

Procedure file

Basic information		
CNS - Consultation procedure Directive	2008/0231(CNS)	Procedure completed
Community framework for the nuclear safety of nuclear installations Amended by 2013/0340(NLE)		
Subject 3.60.04 Nuclear energy, industry and safety		

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	ITRE Industry, Research and Energy		17/12/2008
		PPE-DE HÖKMARK Gunnar	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		21/01/2009
		Verts/ALE HARMS Rebecca	
Council of the European Union	Committee for opinion on the legal basis	Rapporteur for opinion	Appointed
	JURI Legal Affairs		03/11/2008
		Verts/ALE FRASSONI Monica	
Council of the European Union	Council configuration	Meeting	Date
	Environment	2953	25/06/2009
European Commission	Commission DG	Commissioner	
	Energy and Transport	PIEBALGS Andris	

Key events			
26/11/2008	Legislative proposal published	COM(2008)0790	Summary
03/02/2009	Committee referral announced in Parliament		
31/03/2009	Vote in committee		Summary
03/04/2009	Committee report tabled for plenary, 1st reading/single reading	A6-0236/2009	
21/04/2009	Debate in Parliament		
22/04/2009	Results of vote in Parliament		
22/04/2009	Decision by Parliament	T6-0254/2009	Summary
	Act adopted by Council after consultation		

25/06/2009	of Parliament		
25/06/2009	End of procedure in Parliament		
02/07/2009	Final act published in Official Journal		

Technical information

Procedure reference	2008/0231(CNS)
Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Directive
	Amended by 2013/0340(NLE)
Legal basis	Euratom Treaty A 032; Euratom Treaty A 031
Stage reached in procedure	Procedure completed
Committee dossier	ITRE/6/70759

Documentation gateway

Legislative proposal		COM(2008)0790	26/11/2008	EC	Summary
Document attached to the procedure		SEC(2008)2892	26/11/2008	EC	
Document attached to the procedure		SEC(2008)2893	26/11/2008	EC	
Committee draft report		PE418.351	28/01/2009	EP	
Amendments tabled in committee		PE421.201	26/02/2009	EP	
Committee opinion	ENVI	PE420.059	18/03/2009	EP	
Specific opinion	JURI	PE423.704	01/04/2009	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0236/2009	03/04/2009	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0254/2009	22/04/2009	EP	Summary
Economic and Social Committee: opinion, report		CES1030/2009	10/06/2009	ESC	
Commission response to text adopted in plenary		SP(2009)3507	25/06/2009	EC	
Follow-up document		COM(2015)0573	18/11/2015	EC	Summary
Follow-up document		SWD(2015)0244	18/11/2015	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

[Directive 2009/71](#)
[OJ L 172 02.07.2009, p. 0018](#) Summary

Community framework for the nuclear safety of nuclear installations

PURPOSE: to re-start the process of establishing a common EU framework on nuclear safety with the objective of achieving and maintaining a high comparable level of nuclear safety throughout the Community.

PROPOSED ACT: Council Directive (Euratom).

BACKGROUND: on 30 January 2003, the Commission adopted two proposals of Directives dealing respectively with the [safety of nuclear facilities](#) and the [management of spent fuel and radioactive waste](#).

At the same time, both proposals were discussed in the Council, under the Italian and Irish Presidencies. As a majority allowing the adoption or the rejection of both proposals was not possible to be obtained, 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 adopted by the Council in June 2004, leading to the creation of the Council Working Party on Nuclear Safety (WPNS).

The renewed interest in nuclear power expressed by a number of Member States, with the perspective of numerous life extensions and construction of new plants, 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 and citizens, but also wide ranging economic implications for the energy generating industry. Enacting in binding Community legislation internationally endorsed nuclear safety principles would ensure an additional level of guarantee for the public in the EU.

CONTENT: the present draft Directive setting up a Community framework on Nuclear Safety aims at restarting the process of establishing a common EU framework on nuclear safety, by updating and replacing the 2003 Commission proposal for a Council (Euratom) Directive setting out basic obligations and general principles on the safety of nuclear installations, included in the initial Nuclear Safety Package.

Its basic approach is that a set of common principles in the field of nuclear safety, already included in the CNS, are regulated at Community level, 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 European High Level Group on Nuclear Safety and Waste Management (HLG). In addition, the revised legislative proposal builds on 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.

The main provisions of the proposal are as follows:

Responsibility and framework for the safety of nuclear installations: responsibility for the safety of nuclear installations reflects one of the fundamental principles of nuclear safety. The prime responsibility for the safety of nuclear installations, throughout their lifetime, rests with the holder of the license under the control of the regulatory body. Furthermore, the safety measures and controls to be implemented in a nuclear installation shall be decided only by the regulatory body and realised by the licence holder. Member States should establish and maintain a legislative and regulatory framework for nuclear safety. This provision is already adhered to by all Member States and should not pose any difficulty for implementation.

Regulatory bodies: the proposal reinforces the role and the independence of the national regulatory bodies, building on their competencies. In order to facilitate autonomous decisions giving priority to nuclear safety, the effective independence of the regulatory body from all organizations tasked to promote, operate nuclear installations or justify societal benefits, as well as its freedom from undue influence must be ensured.

The regulatory body, provided with adequate authority, competence and financial and human resources to fulfil its responsibilities and duties, will:

- be entrusted with the supervision and regulation of the safety of nuclear installations, as well as with ensuring of the implementation of safety requirements, conditions and regulations;
- have the responsibility of granting licences and monitoring their application on siting, design, construction, commissioning, operation or decommissioning of nuclear installations;
- have the duty to ensure that licence holder have staff in sufficient numbers and level of qualification to run the installations.

In order to continuously improve the regulatory infrastructure, the regulatory body and the national regulatory structure will be subject to periodic international peer reviews.

In the framework of this provision, the national regulatory bodies and the regulatory systems will be subject to regular international peer review missions by the IAEA International Regulatory Review Service (IRRS) missions, and subscribe to prepare at least a self assessment every ten years.

Transparency: the provisions set out respond to the necessity ensure access to reliable information and to allow the public to participate to a transparent decision-making process.

Safety requirements and regulations for nuclear installations: the proposal reiterates and reinforces Member States' obligation to respect the IAEA safety fundamentals as well as to observe the internationally agreed obligations and requirements of the CNS.

As regards 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 this context, it should be underlined that, once the Council has agreed on the text of the Directive, the Commission will adapt accordingly the mandate of the HLG as established by its founding Commission Decision.

Obligations of licence holders: this proposal sums up the obligations of licence holders for fulfilling the requirements as regards nuclear safety and emphasises their duties to establish and implement management systems and possess adequate financial and human resources for nuclear safety.

Supervision: the nuclear safety assessments, investigations, control and enforcement actions of the regulatory body must be carried out throughout the whole lifetime of installations, including during decommissioning. This is another commonly agreed principle. In order to

strengthen the powers of European regulators, the present Directive provides for extended regulatory powers in the interest of safety. In case of serious or repeated safety rules breaches, the regulatory body shall have the power to withdraw the operating licence and order the suspension of operations of any plant if it deems that safety is not fully guaranteed.

Nuclear safety expertise: appropriate education and training opportunities for continuous theoretical and practical training in nuclear safety shall be made available by Member States separately and through trans-national cooperation.

Priority to safety: in line with the principle of priority of safety, Member States have the possibility to impose at national level more stringent safety measures than those provided for in the draft Directive.

Community framework for the nuclear safety of nuclear installations

The Committee on Industry, Research and Energy adopted the report by Gunnar HOKMARK (EPP-ED, SE) amending, under the consultation procedure, the proposal for a Council directive (Euratom) setting up a Community framework for nuclear safety.

The main amendments are as follows:

Objective and scope: Members stress that the Directive aims at creating a Community framework for nuclear safety in the European Union. It sets out a foundation for legislation and regulatory arrangements in the Member States concerning nuclear safety and aims at achieving, maintaining and continuously improving nuclear safety in the Community and to enhance the role of the national regulatory bodies.

The directive will apply to work carried out by subcontractors used by operators.

Definitions: the committee made some amendments to the definitions of "nuclear installation?", "regulatory body", "licence" and "new power reactors?".

Legal framework for the safety of nuclear installations: the amended article is a reorganisation of the text and concerns the obligation of Member States to adopt a legislative and regulatory framework ensuring the regulation and the supervision of nuclear installations. This includes: (i) an appropriate regulatory framework, notably providing for national safety requirements, licensing system and regulatory inspections, and the right for Member States to impose more stringent safety measures; (ii) a priority given to safety policies; (iii) a peer review of the regulatory framework and regulatory body in place. The text specifies that Member States shall ensure that at least every 10 years the regulatory body and the national regulatory system is submitted to an international peer review aimed at continuously improving the regulatory infrastructure.

Designation and responsibilities of the regulatory bodies: this reorganised article is dedicated to the regulatory body, its tasks, resources and competences. The committee feels in particular, that the independence of the regulatory body as regards governments and nuclear industry policy should be clearly strengthened and further developed. The regulatory body must be legally distinct and functionally independent from any other public or private entity. The staff of the regulatory body and the persons responsible for its management must act independently from any market interest and shall not seek or take instructions from any government or other public or private entity, when carrying out its regulatory duties.

The national regulatory body is responsible for regulating, supervising and assessing the safety of nuclear installations. The committee deleted the clause enabling regulatory authorities to grant licences. It states that responsibilities should be clearly assigned to the regulatory body in charge of regulating and controlling safety aspects of nuclear installations. This process is distinct from licensing schemes which will be under the responsibility of competent national or governmental authorities.

Member States must ensure that the regulatory body is empowered to order the suspension of operations of any nuclear installations in cases where safety is not guaranteed.

Transparency: Member States shall inform the public and the Commission about the procedures and the results of the surveillance activities on nuclear safety and shall inform the public immediately in the event of any incident.

Safety requirements for nuclear installations: Members note that the International Atomic Energy Agency (IAEA) rules should reflect best international practice as regards safety requirements and therefore constitute a good basis for Community legislation. They cannot be introduced into Community law by simple reference to the IAEA Safety Standards Series No. SF-1 (2006) in this Directive. The committee considered that an Annex containing the Fundamental Safety Principles should be added to the Directive.

Accordingly, an Annex entitled "Safety Objectives" is added to the text.

In addition, Members deleted the reference to additional safety requirements which must be in line with the continuous improvement of safety on the basis of the safety levels developed by the Western European Nuclear Regulators' Association (WENRA) and in close collaboration with the European High Level Group on Nuclear Safety and Waste Management. They state that the reference to the safety levels developed by WENRA, as regard new nuclear reactor, cannot be inserted in the core of the Directive since common safety reference levels for future reactors are not mature yet.

The Commission shall ensure that all third countries that wish to enter or are in the process of negotiating their accession to the EU will comply, as a minimum, with the standards set out in the Directive and the principles in the Annex, as set by the IAEA.

Responsibilities of licence holders: the committee confirms that the prime responsibility for the safety of nuclear installations, throughout the lifetime of the nuclear installations, shall rest with the holder of the licence. This responsibility of the licence holder cannot be delegated. It adds that the regulatory body must assess regularly the sufficiency and qualifications of the staff of the licence holder, as a prerequisite for ensuring nuclear safety, on the basis of a report presented by the licence holder on the evaluation of employment issues such health and safety and the safety culture, qualifications and training, numbers of staff employed and use of subcontractors.

In addition, the relevant regulatory authorities shall, every 3 years, present a report on nuclear safety and safety culture. The Commission, in consultation with the European social partners, may propose improvements to ensure nuclear safety including health protection at the highest possible level in the EU.

Report: Member States shall report to the Commission on the implementation of this Directive at the same time and frequency as for their

Community framework for the nuclear safety of nuclear installations

The European Parliament adopted by 511 votes to 116, with 36 abstentions, a legislative resolution amending, under the consultation procedure, the proposal for a Council directive (Euratom) setting up a Community framework for nuclear safety.

The main amendments are as follows:

Objective and scope: Members stress that the Directive aims at creating a Community framework for nuclear safety in the EU. It sets out a foundation for legislation and regulatory arrangements in the Member States concerning nuclear safety and aims at achieving, maintaining and continuously improving nuclear safety in the Community and to enhance the role of the national regulatory bodies.

The directive will apply to work carried out by subcontractors used by operators.

Definitions: Parliament made some amendments to the definitions of "nuclear installation", "regulatory body", "licence" and "new power reactors".

Legal framework for the safety of nuclear installations: the amended article is a reorganisation of the text and concerns the obligation of Member States to adopt a legislative and regulatory framework ensuring the regulation and the supervision of nuclear installations. This includes: (i) an appropriate regulatory framework, notably providing for national safety requirements, licensing system and regulatory inspections, and the right for Member States to impose more stringent safety measures; (ii) a priority given to safety policies; (iii) a peer review of the regulatory framework and regulatory body in place. The text specifies that Member States shall ensure that at least every 10 years the regulatory body and the national regulatory system is submitted to an international peer review aimed at continuously improving the regulatory infrastructure. The results of the international peer review must be notified to the Commission.

Designation and responsibilities of the regulatory bodies: this reorganised article is dedicated to the regulatory body, its tasks, resources and competences. The independence of the regulatory body as regards governments and nuclear industry policy is strengthened and further developed. The regulatory body must be legally distinct and functionally independent from any other public or private entity. The staff of the regulatory body and the persons responsible for its management must act independently from any market interest and shall not seek or take instructions from any government or other public or private entity, when carrying out its regulatory duties.

The national regulatory body is responsible for regulating, supervising and assessing the safety of nuclear installations. Parliament deleted the clause enabling regulatory authorities to grant licences. The regulatory body must carry out nuclear safety assessments, investigations and controls and, where necessary, enforcement actions in nuclear installations throughout their lifetime, including during decommissioning. It must be empowered to order the suspension of operations of any nuclear installations in cases where safety is not guaranteed.

Regulatory bodies of Member States shall exchange best regulatory practice and develop a common understanding of internationally accepted nuclear safety requirements.

Transparency: Member States shall inform the public and the Commission about the procedures and the results of the surveillance activities on nuclear safety and shall inform the public immediately in the event of any incident.

Safety requirements for nuclear installations: Members note that the International Atomic Energy Agency (IAEA) rules should reflect best international practice as regards safety requirements and therefore constitute a good basis for Community legislation. They cannot be introduced into Community law by simple reference to the IAEA Safety Standards Series No. SF-1 (2006) in this Directive. An Annex containing the Fundamental Safety Principles is inserted into the text, in order to make observance of the principles legally binding.

Accordingly, an Annex entitled "Safety Objectives" is added to the text.

In addition, Members deleted the reference to additional safety requirements which must be in line with the continuous improvement of safety on the basis of the safety levels developed by the Western European Nuclear Regulators' Association (WENRA) and in close collaboration with the European High Level Group on Nuclear Safety and Waste Management. Parliament considered that the reference to the safety levels developed by WENRA, as regard new nuclear reactor, cannot be inserted in the core of the Directive since common safety reference levels for future reactors are not mature yet.

The Commission shall ensure that all third countries that wish to enter or are in the process of negotiating their accession to the EU will comply, as a minimum, with the standards set out in the Directive and the principles in the Annex, as set by the IAEA.

Responsibilities of licence holders: Parliament confirms that the prime responsibility for the safety of nuclear installations, throughout the lifetime of the nuclear installations, shall rest with the holder of the licence. This responsibility of the licence holder cannot be delegated. licence holders are responsible for the design, construction, operation and decommissioning of their nuclear installations in accordance with the provisions set out in the text. It adds that the regulatory body must assess regularly the sufficiency and qualifications of the staff of the licence holder, as a prerequisite for ensuring nuclear safety, on the basis of a report presented by the licence holder on the evaluation of employment issues such health and safety and the safety culture, qualifications and training, numbers of staff employed and use of subcontractors.

In addition, the relevant regulatory authorities shall, every 3 years, present a report on nuclear safety and safety culture. The Commission, in consultation with the European social partners, may propose improvements to ensure nuclear safety including health protection at the highest possible level in the EU.

Report: Member States shall report to the Commission on the implementation of this Directive at the same time and frequency as for their national reports under review meetings of the Convention of the Nuclear Safety.

Community framework for the nuclear safety of nuclear installations

PURPOSE: to establish a Community framework for nuclear safety of nuclear installations.

LEGISLATIVE ACT: Council Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations.

CONTENT: the objectives of the Directive are as follows:

- to establish a Community framework in order to maintain and promote the continuous improvement of nuclear safety and its regulation;
- to ensure that Member States shall provide for appropriate national arrangements for a high level of nuclear safety to protect workers and the general public against the dangers arising from ionising radiations from nuclear installations.

The Directive does not prevent Member States from taking more stringent safety measures in the subject matter covered by this Directive, in compliance with Community law. Each Member State can decide on its energy mix in accordance with relevant national policies.

Legislative, regulatory and organisational framework: Member States shall establish and maintain a national legislative, regulatory and organisational framework for nuclear safety of nuclear installations that allocates responsibilities and provides for coordination between relevant state bodies.

The national framework shall establish responsibilities for :

(a) the adoption of national nuclear safety requirements ; (b) the provision of a system of licensing and prohibition of operation of nuclear installations without a licence; (c) the provision of a system of nuclear safety supervision; (d) enforcement actions, including suspension of operation and modification or revocation of a licence.

Competent regulatory authority: Member States shall establish and maintain a competent regulatory authority in the field of nuclear safety of nuclear installations. They must also ensure that the prime responsibility for nuclear safety of a nuclear installation rests with the licence holder. This responsibility cannot be delegated.

Expertise and skills in nuclear safety: all parties must take the necessary measures with regard to education and training of staff having responsibilities relating to the nuclear safety of nuclear installations in order to maintain and to further develop expertise and skills in nuclear safety.

Information to the public: information in relation to the regulation of nuclear safety must be made available to the workers and the general public.

Reports: Member States shall submit a report to the Commission on the implementation of this Directive for the first time by 22 July 2014, and every three years thereafter. On the basis of the Member States' reports, the Commission shall submit a report to the Council and the European Parliament on progress made with the implementation of this Directive. Member States shall at least every 10 years arrange for periodic self-assessments of their national framework and competent regulatory authorities and invite an international peer review of relevant segments of their national framework and/or authorities with the aim of continuously improving nuclear safety. Outcomes of any peer review shall be reported to the Member States and the Commission, when available.

ENTRY INTO FORCE: 22/07/2009.

TRANSPOSITION: 22/07/2011.

Community framework for the nuclear safety of nuclear installations

The Commission presents a report on the implementation of Council Directive 2009/71/Euratom 2009 establishing a Community framework for the nuclear safety of nuclear installations.

The Council's adoption of the Nuclear Safety Directive on 25 June 2009 was a major step towards achieving a common legal framework on nuclear safety in Europe. The objective of the Directive is to maintain and promote the continuous improvement of nuclear safety. The Directive entered into force on 22 July 2009. Member States had until 22 July 2011 to transpose it.

Major developments since the publication of Directive 2009/71/EURATOM: following the 2011 Fukushima nuclear accident, the European Council asked the Commission and the European Nuclear Safety Regulators Group (ENSREG) to reassess the EU's 131 nuclear power reactors. The Commission and ENSREG carried out stress tests, which resulted in a number of recommendations.

The review of the Euratom legal framework for nuclear safety led to a Commission proposal for substantial amendments to Directive 2009/71/EURATOM. The Council adopted these on 8 July 2014. The [amended Directive](#) is to be transposed into national law by 15 August 2017. Member States had to send their implementation reports by 22 July 2014.

Purpose of the report: the report aims to provide the Council and Parliament with a complete overview on the current state of implementation of the Directive across the EU. It makes recommendations to Member States in connection with challenges and states what corrective measures the Commission has taken or plans to take.

Having reviewed the national reports, the Commission concludes that there is, in general, a good level of compliance with the 2009 Nuclear Safety Directive and that the Directive has proven to be an effective instrument in improving nuclear safety.

1) Legal framework and regulatory authority: national reports show that all Member States have adopted legislative measures in compliance with the Directive's obligations regarding the establishment of a legal framework for nuclear safety, the setting-up of a regulatory authority, the allocation of appropriate resources, and the performance of international peer reviews of the system.

However, the report recommends that Member States:

- should ensure a clear allocation of responsibilities and coordination between relevant state bodies, especially when several administrative levels or several bodies contribute to decision-making. The Commission will pay special attention to this matter when monitoring the transposition of the amended Directive;
- systematically take into account lessons learned from operating experience, the development of technology and safety research. The Commission will enhance coordination among Member States in this regard;

- ensure an effective independence of their competent regulatory authorities and that the regulatory authority has human and financial resources commensurate with the country's current nuclear profile, nuclear power development projects and decommissioning plans. Cooperation between Member States will be encouraged in order to ensure an effective use of existing resources, for instance in the case of Long Term Operation of nuclear power plants' or new builds' licencing procedures. Such cooperation would be particularly beneficial for smaller competent regulatory authorities;
- systematically report the outcomes of any international peer review to the Member States and the Commission;
- host an international peer review to assess their national framework and competent regulatory authorities, given that the Directive requires that these are organised at least every ten years. Member States should consider in particular hosting full scope rather than limited scope missions in which the country chooses to leave some issues out.

2) Safety of nuclear installations: the report confirms that safety arrangements imposed on nuclear installations (under the supervision of regulatory authorities), including development of expertise and skills, are largely in place. Wherever appropriate, nuclear plant licence holders tend to establish strong synergies with national or international research and training organisations dedicated to the improvement of reactor safety regulation, technology and culture.

However, although most of Member States reported having national provisions as regards the human and financial resources of the licence holders, it should be clarified whether the regulatory authority has the ability to assess the adequacy of such resources, particularly financial ones, and whether these obligations are effectively implemented and enforced.

As confirmed through the nuclear stress tests and the initial check of Member States transposition of the Directive, there are differences from country to country over the identification and management of safety issues. This is partly due to the fact that the 2009 Directive only contained broad principles, leaving some leeway to Member States as regards their implementation, and failed to impose some important requirements. The amended Nuclear Safety Directive addressed these deficiencies. As a result, the transposition of the amended Directive represents a new challenge for Member States.

The report recommends that Member States:

- ensure that the next national implementation reports take into account all installations covered by the amended Directive and not only nuclear power plants. The Commission will pay special attention to Member States' application of the Directive to all nuclear installations in the remit of the Directive and the adequate reporting;
- complete the implementation of the recommendations of nuclear stress tests to improve the safety of nuclear installations. The Commission will continue to closely monitor progress and publish a nuclear illustrative programme to provide clarity on the needs for new investment in the nuclear field including safety upgrades of current nuclear installations;
- monitor licence holders use of contractors and subcontractors and the possible safety implications give special consideration to this issue when transposing the amended Directive;
- ensure that national legal frameworks require licence holders to maintain well-qualified human and adequate financial resources during the whole lifecycle of installations;
- better coordinate national approaches to emergency preparedness and response. This issue is being addressed in the relevant international forums and in bilateral cooperation between Member States.

The next national reports on the implementation of the Directive should be sent to the Commission by 22 July 2020. The Commission's report to the Council and Parliament will then follow. By that time, the Commission will have received and analysed the Member States national provisions transposing the amended Directive.