy efficiency, renewables and sustainable biofuels all have a very important and growing contribution to a sustainable energy policy. However, for the production of base-load energy at competitive prices, nuclear energy is currently the main low-carbon source in many EU Member States. The EU is the largest nuclear electricity generator in the world, having a mature nuclear industry spanning the entire fuel cycle with its own technological base and highly skilled workforce. Nuclear energy provides more than a third of the EU electricity and it has proven to be a stable, reliable source, relatively shielded from price fluctuations when compared to the oil and gas markets. Continued use of nuclear energy therefore would increase the EU energy independence and security of supply as well as contribute to the limitation of CO_2 emissions, but it is also still confronted with a number of outstanding issues that need to be resolved. Provided an adequate level of safety is ensured, nuclear energy can

[10] OJ No C 185 of 14 August 1975, p. 1.
[11] OJ No C 172 of 18 June 1992, p. 2.

continue to play an important role in the EU, supported by a firm commitment in research and promotion of technological developments, aimed at further enhancing its safety.

Safety infrastructure includes many components, including the legal framework and regulatory capability, emergency preparedness and response, educated and trained manpower, a stable electrical grid, adequate financial and industrial resources, and the nurturing of an appropriate safety culture in the generating entity. Therefore, there are many responsibilities that arise from the commitment to using nuclear energy and the new and expanding programmes must take appropriate and timely actions to fulfil those responsibilities. The Member States must remain mindful of the fact that the prime responsibility for safety always rests with the operator and that an appropriate safety infrastructure, independent of any contractual arrangements is necessary. All these aspects are for the time being regulated at the level of Member States, which creates a too heterogeneous situation.

Replacement and/or life extension of ageing nuclear power plants (NPPs) deserve special attention, since a large number of currently operating plants in the EU will come to the end of their originally foreseen lifetime before 2030, leading to a substantial decrease in the contribution of nuclear energy, unless new plants are built or older ones are upgraded, so that they can safely operate for an extended period. Also, a high level of nuclear safety in the EU requires ensuring the safe closure and decommissioning of those nuclear reactors reaching the end of their lifetime, or for which safety cannot be upgraded at an appropriate high level in an economical manner. According to recent forecasts[12], as a result of political decisions on nuclear phase-out in certain old Member-States and the closure of plants with safety concerns in some new Member-States, nuclear energy output will be 20% smaller in 2030 than it was in 2005. As a consequence, in order to maintain the share of nuclear energy in the energy mix, new investments are expected to replace or upgrade aging generation capacities. In the EU, currently two new nuclear installations are under construction (1 in Finland and 1 in France). Several others are planned or firmly decided in some Member States (e.g. Mochovce (Slovakia), Belene (Bulgaria), Cernavoda (Romania), Ignalina (Lithuania), as well as an indefinite number of installations especially in France and the UK). In addition, other types of installations are under construction (e.g. enrichment plants). The absence of an EU framework establishing fundamental safety principles and requirements creates uncertainties for the investors. Therefore, in the current context it is the right time to reconsider the project of setting up a Community nuclear safety approach that would create a legal reference and a level playing field throughout the EU, as currently there is a different system in each Member State, leading to a certain degree of fragmentation.

Moreover, this exercise would also reflect externally, by ensuring the existence of a comparable basis for discussions in the process of negotiation of nuclear-related International Agreements between the Community and third parties.

Another aspect that has to be highlighted is that, even if following the Chernobyl accident, no major accidents have occurred within the EU or in its neighbourhood, nevertheless several incidents on a low INES scale of 0-2 have been reported. This sporadic recurrence of events of concern make clear that the promotion of a strong safety culture at EU level — for both operators and regulators — supported by appropriate legal instruments, should represent a priority.

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[12] European Energy and Transport - Trends to 2030 Update 2007 (http://ec.europa.eu/dgs/energy_transport/figures/trends_2030_update_2007/energy_transport_trends_2030_update_2007_en.pdf)

The nuclear sector is also confronted with the problem of the ageing of qualified human resources dealing with technical matters. Efforts are needed to establish an effective process for the development and transfer of knowledge areas and to ensure the preservation and availability of resources.

Finally, public acceptance should be considered, as it is one of the driving factors of the future development of nuclear energy. The existence of different national regulatory systems will only perpetuate the current lack of information in the field, illustrated by the results of the opinion polls carried on by the Commission with the participation of respondents from the Member States. Information on the measures adopted by the Member States on nuclear safety matters should be openly made available to the public in a timely and accurate manner.

2.2. Underlying drivers of the problem

Following the Chernobyl accident in 1986 - undoubtedly the most serious accident in the history of atomic energy, and the G-7 Summit in Munich in 1992, the EU began to concern itself with the safety of nuclear installations in the Central and Eastern European countries and the Republics of the former Soviet Union.

Nuclear safety is still a central issue in the context of the recent enlargements of the EU. The work carried out in the Community framework in order to bring nuclear installations in the former candidate countries up to a high level of safety allowed a European perspective to emerge in this context.

Four first generation Soviet-design nuclear reactors (Ignalina 1 and 2 in Lithuania and Bohunice 1 and 2 in Slovakia) are being shut down in predetermined stages in compliance with the 2004 Accession Treaty. The EU is providing financial assistance, subject to certain conditions, to various projects on decommissioning and replacement of electricity generation capacity. Similar arrangements are in place for four of the six reactors at Kozloduy, two of which were already closed prior to Bulgaria's accession to the EU and another two were closed by the end of 2006 as part of Bulgaria's EU Accession Treaty. Two Regulations[13] were adopted, providing for continued financial assistance to Lithuania and Slovakia until 2013, guaranteeing at least the same level of funding as agreed for the period 2004-2006. Euratom loans have been provided to Kozloduy 5 and 6 in Bulgaria (€212.5 million in 2000 to improve safety-related equipment), Cernavoda 2 in Romania (€223.5 million in 2004 for construction).

Also, the extension of plant lifetime where safely possible and/or new construction aiming at meeting the electricity demand, is necessary in order to maintain the share of nuclear energy in the current energy mix.

Evidence of widely differing safety and security measures were observed by the Commission when giving its point of view on the built of new plants proposed since 2004. Such differences not only impact on the overall safety of the workers and the population, but may entail cost differences for the construction and operation of the plants.

Protection from ionising radiation is also a concern after the end of the active life of a nuclear installation. In practice, final shutdown of a nuclear installation marks the start of a new phase with the objective of lifting the radiological protection restrictions imposed while it was in operation. These restrictions are due to the presence of large quantities of radioactive materials in the form of structural materials, equipment, operational waste and spent fuel. It is therefore necessary to remove these materials and to subject them to the treatment appropriate

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[13] Council Regulation (EC) No 1990/2006 (OJ L 411, 30.12.2006, p. 10–17)
Council Regulation (Euratom) No 549/2007 (OJ L 131, 23.5.2007, p. 1–4)

to their physical characteristics and their levels of radioactivity, in accordance with safety standards in force.

Also, the climate change issue has revamped the public debate on nuclear power. Public opinion constantly requires the highest possible level of nuclear safety and information on it, because of the keen public awareness of the risks for human health and the environment, linked to the operation of NPPs. Concerns about the safety of NPPs, management of radioactive waste, security, proliferation and terrorism have all had an influence on public opinion.

2.3. Who is affected, in what ways, and to what extent?

Euratom legislation in force does not address the particular aspects of nuclear installation safety. The primary responsibility for the safety of nuclear installations rests with the holders of the relevant licence, under the control of the national regulatory authority of each Member State.

Along the lines of the existing national systems, it is necessary to consider nuclear safety in a Community perspective. Enshrining in Community legislation the obligations and requirements of the Convention on Nuclear Safety and the principles laid down in the IAEA Safety Fundamentals will make it possible to reconcile efficiency and speed of implementation. Interlinking the national systems and the Community system will guarantee the maintenance of a high level of safety for nuclear installations in the enlarged EU and will enhance the transparency of the EU regulatory mechanisms. In a long-term perspective, this shall result in an improved public confidence in the decision-making process applied at EU level on nuclear safety matters.

The nuclear safety Directive will benefit EU citizens by enhancing their safety and giving them legal certainty. It would also benefit Member States, as it would give them a reference for their national nuclear safety systems. It would benefit the national nuclear safety control bodies as it would ensure that they get enough means for their work and give them the driving role in implementing the common EU rules.

Also, the establishment of a common approach in the field of nuclear safety will lead to the increase of the nuclear energy's competitiveness.

2.4. The evolution of the problem all things being equal

At present, EU is facing major challenges linked with climate change, increasing import dependence and higher energy prices, in the overall context of a growing interdependence of EU Member States in energy aspects.

Under the New Energy Policy projections[14], total EU-27 energy requirements continue to increase slightly (1.5%) by 2020 in case of moderate oil prices and to decrease slightly (-2%) in case of high oil prices[15]. Under these projections, only renewable energy sources increase their market share. The share of nuclear in total energy consumption drops slightly, from 14% in 2005 to between 12 and 14 % by 2020. In total the share of indigenous and low carbon energy sources rises from 21% in 2005 to 30% in 2020.

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[14] The figures under this section have been updated in line with the Commission's Second Strategic Energy Review adopted on the 13 November 2008. Figures presented elsewhere in the graphs are based on the Nuclear Illustrative Programme adopted in 2007.

[15] Commission staff working document: Europe's current and future energy position, Demand – resources – investments, COM(2008) 744

Import dependence continues to grow even under the New Energy Policy projections, from around 52% in 2005 to between 56 and 58% in 2020. Import dependence for oil continues to be the highest, reaching 92% in 2020. Gas import dependence rises substantially, from 58% at present to between 71 and 73% in 2020. Similarly, solid fuel supply will be increasingly based on imports, reaching around 50% in 2020 (up from just under 40% today). EU-27 energy related CO2 emissions are expected to remain below the 1990 level and to decline another 18 to 20% by 2020 under the New Energy Policy scenario.

Currently, NPPs generate approximately one third of the electricity and 14% of the energy consumed in the EU. Nuclear power is currently the largest source of low-carbon dioxide (CO2) production of energy in the EU. Also, it is less vulnerable to fuel price changes than coal or gas-fired generation, as uranium represents a limited part of the total cost of generating nuclear electricity and is based on sources which are sufficient for many decades and widely distributed around the globe, being as well one of the cheapest sources of low carbon energy that is presently produced in the EU.

To meet the expected energy demand and to reduce European dependency on imports, decisions are expected to be made on new investments or on the life extension of some plants. Having in view the fact that a significant number of NPPs are due to close down within the next 20 years, construction of new plants and/or extension of the current operating lifetimes of existing reactors will be required if the Member States choose to keep the low CO2 option and maintain or even increase the current share of nuclear power in the overall energy mix.

While each Member State and energy utility chooses its own energy mix, individual national decisions relating to nuclear energy can have more general impacts in terms of the electricity market, the EU's overall dependence on imported fossil fuels, CO2 emissions, and competitiveness, but also in terms of the environment and safety. In particular, a serious incident at a NPP could affect neighbouring Member States. Cross-border impacts are possible also in managing the back-end of the fuel cycle (radioactive waste, including from decommissioning). In addition, it should be mentioned that some companies intend to invest in the EU in the construction of NPPs in different Member States.

Experience of managing industrial risks has already shown the possible trans-boundary environmental consequences. There are already similar provisions foreseen in the Euratom Treaty in Article 37 in the field of radioprotection, that provide the obligation of each Member State to notify to the Commission any plans for the disposal of radioactive waste that would result in the radioactive contamination of the water, soil or airspace of another Member State.

Therefore, at present it is no longer possible to consider nuclear safety from a purely national perspective. Only a common approach can guarantee the continuous improvement of nuclear safety in an enlarged Union of 27-Member States.

2.5. Community competence

2.5.1. Euratom Treaty legal basis

Civil nuclear activities are regulated in the European Union by the Euratom Treaty, signed in 1957. The Euratom Treaty contains provisions allowing the Community to regulate the use of nuclear energy by the Member States, in particular those governing health protection (Chapter 3) and nuclear safeguards (Chapter 7).

The competence of the European Atomic Energy Community to regulate in the field of the health protection against ionizing radiation is explicitly recognised by the Euratom Treaty. Accordingly, in the Treaty's Preamble, the Member States declare that they are *"resolved to create the conditions necessary for the development of a strong nuclear industry"* and also

"anxious to create conditions of safety necessary to eliminate hazards to the life and health of the public". In addition, pursuant to Article 2(b) of the Treaty, the Community is mandated to *"establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied."* Title II, Chapter 3 "Health and Safety", sets up a number of detailed provisions intended to establish, give effect and apply the basic safety standards mentioned in Article 2(b) of the Euratom Treaty. Article 30 paragraph 1 of the Euratom Treaty establishes that "*Basic standards shall be laid down within the Community for the protection of the health of workers and the general public against the dangers arising from ionizing radiations*." Article 32 provides that the basic standards may be revised or supplemented. A substantial corpus of Euratom legislation in the field has been adopted and updated during the years and is completed by a set of legal instruments of different binding nature, covering a wide range of aspects such as operational protection of workers (including outside workers) and population, natural radioactive sources, high activity sealed sources and orphan sources, emergency preparedness, medical applications, control and supervision of shipments of spent fuel and radioactive waste, as well as a number of regulations establishing provisions on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl NPP, aimed at safeguarding the health of consumers of such products. The central element of this legislation is the Council Directive 96/29/Euratom laying down basic safety standards for the health protection of the general public and workers against the dangers of ionising radiation (Basic Safety Standards Directive)[16].

Chapter 3 of the Euratom Treaty has been used so far mainly for radiation protection purposes. It is, however, undeniable that health protection covers both radiation protection and nuclear safety, two closely linked concepts serving a common health protection objective.

This approach has been confirmed by the jurisprudence of the European Court of Justice. In its judgement from 10 December 2002 in the Case C-29/99, the Court stated[17] 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.*" The Court confirms on the other hand the technical competence of national safety authorities to authorise the construction or operation of nuclear facilities. However, the Court recognises that this technical competence does not prevent the Community from legislating in this field. The Court judgement is on this point explicit[18]: "*Even though the Euratom Treaty does not grant the Community competence to authorise the construction or operation of nuclear installations, under Articles 30 to 32 of the Euratom Treaty the Community possesses legislative competence to establish, for the purpose of health protection, an authorisation system which must be applied by the Member States. Such a legislative act constitutes a measure supplementing the basic standards referred to in that article*."

In the conclusions of the Advocate-General Jacobs delivered on 13 December 2001 in the Case C-29/99 it is concluded that *"In the light of the current scientific knowledge, it is neither possible nor desirable to maintain artificial boundaries between radiation protection and nuclear safety. From a legal perspective it is also evident that modern radiation protection systems such as the Basic Standards Directive are increasingly source-oriented and therefore*

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16 OJ L 159, 29.6.1996.

17 Commission of the European Communities v Council of the European Union (Case C-29/99)- paragraph 82

18 paragraph 89

necessarily also regulate aspects of the safety of installations."[19] Furthermore, the Advocate-General states that *"The fact that the Member States retain exclusive competence over the technological aspects of nuclear safety does not prevent the Community from adopting legislation which establishes certain safety requirements, authorisation requirements, inspection and assessment requirements or enforcement mechanisms."*[20]

2.5.2. Competence recognised by the Council of the European Union

With the development of the European nuclear industry, convergence at Community level became necessary in order to support the Member States in their efforts to harmonise safety practices. The Council Resolution of 22 July 1975 on the technological problems of nuclear safety recognised that it was the Commission's responsibility to act as a catalyst in initiatives taken at international level in the field of nuclear safety. This Resolution, while *"taking into account the prerogatives and responsibilities assumed by national authorities"*, makes reference to the alignment of safety requirements in the context of a desirable harmonised approach at Community level. It calls for effective collaboration among Member States at EC level and specifically requires the *"progressive harmonization of safety requirements and criteria in order to provide an equivalent and satisfactory degree of protection of the population and of the environment against the risks of radiation resulting from nuclear activities and at the same time to assist the development on trade on the understanding that such harmonization should not involve any lowering of the safety level already attained"*. As a result of this Resolution, the Commission set up several expert groups dealing with nuclear safety matters.

Against this background, a second Council Resolution was adopted in 1992. In this Resolution, the Council reaffirmed the intentions of the 1975 Resolution and invited Member States to continue and intensify concerted efforts towards harmonization of safety issues. In this context, the Council *"requests the Member States to continue - with an active contribution from the Commission - to ensure greater concerted effort between the national safety authorities in the Community on safety criteria and requirements and on the incorporation of the conclusions reached into the practice followed in the Member States, in order to arrive at a system of safety criteria and requirements recognized throughout the Community."* and *"encourages the Member States and the Commission to act in a coordinated manner in international fora on the basis of the achievements reached in the Community towards a system of internationally accepted nuclear safety criteria and requirements, in particular in the framework of the International Atomic Energy Agency (IAEA)."* The European Council has regularly recalled the 1992 Resolution in the context of the enlargement process and the importance of developing high standards of nuclear safety in Central and Eastern Europe. Following this Resolution, participation in the expert groups was extended to representatives of the Central and Eastern European Countries and the Republics of the former Soviet Union (NIS).

In the framework of the discussions on Commission proposals for Council Directives (Euratom) setting out the basic obligations and general principles on the safety of nuclear installations and on the management of spent nuclear fuel and radioactive waste, in the June 2004 Council Conclusions on nuclear safety and on the safety of the management of spent nuclear fuel and radioactive waste[21], the following statements were made:

"(the Council) urges Member States together with the Commission:

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19 paragraph 166
20 paragraph 167
21 10823/04

to avail themselves in particular of the possibilities offered by the review meetings under the Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management in 2005 and 2006 respectively,

to assess the results achieved under these Conventions, including at previous Conferences of the Parties,

to take stock of the outcome of the work conducted by national nuclear regulatory authorities in multinational fora, including in the WENRA framework,

and on that basis

to engage in a wide ranging consultation process facilitating the choice of instrument(s), in the framework of the Euratom Treaty, that can contribute more effectively to achieving nuclear safety and the safe management of spent fuel and radioactive waste, without excluding any instrument and in line with the principles of better law making."

The importance of an EU action in the field of nuclear safety is also emphasised in the May 2007 Council Conclusions on Nuclear Safety and Safe management of spent nuclear fuel and radioactive waste[22]. In the Preamble of the Conclusions, it is stated that *"Bearing in mind that nuclear safety is a national responsibility exercised where appropriate in an EU-framework. Decisions concerning safety actions and the supervision of nuclear installations remain solely with the operators and national authorities."*

2.5.3. Competence recognised by the European Council

The Cologne European Council in June 1999[23] asked the Commission to ensure that high nuclear safety standards are applied in Central and Eastern Europe. Following on from this request, the safety of nuclear installations in the candidate countries was evaluated by the Commission and the Council in 2001, making it possible to arrive at a European perspective on nuclear safety, agreed by the fifteen Member States and the Commission.

The Laeken European Council in December 2001 marked the transition from reflection conducted in the perspective of enlargement to that of a global political vision at the level of the enlarged EU. One of the conclusions[24] of this meeting was that *"the European Council undertakes to maintain a high level of nuclear safety in the Union. It stresses the need to monitor the security and safety of nuclear power stations. It calls for regular reports from Member States' atomic energy experts, who will maintain close contacts with the Commission".* The Conclusions of the Laeken Council apply the Cologne Conclusions within the EU, the objective of both sets of conclusions being to maintain a high level of nuclear safety.

In the Presidency Conclusions[25] of the Brussels European Council from March 2007, it is stated that the European Council *"confirms that it is for each and every Member State to decide whether or not to rely on nuclear energy and stresses that this has to be done while further improving nuclear safety and the management of radioactive waste, and to that effect it…can envisage the creation of a high-level group on nuclear safety and waste management."*

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22 Adopted at the 2798th meeting of the Council of the European Union (Economic and Financial Affairs) - 8784/07

23 150/99 REV 1

24 SN 300/1/01 REV 1

25 7224/1/07 REV 1

2.5.4. Competence underlined by the European Parliament Reports

The Committee on Industry, External Trade, Research and Energy of the European Parliament published in 2002 a report on the Commission Communication on the Operation of the Euratom Safeguards Office in 1999-2000, with Paul Rübig as a rapporteur[26]. In this report, the European Parliament encourages the Commission "*to propose a Directive to fix a reference framework for all activities of auditing and certification in the field of Nuclear Safety, Security and Safeguard*".

In the 2007 Report on Assessing Euratom – 50 Years of European nuclear energy policy[27], published by the Committee on Industry, Research and Energy, with Eugenijus Maldeikis as a rapporteur, one of the gaps identified by the European Parliament was exactly *"the absence of a legislative corpus on harmonised standards with real added value, particularly in comparison with the existing international framework, for nuclear safety, the management of radioactive waste and the decommissioning of nuclear plants"*. In this context, the Report reiterates the Commission's competence to regulate in the area of nuclear safety under Euratom Treaty, as confirmed by the judgment of the Court of Justice in the Case C-29/99. Furthermore, it is pointed out that *"in the context of a need to adapt European energy policy and extend the working lives of power stations, there is an urgent need to draw up robust legislation and adopt concrete measures at Community level in the fields of nuclear safety, the management of radioactive waste and the decommissioning of nuclear plants"*. For that matter, the Parliament "*invites the Commission to review the relevant drafts of its legislative proposal and submit new proposals for directives on the safety of nuclear facilities, on waste management, and on closure and decommissioning of nuclear facilities taking into account the 'polluter-pays' principle*". It also *"urges the Commission and Council to look into this question with all due speed"* and asks to be consulted in this work.

A similar position is reflected in the Report on Conventional energy sources and energy technology[28], published by the Committee on Industry, Research and Energy, having Herbert Reul as rapporteur, which *"welcomes the Commission's call for the imposition in the EU of common reference levels for nuclear safety; in that connection, urges that, on the basis of a best practice peer review, these reference levels should reflect the highest possible safety standards"*. Moreover, the report *"recalls that dozens of nuclear power plants are planned or being built worldwide, and that it is vital for the EU to be involved in their construction, both from the point of view of industrial strategy and in order to promote the most stringent possible safety principles throughout the world"*. This approach is in line with the Nuclear Illustrative Programme[29], adopted in accordance with Article 40 from the Euratom Treaty.

2.5.5. Initial Nuclear Safety Package

On 30 January 2003, after receiving in December 2002 the opinion of the Group of Experts set up by Article 31 of the Euratom Treaty, the Commission adopted two proposals of Directives dealing respectively with the safety of nuclear facilities and the management of spent fuel and radioactive waste[30]. The legal bases of these two proposals are included in Chapter 3 of Title II of the Euratom Treaty, which concerns health protection. The initial draft Directive setting out basic obligations and general principles on the safety of nuclear installations proposed common safety standards and verification mechanisms to guarantee the

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[26] A5-0196/2002
[27] A6-0129/2007
[28] A6-0348/2007
[29] COM(2007) 565 final
[30] COM 2003/32 final

application of common methods and criteria with regard to nuclear safety throughout the enlarged EU.

After the European Economic and Social Committee gave its opinion on 26 March 2003, both proposals were forwarded to the Council. In accordance with the procedure in Article 31 of the Euratom Treaty, the Council requested the opinion of the European Parliament. Debates took place within the ITRE subcommittee. The European Parliament adopted opinions on the proposals in its plenary session on 13 January 2004. The opinion of the European Parliament supports the approach taken by the Commission of endowing the enlarged EU with binding legislation in the field of safety of nuclear facilities and of radioactive waste management. Parliament adopted a number of amendments, the majority of which were acceptable to the Commission. Subsequently, revised proposals[31] were elaborated taking into account certain amendments brought by the European Parliament, but also the developments of the texts following the discussions within the Council. The main request of the European Parliament concerned the financing of the decommissioning of nuclear facilities. The European Parliament pointed out that there existed among Member States a diversity of methods to finance decommissioning operations which could lead to distortions of competition and to discriminations between the producers of nuclear power. The Commission had stressed during the debates in the European Parliament the importance of this question in the context of the internal market of electricity. In October 2006 the Commission adopted a recommendation on the use of decommissioning funds[32] which is the basis of annual reports to the European Parliament on the subject.

At the same time, both proposals were discussed in the Council, under the Italian and Irish Presidencies. One of the problems encountered by delegations was the absence of clear safety standards to be used in conjunction with the directive. This obstacle is removed since 2006, when WENRA finalized the publication of safety reference levels for existing nuclear reactors, which can be used by the Member States as a reference. An additional major concern expressed by the Council was the intention of the Commission to create a body of safety inspectors, removing such competence from the national regulators. The budgetary provisions in the safety directive were designed for such purpose. It should be remarked that the current approach reverses this point completely, leaving the nuclear safety inspections solely to the national regulators. The Atomic Questions Group (AQG) referred the matter to the Permanent Representatives Committee in November 2003 and May 2004. As a majority allowing the adoption or the rejection of both proposals for Directives was not possible to be obtained at the Coreper II meeting of 13 May 2004, it was agreed that Council conclusions would be worked out by consensus.

Draft conclusions on nuclear safety and on the safety of the management of spent nuclear fuel and radioactive waste were agreed by Member States within the AQG and were adopted by the Council on 28 June 2004[33]. Subsequently, as a consequence of the June 2004 Council Conclusions, the WPNS was activated.

In addition, in 2007, the Commission launched two initiatives to further debate the future of nuclear energy and to identify requirements for its development. The first is the HLG focusing on identifying safety issues for priority handling and recommending actions to be taken at EU level. The second, the European Nuclear Energy Forum, intends to provide a platform for a broad and transparent stakeholder discussion on the opportunities and risks of nuclear energy.

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31 COM(2004) 526 final

32 Commission Recommendation of 24 October 2006 on the management of financial resources for the decommissioning of nuclear installations, spent fuel and radioactive waste, OJ L330, 28.11.2006.

33 10823/04

2.6. 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 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, 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 the protection of 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, as well as that the technical competence of the national authorities with responsibility for safety does not preclude the Community from legislating in this connection.

After the Chernobyl accident in 1986, the problem of ensuring nuclear safety worldwide was addressed with new vigour, especially within the IAEA, under whose auspices the Convention on Nuclear Safety has been enacted. However, this Convention is a voluntary mechanism that does no allow to verify the Contracting Parties' compliance with its rules. In the current context of the expansion of the global demand for nuclear generation which has a trans-national impact, enacting Community legislation recognising internationally endorsed nuclear safety principles and aiming to achieve and maintain a high level of nuclear safety at EU level becomes a prerequisite of the future development of nuclear energy. Over the years, the support for the elaboration of EU nuclear safety legislation has been constantly reflected by the Council and the European Parliament, and more recently by the European Nuclear Energy Forum. A revised proposal would also respond to the expectations of citizens that consider nuclear safety an essential matter to be handled at EU level, as demonstrated by the 2007 Eurobarometer. Despite this support and despite a previous proposal in the area, no EU nuclear safety legislation is in force today.

The new proposal reverses the top-down approach of the 2003/2004 proposal to a bottom-up one and encourages Member States' cooperation, 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 endorsed principles of the Convention on Nuclear Safety and of the IAEA

Safety Fundamentals, thus not imposing any additional burden on the Member States' authorities. All the EU Member States and Euratom are Contracting Parties to the Convention on Nuclear Safety. The IAEA safety standards, comprising Safety Fundamentals, Safety Requirements and Safety Guides, are binding on the IAEA for its own operations, are applied by other sponsoring organizations for their own operations, and are recommended for use by States and national authorities in relation to their own activities.

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 the safety of 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 inspections solely to the national regulators.

SECTION 3: OBJECTIVES

3.1. General objective

The general objective of the proposed Directive is to achieve, maintain and continuously improve nuclear safety and its regulation in the Community and to add value by enhancing the role of the regulatory bodies. This would lead to the increase of the safety of the operation of NPPs, the sustainable contribution of nuclear energy to the EU's growing energy demands, ensuring a level playing field for new investment in NPPs, tackling the trans-boundary effects of eventual nuclear incidents by creating the premises of a unitary and coordinated EU response, increasing the level of public acceptance of nuclear energy.

Its scope of application is the design, siting**,** construction, maintenance, operation and decommissioning of nuclear installations, for which consideration of safety is required under the legislative and regulatory framework of the Member State concerned. Nuclear installations cover nuclear fuel fabrication plants, research reactors (including sub-critical and critical assemblies), nuclear power plants, spent fuel storage facilities, enrichment plants or reprocessing facilities.

In this context, it should be clarified that the transport of radioactive material falls outside the scope of the revised Directive on nuclear safety. The recast of the Community regulatory framework on the transport of radioactive material is a separate item on the Commission legislative agenda.

3.2. Operational objectives/ principles

Through creating a Community framework for Nuclear Safety the following operational objectives should be achieved:

- Enhancing the role of national regulators;
- Prime responsibility of the licence holder for safety under the control of the regulatory body;
- Reinforcing the 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.

3.3. The consistency of these objectives with other EU policies

The development of a Community approach in the field of nuclear safety, supported and complemented by national legislation, will have as a result the achievement of an increased level of protection of the health of workers and public, as well as of the environment, against radiation hazards. Therefore, it would contribute to the full achievement of the objectives of the Basic Safety Standards Directive, as well as of all the legislation in the area of radiation protection, namely protecting the workers and the general public against the dangers of ionising radiation without unduly limiting the beneficial uses of the practices giving rise to radiation exposure.

SECTION 4: POLICY OPTIONS

Policy option 0 assumes that no additional rules in the field of nuclear safety are established at Community level, in order to harmonise the existing approaches. Option 0 would leave things as they are. This is the business-as-usual scenario.

Policy option 1 assumes the elaboration of Community legislation that has the objective of establishing common safety standards for existing nuclear installations. This was the approach envisaged in the process of elaboration and negotiation of the Commission proposal for Council (Euratom) Directive setting out basic obligations and general principles on the safety of nuclear installations.

Policy option 2 assumes 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 principles analysed and confirmed at international level. The implementing guidelines and arrangements will be prepared at the level of the HLG that comprises high – level representatives of the regulatory and safety authorities from the EU Member States.

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.

A presentation of the envisaged sharing of competencies between the EU, Member States and the HLG under this policy option is included in the table below.

EU	Member States	HLG
– Setting basic nuclear safety principles in the Directive; – HLG secretariat; – Supervising the implementation of the Directive, including non compliance cases.	– Transposing the Directive in national law; – Fulfilling the obligations and requirements set up in the nuclear safety EU legislation (e.g. establishing and maintaining a legislative and regulatory system, ensuring the independence of the regulatory body, informing the public on the issues related to nuclear safety, respecting the principles of the IAEA Safety Fundamentals and the obligations and principles of the Convention on Nuclear Safety, developing, if considered appropriate, additional safety requirements); – Sending HLG delegates; – Cooperating with the HLG in the process of defining additional safety requirements; – Collaborating within WENRA.	– Focal point for the cooperation of the national regulators; – Cooperate with the Member States in the process of defining additional safety requirements; – Upon the adoption of a EU Directive on nuclear safety, the initial mandate of the HLG will be revised in line with the new legal framework.

SECTION 5: ANALYSIS OF IMPACTS

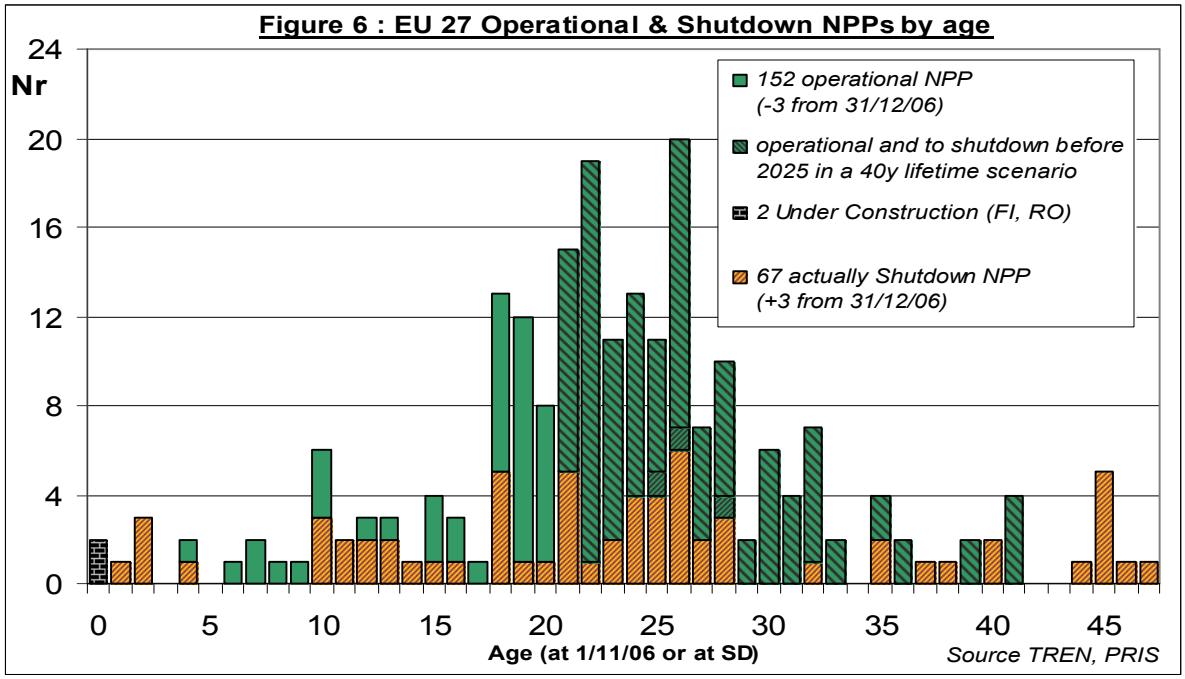
5.1. Policy option 0 – no policy change.

a) Safety-related impact

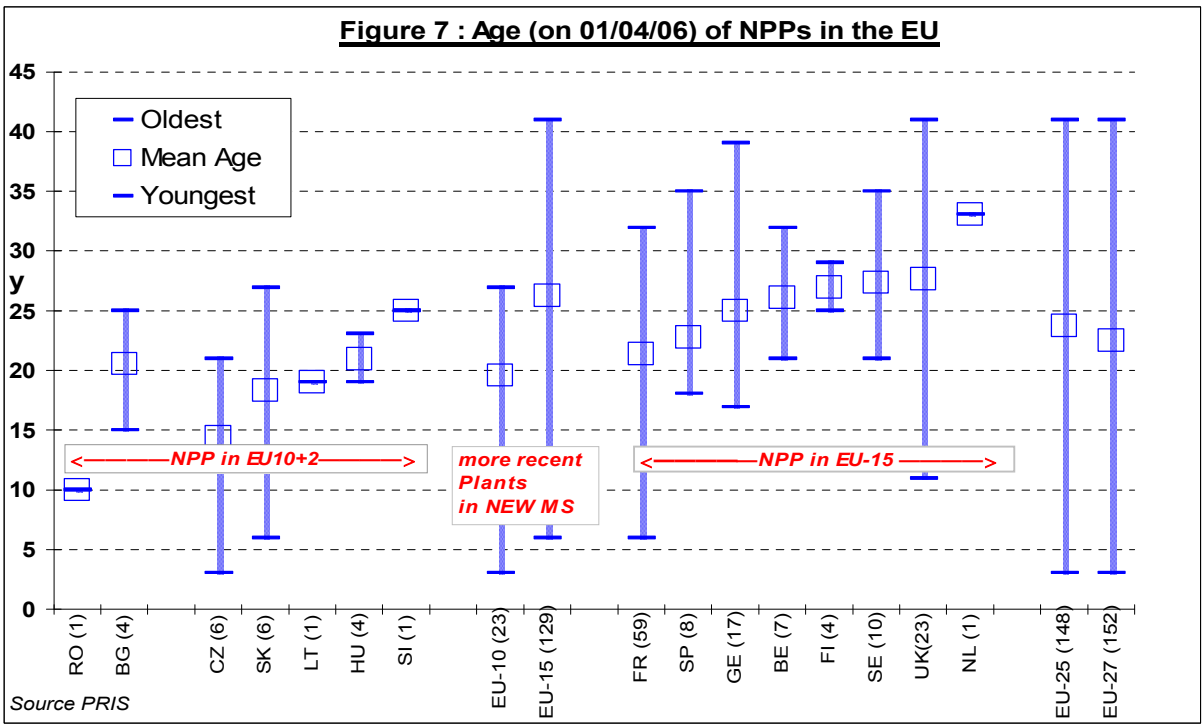
At the end of 2007, in EU-27 a total of 146 nuclear reactors are in operation in 15 Member States, totalling a capacity of 132 GWe. The average age of NPPs is approaching 25 years. In France, which has the largest fleet (59) of nuclear reactors accounting for nearly 80% of its electricity generation, and Lithuania, with only one NPP yet accounting for 70%, the average age is around 20 years. The UK fleet of 19 NPPs has an average age approaching 30 years, while in Germany the average age of their fleet of 17 operational NPPs is nearly 27 years[34]. Also, within the EU, some Member States have decided or planned to construct new nuclear reactors. For those EU countries that choose to continue or to start making use of nuclear energy generation, Member States' Governments need to take the necessary decisions. In the current context, as nuclear safety is paramount in Member States' decision on whether to continue to use nuclear energy, being also the foundation upon which a nuclear power programme must be built upon, a Community nuclear safety approach represents an essential element for developing a sustainable safety infrastructure at the national level. It requires common or shared approaches, built on solid national and international experience. The lack of such a common framework will have negative effects for the sustainability of nuclear energy at EU level.

[34] source: update of COM (2007) 565 final data

The distribution of operational and planned shutdown for NPPs in the enlarged EU as well as potential new build, and the distribution of age of NPPs in the EU are presented in the figures below, as adopted by the Commission in October 2007.



source: COM(2007) 565 final



source: doc. COM(2007) 565 final

b) Competitiveness impact

Since legislation on the liberalisation of the energy market has been enacted, the role of governments has evolved towards creating the appropriate framework for competition. On liberalised markets, investment decisions are taken by investors and not by governments.

Cost and investment risks are important issues when considering construction of nuclear reactors. Nowadays a new NPP involves an investment in the range of € 2 to 3.5 billion (for 1000 MWe to 1600 MWe respectively)[35]. It is essential that plans for both new and reinvigorated nuclear power development and other uses of nuclear technology are complemented with equally ambitious plans for the establishment and enhancement of sustainable safety infrastructures.

Investments in new nuclear facilities require a stable legislative and political framework given the time lag between the initial investment and sizeable returns. Uncertainty about future electricity prices, market structure and conditions and about future energy and climate change policies poses a major risk to long-term investment in the energy sector. This is particularly important for nuclear energy, due to the high capital investment associated with construction of a new NPP and the relatively long period before any such investment starts to show a profit. In practical terms, investments of approximately 900 billion euros are estimated in the EU energy generation with a 2030 horizon. As far as nuclear construction, currently, two 1600 MWe European Pressurized Reactor (EPR) reactors are being built: in Finland (3rd Unit of the Olkiluoto NPP) and at Flamanville, France; expected to be operational by 2012. Finland is also starting the procedure for the possible construction of a 6th reactor, and EDF (France) is planning more EPR reactors by 2020-30. Other on-going, or firmly planned, new build in the EU are the two units of the Belene AES-92 VVER in Bulgaria, Units 3 and 4 of the Mochovce VVER in Slovakia, and Units 3 and 4 of the Cernavoda CANDU NPP in Romania (unit-2 connected to the grid in 2007). In January 2008 the UK government gave the go ahead for new nuclear build, stating that nuclear power should play a role in providing the UK with clean, secure and affordable energy. Italy has also taken a decision in principle to reconsider nuclear power as a possible energy source. It is therefore important to try to establish firm policy frameworks so that the conditions are clear and predictable for new investments. The absence of an EU legislative framework creates uncertainties for the investors.

c) Social impact

A factor to be taken into account, which influences the debate on the future of nuclear power, is the issue of public opinion, because of its impact on the political decisions to be taken and of the legitimate right of population to be involved. Public opinion and perception of nuclear power is paramount to the future of nuclear policy. It is essential that the public has access to reliable information and can participate in a transparent decision-making process. Public confidence and acceptance are inextricably tied to safety which itself has a direct impact on operating the facility without incidents. The active participation of all stakeholders in all appropriate phases of a NPP project is essential. They are very visible activities that need strong involvement from all stakeholders, especially citizens who are directly affected. It is essential that this involvement is established in a transparent way and that public trust in the project is established at the earliest stage.

Until now, even though the safety and reliability record of EU nuclear power is excellent, nevertheless the public does not have the highest confidence in nuclear safety. According to the Eurobarometer on nuclear safety[36], most citizens think that they are not well informed about nuclear safety. Even if Europeans on average have a fair level of knowledge of nuclear issues, in particular whether or not there are NPP in their countries, **they feel unfamiliar with**

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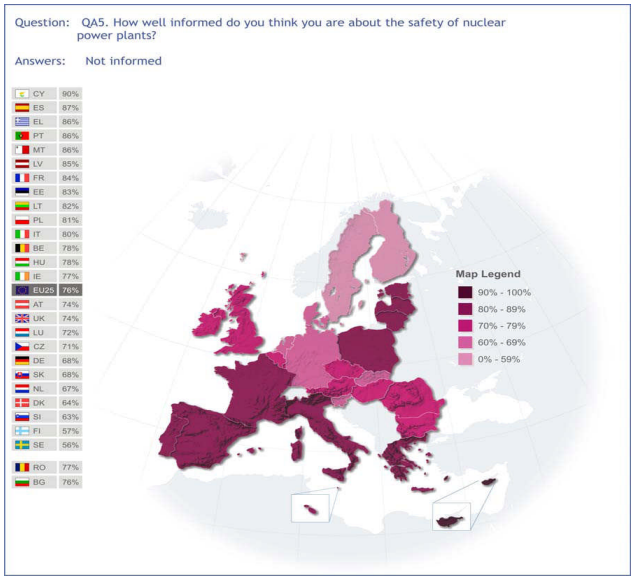
35 COM(2007) 565 final

36 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

the issue of nuclear safety (ranging from 56% to 90%). In this context, it should be underlined the fact that even in countries with a high share of electricity produced from NPPs, the percent of citizens who do not feel informed about nuclear safety-related issues is high (e.g. France – 84%, Lithuania - 82%).



source: Eurobarometer no 271 "Europeans and nuclear safety"

In the light of the above considerations, an enlarged EU needs a common approach in the field of nuclear safety as the current system of each Member State operating its own set of safety rules is too complicated and confuses the public's understanding of how nuclear safety is regulated. The lack of a common nuclear safety framework at EU level can have negative effects on the public confidence in nuclear safety matters.

5.2. <u>Policy option 1</u> - Community legislation setting up common safety standards for existing nuclear installations

The impact of this approach was already detailed in the Impact Assessment accompanying the previous Nuclear Safety proposal[37] . As presented in 2004, this option was not acceptable to the Council. Therefore, only a short summary is given below.

a) Safety-related impact

The Commission has actively intervened in connection with the harmonisation of nuclear safety practices for over 25 years. Despite its efforts, nuclear safety measures differ considerably from one Member State to another. It is necessary to consider nuclear safety in a Community perspective. The Commission concluded that only a common approach can guarantee the maintenance of a high level of nuclear safety in an enlarged EU. This conclusion is still valid, while the implementation needs to be tailored to the existing safety arrangements in place in the Member States, in line with the subsidiarity principle.

b) Competitiveness impact

The beneficiaries of the proposed actions will be the operators of nuclear installations and the national safety authorities, as the objective of the proposal is to introduce basic obligations and general principles for the safety of nuclear installations.

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37 included in COM 2003/32 final

c) Social impact

The public acceptance of nuclear energy may increase, in particular in Member States which have no nuclear industry or in which public confidence in national safety regulation is low.

d) Environmental impact

Policy option 1 has no direct environmental impact.

e) Impact on the EU budget

The financial impact is detailed in the 2003 Impact Assessment which estimated the following overall multi-annual estimate of expenditure at 247 000 euros, excluding staff costs.

5.3. Policy option 2 – Community legislation setting up a common framework of internationally recognised principles, supplemented by implementing measures prepared by the HLG

a) Safety-related impact

All the technical analysis supporting the proposed reference principles and highlighting their role for the improvement of the safety culture has already been done at different expert levels (for a detailed description of their activity – see Annex of the present Impact Assessment).

Also, these fundamental nuclear safety principles have already been recognised at international level, within the Convention on Nuclear Safety, to which Euratom and all the EU Member States are Contracting Parties and consequently, submit National Reports on the implementation of their obligations for the Review Meetings of the Parties. Therefore, binding Community legislation recalling principles already unanimously endorsed at EU level would only add value to the existing cooperation between the Member States within the Review Meetings that provide a forum for the exchange of good practices and information in the field. This approach is also endorsed by the Council in the WPNS SG 1 Report[38], according to which "*The CNS process is an incentive approach for improving regulatory and safety practices in a general sense through positive examples, questions and peer review comments. In this way the CNS promotes harmonisation in the broad sense of the regulatory and safety issues covered. Especially it seems to have been an efficient driving force for improvements of the legal basis and the regulatory framework. The CNS is the only international convention obliging parties to report on the status of nuclear power plant safety in their countries. As such the CNS has a very important role for improvement of nuclear safety worldwide, enhanced by the fact that all states with operating nuclear power plants now have ratified it."*

This approach is also supported by the May 2007 Council Conclusions on Safe management of spent nuclear fuel and radioactive waste, which identify amongst the actions related to harmonised approaches, shared knowledge and joint efforts in the area of the safety of nuclear installations, the *"Promotion of the practical use of current international contexts (Convention on Nuclear Safety, Joint Convention, IAEA, OECD/NEA, WENRA) at EU-level in terms of common approaches and good practices to the safety of nuclear installations and how the results are used, also taking into account the interaction between the different contexts. The work at EU-level has to build on the existing high level of cooperation which shall be maintained and encouraged by EU Member States and the Commission."* The same solution is also proposed in the Maldeikis Report on Assessing Euratom – 50 Years of European nuclear energy policy, where the European Parliament, after underlining the

[38] 15475/2/06 REV 2 ADD 1

absence of appropriate EU legislation in the field of nuclear safety, "*calls on the Commission to draw on the experience gained from implementing the conventions governed by the IAEA (Convention on Nuclear Safety and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management) and to take account of the assessments, conducted by the OECD's Nuclear Energy Agency (NEA), of the most advanced national practices in the field of radioactive waste management; notes that concerted initiatives, such as those carried out by the Western Europe Nuclear Regulators Association (WENRA), to develop a joint approach to nuclear safety, are likely to help with drawing up a basis for legislation*". Also, in its Opinion on the Nuclear Illustrative Programme[39], the European Economic and Social Committee states that it "*agrees with the Commission's present view that the common nuclear safety reference levels and their appropriate implementation should be built on the extensive expertise of Member States' national nuclear safety authorities in collaboration within WENRA. Any other approach could possibly put in some member states the present high safety performances at risk*".

Moreover, the approach under review recognises the principle of national responsibility for the safety of nuclear installations in a Community framework. This is why the detailed implementing rules necessary for putting into practice the Community framework will be prepared within a formalised forum, the HLG, comprising representatives of the regulatory and safety authorities from all the EU Member States, on a "as needed" basis. This solution is fully in compliance with the principle of subsidiarity that requests the EU not to take action unless Community action is more effective than action taken at national, regional or local level.

b) Competitiveness impact

Nuclear power has traditionally shown a combination of higher construction and lower operating costs than fossil-fuel-based energy production, which exhibits lower capital costs but higher and potentially fluctuating fuel and, hence, operating costs.

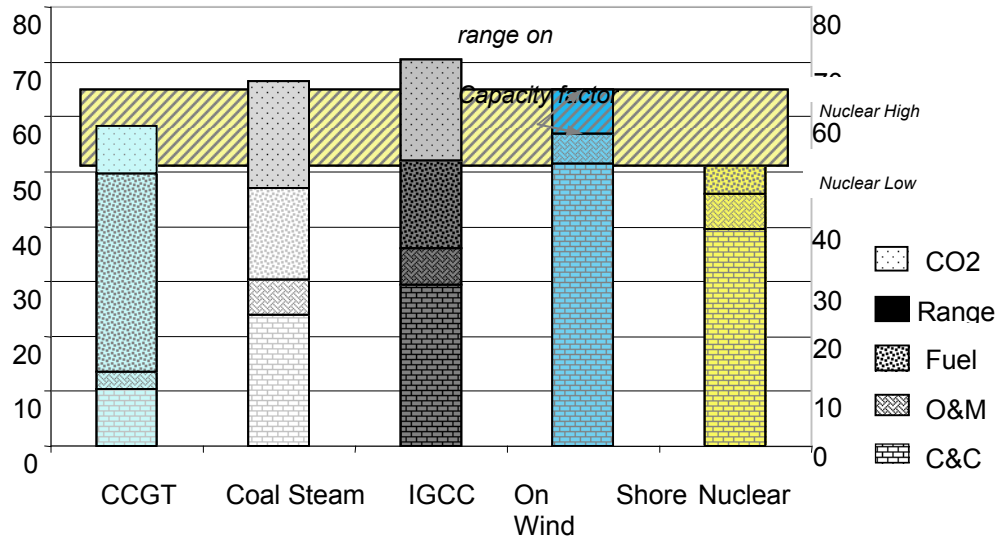
Nuclear construction lead times are, for engineering and licensing reasons, much longer than for combined cycle gas turbines (CCGT) or renewable energy sources.

The economic competitiveness of nuclear power depends on several factors, with construction times, capital costs, waste disposal, decommissioning and the operational capacity factor playing a key role. The private sector will be ultimately responsible for proposing, developing and operating new NPPs. Hence, it will be the private sector, including developers and financial institutions, which will bear many of the procedural risks involved in furthering the nuclear option. Both private and public institutions would release loans only if safety features are accomplished by the applicant. Setting up a Community approach on nuclear safety, while maintaining rigorous safety and quality standards, will increase the competitiveness of nuclear energy, by allowing shorter and more predictable licensing processes, thus mitigating construction risks.

The range of levelised costs of generating electricity, with 10% discount rates and C costs at 30$/tCO2 (1€ = 1.25 $) is presented in the figure below.

[39] 2007/C 256/11

Figure 11b: Electricity Generation Costs in High Discount rate Case



source: COM(2007) 565 final

c) Social impact

The elaboration of a common nuclear safety EU framework will have as a result the increase of the degree of public acceptance towards nuclear energy by efficiently addressing societal expectations on public access to information and public participation to the decision-making process, in the context of nuclear activities. Such an approach will ensure an open and transparent communication of the Community with the public in the field of nuclear safety, especially having in view the results of the 2007 Eurobarometer on nuclear safety (for details, see the assessment of the social impact of Policy option 0).

d) Environmental impact

Within the concept of the European Atomic Energy Community, human beings ("workers and the general public") are protected against the dangers arising from ionising radiation and aspects of the environment (water, air, soil) in so far as this is necessary to protect the human health. In this context, the intrinsic link between radiation protection and nuclear safety is confirmed in the European Court of Justice judgement from 10 December 2002 in the Case C-29/99, according to which "*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.*"[40]

In the area of nuclear safety, important aspects of environmental protection go beyond the scope of the Euratom Treaty. However, there is a major environmental dimension.

Nuclear installations and their operation present potential hazards and have to be managed in ways that ensure the protection of people and the environment, now and in the future, against the dangers arising from the ionising radiation which they emit.

Technical solutions exist that meet these objectives and are based on shared common principles of a high level of safety. The continuing improvement and implementation of these

[40] paragraph 82

solutions and principles by Member States should ensure that a uniformly high level of protection within their respective territories is reached.

However, policy option 2 has no direct environmental impact at this stage, as it proposes only a set of Community nuclear safety principles. Nevertheless, the environmental impacts of the future implementing measures prepared by the HLG will be further assessed when appropriate.

e) Impact on the EU budget

No impact on the EU budget can be foreseen, as this policy option proposes only a set of Community nuclear safety principles. Nevertheless, the HLG has in principle the possibility to propose implementing measures with a financial impact on both the national administrations and/or the utilities operating NPPs or willing to put forward new investments. Such cases will be assessed on a case by case basis if and when specific measures are put forward.

5.4. Policy option 3 - Community legislation setting up a common framework of internationally recognised principles, obligations and requirements, supplemented with additional safety requirements for new nuclear power reactors, that Member States are encouraged to develop.

The main differences of this proposed approach from the 2003/2004 proposals are the following:

- Decoupling from waste issues. One of the major political obstacles of the previous proposals, the regulation of decommissioning funds, is not there anymore.
- Very strong powers of the regulators have been written down clearly, e.g. the power to shut an installation down. This will strengthen the position of regulators in the EU.
- The HLG did not exist at the time of the old proposals. In the new draft, it will become a focal point of cooperation between national regulators; also, if deciding to define additional safety requirements for new nuclear power reactors, Member States should us use the expertise of the HLG and work in close cooperation with it.. This upgrading of the HLG will closely involve the Member States and strengthen the national regulators, as the members come from the national regulatory bodies.

a) Safety-related impact

This policy option has as a foundation the conceptual structure of Policy option 2 (establishing at EU level a framework of basic internationally recognised and endorsed nuclear safety principles). The considerations presented for the assessment of the safety impact of Policy option 2 apply *mutatis mutandis* for Policy option 3.

The proposed Community framework on nuclear safety should aim to the achievement of the following internationally endorsed **fundamental principles**:

Enhancing the role of the national regulators

The regulatory body should be provided with adequate authority, competence and financial and human resources to fulfil its responsibilities (e.g. supervision and regulation of the safety of nuclear installations, ensuring of the implementation of safety requirements, conditions and regulations, granting licences and monitoring their application). This principle is already endorsed in Article 8, paragraph 1 of the Convention on Nuclear Safety, as well as in Principle 2 of the IAEA Safety Fundamentals.

In this context, the safety measures and controls to be implemented in a nuclear installation shall be decided only by the regulatory body and subsequently realised by the licence holder.

Also, in order to continuously improve the regulatory infrastructure, the regulatory body and the national regulatory structure should be subject to periodic international peer reviews.

Enshrining in Community legislation such provision would only add value by supporting and strengthening the already existing competencies of the national regulatory bodies.

Prime responsibility of the licence holder for safety under the control of the regulatory body

The principle of the responsibility of the licence holder for the safety of a nuclear installation has already been widely accepted, as it is already recognised by the Convention on Nuclear Safety (Article 9) and by the IAEA Safety Fundamentals (Principle 1). The WPNS SG1 Report also concludes that *"While the prime responsibility for implementing the defence-in-depth rests with the licence holders (operators), the implementation has to be ensured by an effective national regulatory framework for nuclear safety."*

Reinforcing the independence of the regulatory body

In order to facilitate autonomous decisions giving priority to nuclear safety, the independence of the regulatory body, effectively separated from any other organization tasked to promote, operate nuclear installations or justify societal benefits, as well as its freedom from undue influence, must be ensured. A similar provision already exists in the CNS (Article 8 paragraph 2) and in the IAEA Safety Fundamentals (Principle 2).

One of the conclusions highlighted in the WPNS SG1 Report, in the section dedicated to the Convention on Nuclear Safety and to the assessment of its review meetings, was that *"the CNS process is providing incentives to improve national practices, and thus to harmonise at a high level"*. Furthermore, it is stated that *"a development has taken place during the three review processes towards a common understanding of safety issues, to broaden implementation of evolving safety concepts, e.g. safety management, and to further develop conceptual issues, e.g. independence of regulatory bodies. The CNS has been a major driving force to harmonize the legal basis and the regulatory framework of the Contracting Parties (articles 7, 8, 9) and to provide adequate resources for the regulatory bodies and operators (article 11)."*

A revised nuclear safety proposal should follow the same approach and aim 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 2004 directive proposal.

Ensuring a high level of transparency on issues related to the safety of nuclear installations

A high level of transparency on issues relating to the safety of nuclear installations should consist in the provision of information to the public in an accurate and timely manner about important nuclear safety matters.

Implementation of management systems

A future EU framework should establish principles governing the licence holders' obligations. One of these principles is their obligation to put in place management systems, concept which is included in Principles 1 on the responsibilities of the licence holder and explained more in detail in Principle 3 of the IAEA Safety Fundamentals, according to which it *"has to integrate all elements of management so that requirements for safety are established and applied coherently with other requirements, including those for human performance, quality and*

security, and so that safety is not compromised by other requirements or demands. The management system also has to ensure the promotion of a safety culture, the regular assessment of safety performance and the application of lessons learned from experience". Such management systems should be regularly verified by the regulatory body

Regular safety supervision

Nuclear safety supervision (assessments, investigations, control and enforcement actions) carried out by the regulatory body throughout the whole lifetime of installations responds to the obligation of assessment and verification of safety set up in Article 14 of the Convention on Nuclear Safety. In order to strengthen the powers of European regulators, a EU Directive should provide for extended regulatory powers in the interest of safety, by clearly spelling that in case of serious or repeated safety rules breaches, the regulatory body shall have the power to withdraw the operating licence, to order the stop of operations of any plant if it deems that safety is not fully guaranteed as well as to allow the restart of operation.

Availability of nuclear safety expertise

The availability of nuclear safety experts is an extremely important issue which comes up at every international meeting concerned with nuclear safety. The past decades have not trained enough specialists, so that there is also the problem of aging of safety personnel and inspectors, of which many are approaching retirement. This is an area where the Community can assist with helping trans-national cooperation and training. The obligation to ensure the availability of sufficient and qualified staff is also recognised in Article 11 paragraph 2 of the CNS. WPNS SG1 Report noted on human resources that *"To develop and maintain an effective defence-in-depth of a nuclear facility, an appropriate operating organisation with an effective management system has to be in place, providing a strong management commitment to safety and a strong safety culture. This means e.g. that…sufficient number of adequately trained staff is available".*

Priority to safety

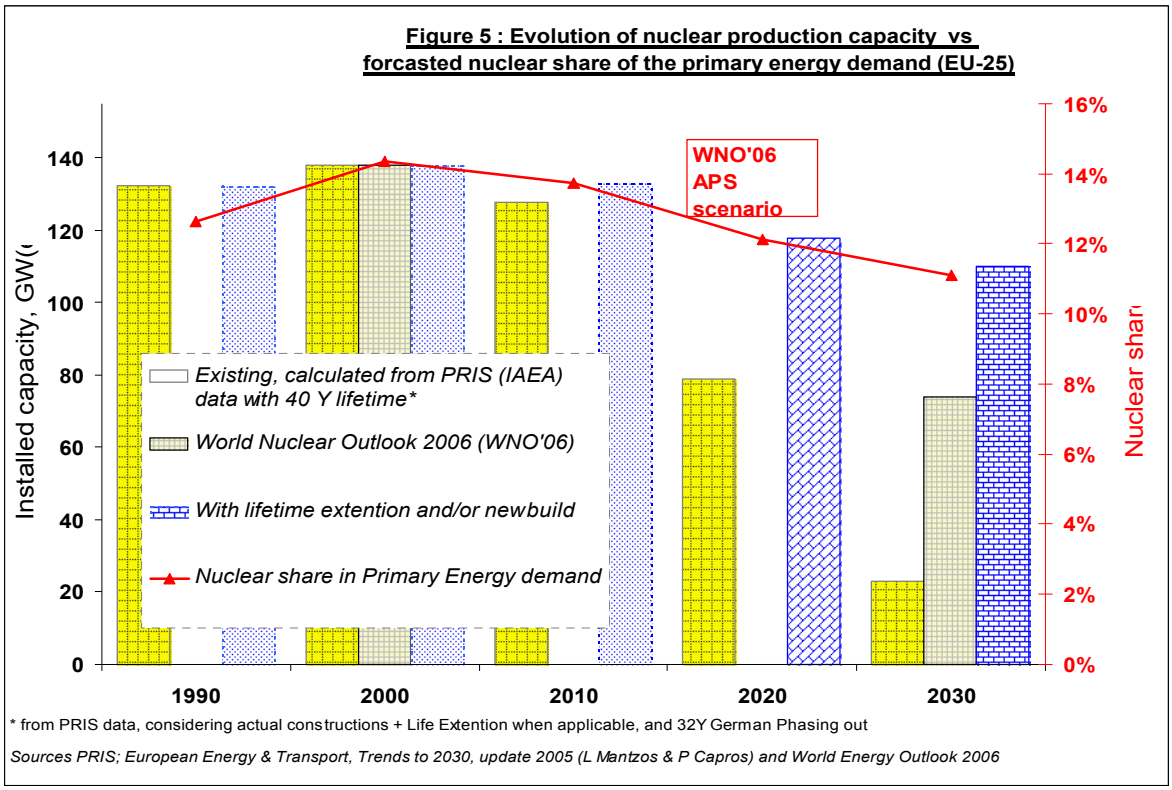
The main aim of the Member States' legislative and regulatory systems should be the achievement of the highest level of safety in nuclear installations. This objective is also provided for in Article 10 of the Convention on Nuclear Safety.

Moreover, the possibility of Member States to impose at national level more stringent safety measures should be provided in the Community legislation. A similar legal provision is also included in Article 54 of the Basic Safety Standards Directive, *"If a Member State is to adopt dose limits which are stricter than those laid down in this Directive, it shall inform the Commission and the Member States"*

Until now, the safety and reliability record of EU NPPs is excellent. Nevertheless, since nuclear power provides one third of Europe's electricity and the typical initial design life of an NPP is currently 40 years, currently, decisions are required on extension of the life of some plants, where safely possible, or on new investments, in order to meet the expected demand and to replace ageing infrastructure over the next 20 years. A significant number of NPPs are indeed due to close down within the next 20 years. Taking into account the current EU energy mix, if the planned phase-out policy in some EU Member States is maintained, without extending plant lifetime and/or new construction, nuclear energy's share of electricity production will be significantly reduced. In this context, policy option 3 aims to go further than setting up a set of nuclear safety principles and it encourages Member States to establish **additional safety requirements** for the safety of the new power reactors, taking as a basis the WENRA safety levels and in close cooperation with the HLG. The WENRA Reactor Safety safety levels cover a wide range of fields covering Safety Policy, Operating Organisation,

Management System, Training and Authorization of NPP staff, Design Basis Envelope for Existing Reactors, Design Extension of Existing Reactor, Safety Classification of Structures, Systems and Components, Operational Limits and Conditions, Ageing Management, System for Investigation of Events and Operational Experience Feedback, Maintenance, In-service inspection and Functional Testing, Emergency Operating Procedures and Severe Accident Management Guidelines, Contents and updating of Safety Analysis Report, Contents and updating of Safety Analysis Report, Probabilistic Safety Analysis, Periodic Safety Review, Plant Modifications, On-site Emergency Preparedness, Protection against Internal Fires.

A projection of the expected nuclear capacity to provide the nuclear share of electricity generation in the EU assuming planned closedown of reactors and potential lifetime extension or/and new build is presented below.



source: COM(2007) 565 final

b) Competitiveness impact

The considerations presented for the assessment of the safety impact of Policy option 2 also apply *mutatis mutandis* for Policy option 3.

c) Social impact

The considerations presented for the assessment of the safety impact of Policy option 2 also apply for Policy option 3.

d) Environmental impact

The considerations presented for the assessment of the safety impact of Policy option 2 also apply for Policy option 3.

e) Impact on the EU budget

No additional financial burden for the EU budget, as the licence holder should possess the adequate financial resources for fulfilling its nuclear safety obligations.

SECTION 6: COMPARING THE OPTIONS

By comparing the individual impacts per option, the following conclusions can be drawn from the Impact Assessment:

Policy option 0 can not be accepted, taking into consideration the fact that the absence of Community legislation would be prejudicial to Community citizens and to the interest of the enlarged EU. Despite a certain degree of harmonisation, today the nuclear safety procedures and practices still vary from one Member State to another and this diversity of measures does not allow the Community to satisfy itself that the health protection requirements of Article 2(b) of the Euratom Treaty are applied in the most effective way. Therefore, Community intervention is indispensable to guarantee the maintenance of a high level of nuclear safety within the EU.

Policy option 1 was considered for the elaboration of the proposal of Directive setting out basic obligations and general principles on the safety of nuclear installations. Having in view the fact that the proposals of the Nuclear Safety Package have not been adopted by the Council until present, this Policy option has not proved to be a feasible one in the light of the necessity to achieve a progress in developing an EU harmonised approach in the area of nuclear safety. Nevertheless, it should be underlined the fact that, although not yet adopted, those proposals have set in motion a process leading to greater awareness of the need to establish a Community framework linking the work of national safety authorities.

Policy option 2 is completely in line with the conclusions adopted by the Council of EU, as well as by the European Council, requesting that nuclear safety should be exercised in an EU-framework (see Section 2.5). However, in order to achieve a progress in developing nuclear safety at EU level, the proposed Community framework should not be restricted simply to taking over a set of basic principles.

In the framework of the above considerations, **Policy option 3** appears to be the preferred approach, as it presents the highest range the benefits, by going beyond the level of principles

A comparative overview of the impacts is presented in the table below.

Table: Impact Assessment: Overview of the impacts

Policy option	Safety impact	Competitiveness impact	Social impact	Environmental impact	Impact on the EU budget
Option 0 Business as usual (no policy change)	- Absence of a harmonised nuclear safety Community framework. - The safety of nuclear installations is the responsibility of the nuclear operators under the supervision of their national authorities. - Different national regulatory systems. - Member States' measures differ considerably from one MS to another. - To meet the	-The most crucial factor affecting the prospect of growth of nuclear power is its underlying economics as a NPP involves an up front investment ranging from €2 to €3.5 billion. -The EU recognises the importance of maintaining a technological lead in the field of nuclear energy - The absence of an EU framework establishing a	- One of the driving factors of the future development of nuclear energy is public acceptance. - According to the 2007 survey on nuclear safety, the European citizens feel unfamiliar with the issue of nuclear safety (ranging from 56% to 90%). - The existence of national	-	-

Policy option	Safety impact	Competitiveness impact	Social impact	Environmental impact	Impact on the EU budget
	increasing energy demand and to reduce European dependency on imports, decisions should be made on new investments or on the life extension of some plants. - The lack of a common nuclear safety approach will have a negative effect on the long term on the future development of nuclear energy at EU level.	comparable level of nuclear safety between the Member States will create uncertainties for the investors.	regulatory systems will only perpetuate the current lack of information in the field.		
Option 1 Community legislation aiming to establish common safety standards for existing nuclear installations	-Nuclear safety measures differ considerably from one Member State to another. -It is necessary to consider nuclear safety in a Community perspective. -Implementation needs to be tailored to the existing safety arrangements in place in the Member States, in line with the subsidiarity principle.	-The beneficiaries of the proposed actions will be the operators of nuclear installations and the national safety authorities, as the objective of the proposal is to introduce basic obligations and general principles for the safety of nuclear installations.	-The public acceptance of nuclear energy may increase, in particular in Member States which have no nuclear industry or in which public confidence in national safety regulation is low.	-Policy option 1 has no direct environmental impact at this stage, as it proposes only a set of Community nuclear safety principles. -Nevertheless, there may be a substantial beneficial impact resulting from the future implementing measures prepared by the HLG.	- Estimations of the overall multi-annual estimate of 247 000 euros, excluding staff costs.
Option 2 Community legislation setting up a common nuclear safety framework (widely recognised principles) + implementing measures prepared by	- Set of widely recognised nuclear safety principles, enshrined in the IAEA Convention on Nuclear Safety: - Euratom and all the Member States are Contracting Parties to the Convention (subsequently, they elaborate National Reports and	- The establishment of a common approach in the field of nuclear safety will lead to the increase of the nuclear energy' competitiveness, by reducing the industry's investment risks	The elaboration of a common nuclear safety EU framework will have as a result the increase of the degree of public acceptance towards nuclear energy	- No direct environmental impact (this Policy option proposes only a set of Community nuclear safety principles). -The environmental impacts of the future implementing	- No impact on the EU budget can be foreseen, as this policy option proposes only a set of Community nuclear safety principles. -

Policy option	Safety impact	Competitiveness impact	Social impact	Environmental impact	Impact on the EU budget
the HLG	participate at the regular Review Meetings). - Implemented rules prepared by the HLG (comprising high-level representatives of the regulatory and safety authorities from all the EU Member States) → subsidiarity principle.			measures prepared by the HLG will be further assessed when appropriate.	Nevertheless, the HLG has in principle the possibility to propose implementing measures with a financial impact on both the national administrations and/or the utilities operating NPPs or willing to put forward new investments. Such cases will be assessed on a case by case basis if and when specific measures are put forward.
Option 3 Community legislation setting up a common framework of internationally recognised principles, obligations and requirements, supplemented with additional safety requirement	-See the considerations from Policy option 2. -Additional element: Member States are encouraged to define additional safety requirements for new nuclear power reactors, using as a basis the WENRA safety standards and in cooperation with the HLG.	- See the considerations from Policy option 2. -	- See the considerations from Policy option 2.	- See the considerations from Policy option 2.	No additional financial burden for the EU budget, as the licence holder should possess the adequate financial resources for fulfilling its nuclear safety obligations

Policy option	Safety impact	Competitiveness impact	Social impact	Environmental impact	Impact on the EU budget
s for new nuclear power reactors, that Member States are encouraged to develop.					

SECTION 7: MONITORING AND EVALUATION

The indicators of progress towards meeting the objectives will be set up at the level of the Member States, solution which is in full compliance with the principle of subsidiarity and it does not hamper the principle of the national responsibility for nuclear safety.

An additional monitoring of the Directive's results will be achieved by means of the HLG obligation set up in its founding Commission Decision to regularly submit to the Commission a report of its activities. Furthermore, the Commission shall transmit this report to the European Parliament and the Council.

As an additional remark, it should be noted that the reporting of the health protection of the public and workers falls outside the scope of the current revised Directive, as it is covered by the radiation protection acquis. Also, there are health-related reporting mechanisms under the International Nuclear Event Scale (INES scale) which represents a means for promptly communicating to the public in consistent terms the safety significance of events reported at nuclear installations. Events are classified on the Scale at 7 levels; the upper levels (4−7) are termed accidents and the lower levels (1−3) incidents. In addition, monitoring of air, water and soil are established in Articles 35-36 of the Euratom Treaty and regularly carried out by the Commission services.

ANNEX

Overview of the consultations and technical expertise supporting the approach of the proposed Directive setting up a Community framework for Nuclear Safety

1. CONSULTATIONS ON THE NECESSITY OF A COMMUNITY NUCLEAR SAFETY LEGISLATIVE FRAMEWORK

1.1 Consultations under Article 31 of the Euratom Treaty

Article 31 of the Euratom Treaty defines the procedure for the adoption of the basic safety standards provided for in Article 30 for the protection of the health of workers and the general public against the dangers arising from ionising radiation. According to the Treaty, these standards shall be worked out by the Commission after it has obtained the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts, and in particular public health experts in the Member States. Also, the Commission shall obtain the opinion of the Economic and Social Committee on these basic standards.

In relation to the first consultation, the Commission submitted in 2002 its draft legislative proposals to the Article 31 Group of experts. The Group of experts supported the Commission initiatives and urged it to continue its efforts as regards harmonisation. The discussions within

the group made it possible to clarify some inaccuracies. Texts were therefore amended in order to take into account constructive criticisms formulated by the Group of experts. Subsequently, the 2003 opinion of the European Economic and Social Committee concluded that the Committee *"reaffirms the basic obligation of the Member States and the Community to guarantee the safety of nuclear installations and the disposal of radioactive waste; fundamentally endorses the Commission's initiative to achieve this, in particular also with a view to harmonising regulatory systems and in anticipation of enlargement"*.

1.2. Stakeholders consultation

In addition to the consultations resulting from the legislative procedure provided for in the Euratom Treaty, the Commission carried out numerous consultations, with both the national authorities and industry, individually or collectively through various fora. Consultations were also undertaken with international organizations, such as the IAEA and the NEA. The Commission took also advantage of its participation in various international meetings to present its plans for EU regulation in the field of nuclear safety. On this point, the following events should in particular be rated:

- European Nuclear Society Conference (France, October 2002);
- International Conference on issues and trends in radioactive waste management (Austria, December 2002);
- International conference on waste disposal in geological formations (France, January 2003);
- International waste management symposium (the United States, February 2003);
- Nuclear waste, second parliamentary meeting (France, March 2003);
- Meeting with the Group of European municipalities with nuclear facilities (Belgium, March 2003);
- Conference organized by the "Consejo de seguridad nuclear" in San Lorenzo de El Escorial (Spain, July 2003);
- General assembly of the World association of Nuclear Operators –WANO - (Germany, October 2003);
- International symposium on the harmonization of nuclear safety approaches (Germany, October 2003);
- Eurosafe 2003 (France, November 2003);
- The European discussions: nuclear waste management (France, November 2003);
- International conference on geological repositories (Sweden, December 2003);
- Energy choices for Europe 2004 (Belgium, March 2004);
- Euradwaste (Luxembourg, March 2004);
- First parliamentary meeting on nuclear energy (Belgium, April 2004);
- Meetings of WPNS (2004-2006);
- Meetings of the Nuclear Regulators' Working Group (NRWG), Reactor Safety Working Group (RSWG) and CONCERTation on European Regulatory Tasks (CONCERT), presented below (2005-2006);
- 4 meetings of the HLG (2007-2008);

– 3 meetings of the European Nuclear Energy Forum (2007-2008).

These various meetings made it possible to present the legislative proposals and to follow their development throughout the discussion process with the European Parliament and the Council.

2. OVERVIEW OF THE ACTIVITY OF EXPERT GROUPS IN THE FIELD OF THE HARMONIZATION OF NUCLEAR SAFETY APPROACHES

2.1. NRWG and RSWG

The Commission has worked with the support of expert groups for more than 30 years and has launched many studies and initiatives in the field of nuclear safety. In order to pursue the objectives of the 1975 Council Resolution on the technological problems of nuclear safety, the Commission set up two expert groups dealing with nuclear installation safety. The NRWG, which met last in June 2005, includes representatives of nuclear regulatory authorities from EU Member States and Candidate States of Central and Eastern Europe. The RSWG, which included all the EU regulatory bodies and industry, was discontinued in 1998.

Their approach to harmonisation consisted in a comparison of national practices, identification of common features, and analysis of the safety relevance of differences. Common technical opinions were expressed on certain safety issues, and, while these were not safety "standards", they were expected to promote good practices. Activities of both Groups included safety aspects of ageing, applications of risk-based approaches and innovative technologies. These activities were widely documented and published either as technical publications, or as Communications to the Council and the European Parliament. The outcome of the work of these expert groups has provided a sound technical background, which can be fully valorised by setting up a framework at EU level, establishing a common approach in the field of nuclear safety regulation.

2.2. CONCERT

The CONCERT Group, formed in 1992, was a forum that brought together EU, Central and Eastern European Countries and Newly Independent States nuclear regulators to share experience and to enhance the progress of assistance and co-operation programmes in general. Among its other activities, the discussions within this group significantly contributed to achieving the objectives of the Convention on Nuclear Safety, by forming a common regulatory view on nuclear safety issues and developing the safety culture. The group held its last meeting in 2005.

2.3. WENRA

In February 1999, the heads of the Nuclear Regulatory Authorities of Western European countries with NPPs decided to create WENRA. The aim of WENRA was to improve nuclear safety, thus pursuing, among others, the objective of developing a *"harmonised approach to selected nuclear safety and radiation protection issues and their regulation, in particular within the European Union"*[41]. The terms of reference of WENRA were signed by the chief nuclear regulators of Belgium, Finland, France, Germany, Italy, the Netherlands, Spain, Sweden, Switzerland and the United Kingdom. The main objectives of WENRA at that time were to develop a common approach to nuclear safety and to provide an independent capability to examine nuclear safety in the applicant countries.

[41] WENRA Policy Statement, signed in Stockholm in December 2005

In March 2003, WENRA extended its membership to the heads of the Regulatory Authorities of all the then EU Candidate Countries with nuclear power programmes. The revised terms of reference were signed by the chief regulators of Bulgaria, Czech Republic, Hungary, Lithuania, Romania, Slovakia and Slovenia, in addition to the earlier members. After 2003, the objectives of the co-operation within WENRA were extended, so that it would become a network of chief nuclear safety regulators in Europe, exchanging experience and discussing significant safety issues.

In order to harmonise safety approaches, two working groups were launched. The mandate of the working groups was to analyse the current situation and the different safety approaches, compare individual national regulatory approaches with the IAEA Safety Standards, identify any differences and propose a way forward to possibly eliminate the differences without impairing the final resulting level of safety.

The Reactor Harmonisation Working Group (RHWG), consisting of experts from the WENRA organisations, was established in 2000. During 2000-2002, the group carried out a pilot study to develop and test a methodology for making systematic comparisons of national requirements on selected reactor safety issues and to arrive at conclusions about what needs to be addressed at the national levels in order to reach common safety levels. A main study started in 2003 with basically the same methodology as the pilot study and with additional issues to be covered.

Another WENRA working group, the Working Group on Waste and Decommissioning (WGWD), has looked into harmonisation of the areas of nuclear waste and spent fuel storage and decommissioning of nuclear facilities.

In January 2006, two reports on reference levels in these areas were published. In connection with publishing, WENRA invited stakeholders to comment on the reports.

As a result, WENRA members have defined many common safety reference levels for power reactors with a view to align national requirements by the year 2010.

A first revision of the reference levels related to reactor safety has been published by WENRA in January 2007, as a result of comments by stakeholders on the report published in January 2006.

The RHWG has given further consideration to some issues raised by the stakeholders. As a result of this work, WENRA members have decided to slightly modify some reference levels to further clarify their intent. A revision of the RHWG Safety Reference Levels was published in March 2007.

In January 2008, WENRA published a new revision of the reference levels applicable to reactor safety, reflecting the work of the RHWG to propose a revised set of reference levels on issue C- "Management Systems" as well as the commitment of WENRA to revise the reference levels when new knowledge and experience are available.

One of the tasks entrusted to the WPNS was to asses the WENRA reports and action plans. In this context, SG1 analysed the WENRA Report on Harmonisation of safety approaches for Nuclear Power Reactors while SG2 evaluated the WENRA Report on Harmonisation of safety approaches for Waste and Decommissioning. The issues investigated covered the extent of harmonised approaches to safety requirements and implementation, indicated by the benchmarking results for the studied issues, and the measures to accomplish harmonised approaches for the issues presented in the WENRA studies that are included in the agreed action plans. As a result, one of the conclusions of the WPNS – SG1 Report is that the *"WENRA methodology is a systematic, documented and logical approach to harmonisation"*.

2.4. WPNS

Following the Council Conclusions on Nuclear Safety and Safe management of spent fuel and radioactive waste, reached in June 2004, a wide ranging consultation process was initiated, aiming to identify new instrument(s) that can contribute more effectively to further improving nuclear safety and the safety of the management of spent fuel and radioactive waste, without excluding any instrument, in the framework of the Euratom Treaty and in line with the principles of better law making.

Subsequently, as a consequence of the June 2004 Council Conclusions, after long negotiations on the Commission's proposals for Council (Euratom) Directives setting out basic obligations and general principles on the safety of nuclear installations and on the management of spent fuel and radioactive waste, WPNS was activated by the WPAQ.

The Council Conclusions call for an "*extensive consultation*" with stakeholders before any instruments in these fields are developed in the framework of the Euratom Treaty. According to the Conclusions, a basis needs to be developed for the consultation process, in particular taking into account the work conducted by national nuclear regulatory authorities to reach harmonised safety approaches. Furthermore, the Conclusions request Member States together with the Commission "*to engage in a wide ranging consultation process facilitating the choice of instrument(s), in the framework of the Euratom Treaty, that can contribute more effectively to achieving nuclear safety and the safe management of spent fuel and radioactive waste, without excluding any instrument and in line with the principles of Better law making*."

On 3 December 2004, the WPAQ agreed on an Action Plan[42] for following up on the Council Conclusions. This Action plan identified three main action areas:

- Actions in relation with the safety of nuclear installations;
- Actions in relation with safety of the management of spent fuel and radioactive waste;
- Actions in relation with the financing of the decommissioning of nuclear installations and safe management of spent fuel and radioactive waste.

The Work Programme[43] of WPNS established three subgroups to address the tasks identified therein. The subgroups were assessing the following fields:

Subgroup 1 (SG1) was assigned the area of Nuclear Installation Safety.

Subgroup 2 (SG2) was assigned the area of safety of the management of spent fuel and radioactive waste (including decommissioning).

Subgroup 3 (SG3) was assigned the area of financing of the decommissioning and dismantling of nuclear installations and financing the safe management of spent fuel and radioactive waste.

The final WPNS Report, comprising overall conclusions and recommendations, was approved by the WPAQ on 13 December 2006. The detailed methodology, organisation of work and data collection, detailed results from data collection and analysis, and justification for the conclusions and recommendations are presented in the attached reports produced by the established subgroups. The main sources of the Reports are the following:

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42 15955/04

43 5574/2/05 REV 2

– International Conventions (Convention on Nuclear Safety, Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management) review process;

– WENRA[44] reports and action plans;

– National use of the IAEA Safety Requirements;

– Harmonised approaches to nuclear safety, safe management of spent fuel and radioactive waste reached within the work of NEA[45]/CNRA[46], RWMC[47], CSNI[48];

– Harmonised approaches to nuclear safety, safe management of spent fuel and radioactive waste reached as a result of Community activities;

– Study of financial arrangements for decommissioning and the management of spent fuel and radioactive waste.

2.5. HLG

In 10 January 2007, the Commission adopted a draft Nuclear Illustrative Programme that proposed the establishment of a High Level Group on nuclear safety, waste management and decommissioning. The Brussels European Council from March 2007 endorsed the Commission's proposal to establish an EU High Level Group on Nuclear Safety and Waste Management. The Council Conclusions of May 2007 on Nuclear Safety and Safe Management of Spent Nuclear Fuel and Radioactive Waste paved the way for the creation of the HLG. The conclusions were adopted based on the results of the work carried by the WPNS; they set out a list of possible actions, acknowledging that any new initiatives at the EU level should be assessed against their potential contribution to the whole system of existing efforts. The actions are connected with the safety of nuclear installations, the safety of the management of spent fuel and radioactive waste as well as the financing of the decommissioning of nuclear installations and the safe management of spent fuel and radioactive waste. The European Parliament subsequently adopted the 50 years of European nuclear energy policy report, wherein it regretted the absence of binding legislation in the nuclear safety domain and urged the Commission and the Council to take the necessary steps for it, taking note of the initiative to establish a High Level Group. On 12 July 2007, the European Economic and Social Committee also adopted a favourable Opinion on the content of the Nuclear Illustrative Programme.

The HLG was established by the Commission Decision of 17 July 2007 (2007/530/Euratom[49]). According to the Commission Decision, the HLG shall assist the EU institutions in progressively developing common understanding and eventually additional European rules in the fields of the safety of nuclear installations and the safety of the management of spent fuel and radioactive waste. The HLG may set up working groups or subgroups to study specific subjects and it shall every two years submit a report of its activities to the Commission, the European Parliament and the Council. With its actions, the HLG shall optimise the efforts and results which Euratom and its Members States achieve, *inter alia*, at the IAEA and the OECD NEA. The HLG comprises the Heads of the national regulatory or nuclear safety authorities of the 27 Member States.

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44 http://www.wenra.org

45 Nuclear Energy Agency (of the OECD)

46 Committee on Nuclear Regulatory Activities (NEA)

47 Radioactive Waste Management Committee (NEA)

48 Committee on the Safety of Nuclear Installations (NEA)

49 O.J. L 195 , 27/07/2007 P. 0044 - 0046

By setting up the HLG, the technical work of WENRA in the field of harmonization will be widened in a more formal framework, in association with representatives of the non nuclear countries of the EU. The importance of the activity carried on at WENRA level is recognised and stressed in the May 2007 Council Conclusions on Safe management of spent nuclear fuel and radioactive waste. In this framework, the role of WENRA is underlined as a reference for the future work of the HLG in the fields of safety of nuclear installations and safety of the management of spent fuel and radioactive waste ("*Building on the WENRA process with regard to further development of Safety Reference levels and to how WENRA States, being also Member States of the EU, implement the WENRA national action plans, thereby including those countries that do not operate any nuclear power plants and the Commission. While the work at EU level shall not duplicate the WENRA process, all the Member States should have the possibility of being informed, putting questions and further contributing to the process done so far."* and "*Building on the WENRA activities and consideration of its relevance to the safety of spent fuel, radioactive waste and decommissioning management in the EU. While the work at EU level shall not duplicate the WENRA process, all the Member States should have the possibility of being informed, putting questions and further contributing to the process done so far"*).

The HLG met for the first time in October 2007. Three subgroups were established, dealing with the following topics:

- Improvements of nuclear safety arrangements;
- Improvements in the decommissioning, radioactive waste management and spent fuel arrangements;
- Improvements in transparency arrangements.

As far as nuclear safety is concerned, HLG has already concluded that any EU legal instrument on nuclear safety should be based upon the Convention on Nuclear Safety as well as on the IAEA Safety Fundamentals. Also, most of the members of the HLG actually support the revised approach currently proposed.

The proposed revised Community legislation on nuclear safety should recognise the key role to the HLG, which will act as a focal point of cooperation between nuclear regulators and will be consulted by the Member States when defining additional safety requirements for new power reactors. For this purpose, its initial mandate will be amended accordingly, in order to properly reflect its competencies under the Directive.