EUROPEAN COMMISSION
IMPACT ASSESSMENT BOARD

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Opinion

Title **DG ENER - Impact Assessment on: 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**

(draft version of 17 November 2010)

(A) Context

Exposure to ionizing radiation can result in various health detriments depending upon the amount of exposure. Based on Article 31 of the Euratom Treaty, the main piece of Community legislation on radiation protection is the Basic Safety Standards Directive 96/29/Euratom (BSS Directive). It has been regularly updated in the light of scientific knowledge, in line with the recommendations of International Commission on Radiological Protection (ICRP), and operational experience. The related acts are Medical Directive 97/43/Euratom, Outside Workers Directive 90/641/Euratom, High-Activity Sealed Sources (HASS) Directive 2003/122/Euratom, Public Information Directive 89/618/Euratom and Commission Recommendation 90/143/Euratom on the protection of the public against indoor exposure to radon. This body of legislation, especially the BSS Directive and the Medical Directive, needs to be aligned with the new ICRP guidance of 2007. In addition, the revision of Euratom legislation is driven by the ongoing revision of the international Basic Safety Standards and the need to simplify the regulatory framework. This impact assessment discusses options for such a review.

(B) Overall assessment

As it stands, the IA report does not provide a clear intervention logic and evidence base in support of the proposed action. The analysis needs to be significantly improved in several important aspects. The IA report should clarify the scope and scale of the main problems and develop a set of corresponding operational objectives. These should then be reflected in a set of credible options. On that basis the IA report should clarify how the specific elements of the proposed amendments have been chosen, how these will comply with international standards and how options contribute to the simplification objective. The IA report should also be more specific about the expected impacts, especially regarding implementation and enforcement costs. It should also compare the effectiveness, efficiency and coherence of the options relative to the operational objectives. Given the uncertainties related to the protection of biota, the report should clarify why a regulatory approach is proposed at this stage rather than a non-regulatory intervention.

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Given the nature of these recommendations, the Board asks DG Energy to submit a revised version of the report, on which it will issue a new opinion.

(C) Main recommendations for improvements

(1) Clarify the core problems and assess their scale. Firstly, the IA report should be clearer what the main problems are – insufficient protection, risk perception issues, hindered mobility of nuclear experts, complexity of the legal framework, lack of regulatory oversight, gap between EU and international standards, etc. All these relatively distinct issues should be systematically assessed and the core problems to be tackled should be described with the support of robust evidence and/or examples. The problem definition should include a clear description of the scale of the problems, the size of industry and markets concerned, and the number of employees or members of the public affected. Where data or evidence problems exist these should be highlighted in the problem definition. Secondly, the IA report should better demonstrate why there is a need for a fuller harmonization of the regulatory environment for the (i) NORM (Naturally Occurring Radioactive Material) industries, and (ii) indoor radon exposures, especially given that the latter appears to be rather a regional issue. In this respect the IA report should provide evidence that the rules in the Member States are insufficient to ensure an appropriate protection.

(2) Strengthen the link between the problems, objectives and options. Based on a more concrete problem definition, the report should develop a set of operational objectives which would link the problems discussed with a set of credible options. The current set of options, which concentrates solely on simplification, seems inappropriate given that the objectives also highlight the need to update the legislation and to harmonise it with the international Basic Safety Standards. Therefore the IA report should clarify (i) which alternative options for update and harmonization were considered, (ii) on what basis new protection measures and values for dose limits were chosen, and (iii) how the proposed stringency levels relate to the ICRP recommendations/international standards. It should also explain better why the option of a full harmonization with international standards would not be feasible or even desirable. Finally, the report should explain how the new legislative framework could better accommodate frequent updates resulting from new scientific knowledge.

(3) Better analyse the impacts and improve the comparison of options. The IA report should be more specific about the benefits and the costs of the proposed amendments. Firstly, it should discuss more concretely to what extent the Member States would need to change their national legislation and what the range of potential enforcement costs for the competent authorities would be. Secondly it should identify the markets/sectors (e.g. building sector, hospitals) concerned and should make an attempt to assess relevant implementation costs (e.g. setting up monitoring mechanisms, acquiring protection equipment, labelling building materials). DG Enterprise should assist with available data. Thirdly, the IA report should identify more concretely where and why the administrative costs for businesses and public administration will be reduced or increased, and quantify these changes where significant. It should clarify how it could be ensured that the costs stay proportionate to the envisaged health benefits, e.g. how the 'graded approach' and 'principle of optimisation' would work in practice. Finally, the effectiveness, efficiency and coherence of the options should be assessed in terms of operational objectives and the scores assigned in the summary table should be consistent with the underlying analysis.

(4) Clarify why legislative measures are necessary for biota protection. Given that the IA report states that (i) there is no evidence on the existence of problems with exposure of biota, and (ii) there is neither an agreed methodology for assessing the impact of radiation on non-human species nor guidance on appropriate protection principles, the report should better justify why there is a need for legislative measures in this domain. It should also explore whether the potential issues are not already addressed by the existing body of the EU environmental legislation. Given that the associated costs and benefits cannot be assessed due to these uncertainties, the IA report should also consider 'no action' or non-legislative measures as alternatives.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation

The different views of stakeholders should be reflected throughout the report, especially in the section on options. The layout and structure of the report should be improved and further efforts need to be made to facilitate its readability by non-specialists. It would be useful to annex to the report a table of correspondence showing how the preferred option compares with the international Basic Safety Standards.

(E) IAB scrutiny process	
Reference number	2008/ENER/002
External expertise used	No
Date of Board Meeting	15 December 2010