

ROADMAP

Title of the initiative: **Proposal for the revision of Council Directive 96/29/EURATOM laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation and the associated directives**

Type of initiative (CWP/Catalogue/Comitology): CWP Simplification measures

Lead DG: ENER, Unit D4

Expected date of adoption of the initiative (month/year): March 2011

Date of modification: 26 March 2010

Version No: 3

Initial IA screening & planning of further work

A. Context and problem definition

(i) What is the political context of the initiative? (ii) How does this initiative relate to past and possible future initiatives, and to other EU policies?

The framework for the radiation protection is established in the Basic Safety Standards Directive (BSS Directive) last amended in 1996. After being issued for the first time in 1959, the basic safety standards were subsequently amended in 1962, 1966, 1976, 1980, 1984 and 1996. These changes were the result of advances in scientific knowledge and to a large extent have always been based on the scientific recommendations of the International Commission on Radiological Protection (ICRP). The latter is recognised internationally, so the European directives are in line with the recommendations of the other large international organisations such as the International Atomic Energy Agency (IAEA), the Organisation for Economic Cooperation and Development (OECD) and the World Health Organisation (WHO). In 2007, after 8 years of discussions, ICRP issued their new Recommendations for a System of Radiological Protection (Recommendation 103). The new recommendations offer a new set-up for the radiation protection which is now based on exposure situations rather than on activities. They put an emphasis on the optimisation of exposures and the protection of the environment.

Following these developments, the IAEA launched a process for the revision of the International BSS. The EURATOM Community has been also invited to participate in this review. At the same time the group of experts established under art. 31 of the Euratom Treaty to advise the Commission on the BSS, has started a review of the Euratom Basic Safety Standards in the light of the new ICRP Recommendations.

What are the main problems identified?

Since the last amendment of the BSS Directive in 1996 the scientific knowledge on the effects of ionising radiation has evolved and new feedback from operational radiation protection is available: In 2007 ICRP has issued their new Recommendations. Thus, the BSS Directive is not anymore in line with the latest scientific developments and it needs to be updated.

Directive 96/29/EURATOM is the main pillar of the body of secondary legislation on basic safety standards, adopted pursuant to Art.31 of the EURATOM Treaty which consists of more than 20 acts. Some of these acts are closely linked with the BSS Directive, either because they develop further the requirements of this directive or because they contain references to different texts from the BSS Directive. In principle, these directives should form a coherent set of radiation protection requirements. Very often this is not the case because of the different language used and the complexity of references which did not change after the amendments of the different requirements. The legal base thus formed, is not coherent and is cumbersome to read and apply. This situation calls for simplification measures.

Some of the associated instruments to the BSS directives like the Medical Directive 97/43/EURATOM, are also concerned by the new scientific developments and the experience gained from their implementation. Hence their amendment should also be considered.

Who is affected?

Basic Safety Standards establish radiation protection rules for performing activities which involve radiation. In this respect, every undertaking performing such activities will be affected by the national laws transposing the Basic Safety Standards Directive. As the purpose of the standards is to protect workers and general public against the dangers arising from ionizing radiation, workers and public are also affected.

(i) Is EU action justified on grounds of subsidiarity? (ii) Why can the objectives of the proposed action not be achieved sufficiently by Member States (necessity test)? (iii) As a result of this, can objectives be better achieved by action by the Community (test of EU Value Added)?

According to art. 2(b) from Euratom Treaty "...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". As the Community's legislative powers under Title 2 Chapter III of the Euratom Treaty are exclusive in nature, they are not subject to the principle of subsidiarity.

B. Objectives of EU initiative

What are the main policy objectives?

The aim of the initiative is to update the legal requirements, in the light of the new ICRP Recommendations published in 2007 (ICRP Publication 103), to take into account the experience gained by Member States and the Commission and to simplify the EURATOM radiation protection legislation (Basic Safety Standards (BSS) Directive (96/29/Euratom), Medical Directive (97/43/Euratom), Directive on High Activity Sealed Sources (2003/122/Euratom), Directive on Outside Workers (90/641/Euratom), Directive on Public Information (89/618/Euratom)).

Do the objectives imply developing EU policy in new areas or in areas of strategic importance?

The new ICRP Recommendations pay particular attention to the protection of biota. Therefore, the BSS will be complemented where appropriate with specific consideration of the exposure of the biota in the environment as a whole.

Based on experience with current regulations, it is proposed to clarify and strengthen requirements in the following areas:

- *Exposure to natural radiation* - the Commission envisages incorporating a comprehensive approach to the management of natural radiation sources within the overall set of requirements of the new BSS Directive;
- Limitation of doses for exposed workers - the Commission has the intention to propose a harmonisation of the annual dose limits for exposed workers;
- Amendment of the exemption levels (clearance levels) – while the values for total activities for exemption will be maintained, those for activity concentrations will be harmonised with clearance levels, which may result in the reduction of the exemption values (same values as the clearance levels which now will be part of the Directive).

C. Options

(i) What are the policy options? (ii) What legislative or 'soft law' instruments could be considered? (iii) Would any legislative initiatives go beyond routine up-date of existing legislation?

Three policy options will be analysed towards the main purpose – simplification of radiation protection legislation and upgrade according to the latest scientific achievements:

1. Codification of five Euratom Directives;
2. Amendment of the BSS Directive and the Medical Directive in accordance with the ICRP Recommendations and operational experience;

3. Revision of the BSS Directive and simplification of Euratom radiation protection legislation through recast or amendment

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

No

Explain how the options respect the proportionality principle

The proposal will set out harmonised standards for the radiological protection of the workers, the public, the patients and the environment related to the latest scientific and technical progress (ICRP, IAEA)

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the Impact Assessment Guidelines pages 32-37), even if these impacts would materialise only after subsequent Commission initiatives?

Option 1 Codification will bring in one legislative act the directives subject to this initiative. It is expected that this will make the radiation protection requirements clearer and more accessible. There will be no changes in the substance.

Option 2 envisages separate amendments of the BSS Directive and the Medical Directive. Within these amendments the key areas that need update and alignment with ICRP Recommendations will be covered. The other directives linked to the BSS Directive will not change and will remain separate pieces of legislation. Together with the changes in the BSS and the Medical directives, this will result in an even less harmonised body of secondary legislation.

Option 3 Within this policy option the BSS Directive and the related 4 directives will merge and the requirements of the BSS Directive and the Medical Directive will be upgraded to the latest scientific knowledge and regulatory experience. BSS related directives will be incorporated in a single new act thus creating clearer and more accessible legal requirements.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No impact on the EU Budget.

Could the options have significant impacts on (i) simplification, (ii) administrative burden or on (iii) relations with third countries?

The initiative should simplify part of the radiation protection legislation enacted under Art. 30-31 of the Euratom Treaty.

E. Planning of further impact assessment work

When will the impact assessment work start?

The discussions on a possible revision of Directive 96/29/EURATOM (BSS Directive) started in 2005 at the meetings of the Group of Experts (Art.31 GoE), established under Art.31 of the EURATOM Treaty. This action was driven by the work of ICRP on new ICRP Recommendations. Since that time the work continues in various ways – working groups of the Art.31 Group of Experts, studies, stakeholders consultation, etc.

(i) What information and data are already available? (ii) Will this impact assessment build on already existing impact assessment work or evaluations carried out? (iii) What further information needs to be gathered? (iv) How will this be done (e.g. internally or by an external contractor) and by when? (v) What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Since February 2010 all planned Impact Assessment initiatives are finished. The Impact Assessment Steering Group will be invited to discuss the Impact Assessment Report.

Which stakeholders & experts have been/will be consulted, how and at what stage?

Extensive consultations took place in the framework of the Art.31 GoE. As far as the subject matter of the Basic Safety Standards and the other directives is very specific and mostly technical, DG ENER used topical networks to consult the relevant stakeholders:

- ALARA network on occupational protection;
- NORM network - a tool for NORM (Naturally Occurring Radioactive Materials) - stakeholders to communicate, share knowledge, identify problems and propose solutions;
- EUTERP – Platform on Training and Education in Radiation Protection

Stakeholders public consultation was performed on the "Proposal for new requirements on natural radiation sources in the Basic Safety Standards Directive" The consultation was held in the period from 02/02/2009 till 20/04/2009.