



EUROPEAN COMMISSION
IMPACT ASSESSMENT BOARD

22 MARS 2011

Brussels,
D(2011)

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 ionising radiation, and the associated directives

(resubmitted draft version of 28 February 2011)

(A) Context

Exposure to ionising 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 the Article 31 Group of Experts, International Commission on Radiological Protection (ICRP), and operational experience. The related acts are the Medical Directive 97/43/Euratom, the Outside Workers Directive 90/641/Euratom, the High-Activity Sealed Sources (HASS) Directive 2003/122/Euratom, the 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

While the structure and presentation of the IA report has been improved, it still does not provide sufficient evidence base in order to satisfactorily demonstrate the magnitude of the problems identified and the need for further legislative action. Therefore the report should be substantially improved in the following key aspects. It should better demonstrate why the current legislation with respect to the control of natural radiation at Member State level does not provide the necessary protection. The report should also consider more thoroughly the relevance and effectiveness of non-binding measures, especially as regards the protection of non-human species. To support the conclusion that all proposed measures are efficient and proportionate, the report should provide a more robust analysis of the expected health benefits as well as the related costs for public administrations and economic operators. The report should also assess the costs of the measures on protecting non-human species. Finally, in the light of the recent events in Fukushima/Japan, the report should clarify the timing and the scope of the initiative.

(C) Main recommendations for improvements

(1) Provide more evidence on the existence and magnitude of the problems. The problem definition of the revised IA report presents more systematically the main review issues and makes an effort to determine the number of employees concerned. However, the analysis and evidence on the existence and scale of the problems needs to be further strengthened by better exploiting the evidence sources listed in Annex II. For instance, the report should estimate the number of (i) interventional radiologists facing high exposures, (ii) patients taken through superfluous procedures and (iii) members of the public at risk of radon exposure. The report should present available observations on the doses radiologists/ employees in NORM (Naturally Occurring Radioactive Materials) industries are exposed to. It should also add references to epidemiological studies which support the claims on radiation induced cataract and lung cancer. Regarding the exposures of workers and members of the public to natural radiation sources, the report should better demonstrate why the current legislation at Member State level does not address these issues adequately. The report should provide examples, where differences in control levels applied by national legislation have led to (a high risk of) inadequate protection.

(2) Consider the relevance and effectiveness of alternative measures. The IA report has revised the specific objectives, proposes a new set of mainly cumulative options and explains why full incorporation of the international BSS in EU legislation would not be feasible. However, the report should justify in a more substantive manner why alternatives in terms of non-legislative approaches (as presented in the new Annex XI) are not discussed in the option section. If these represent realistic options, their effectiveness, efficiency and coherence should be fully assessed in the impact section. The report should also justify why no alternatives have been considered for certain quantitative limits, e.g. the harmonised annual exposure limit proposed in Option 2.

(3) Better demonstrate the efficiency and proportionality of the proposed measures. The revised IA report presents the content of each option and related impacts in a clearer manner. However, it should provide a much more specific and robust assessment of the expected actual risk reduction and related health benefits, and costs in order to support the conclusions that the proposed measures (especially as regards the provisions on NORM industries, building materials and protection of non-human species) are proportionate and efficient. Given that the Euratom Treaty obliges the Member States to report on the national provisions for transposition of the Community radiation protection legislation, it should be possible to assess to what extent the Member States would need to change their national legislation. On that basis the report should assess ranges of (a) potential enforcement costs for competent authorities and (b) implementation costs for economic operators. Administrative costs, including the costs related to establishment of national dose registries, should be assessed more explicitly, and quantified whenever significant. As regards the benefits, the claim that the introduction in Community legislation of restrictions on radon levels in buildings will have “very positive impacts” on public health needs further corroboration, since the IA report also mentions that the relevant Commission Recommendation has already been to a large extent introduced throughout the EU.

(4) Assess the costs of the measures on protecting non-human species. The report has clarified some aspects related to the ICRP guidance on protecting non-human species, and discusses impacts of these measures under the new Option 5. Nevertheless, there seems to be no substantive analysis or evidence supporting the need for and proportionality of legislative measures at this stage, even if these are 'not very demanding', as explained in the report. In order to inform political decision making, the report should assess more specifically related administrative and implementation costs, and compare these with the costs of postponing the decision until relevant evidence can be produced. The report should also discuss the views of the other stakeholders (beyond the Article 31 Expert Committee) on this issue.

(D) Procedure and presentation.

The different views of stakeholders should be reflected throughout the report. The comparison of options table (p.43) should be better presented, for instance by providing a concise one-page overview, which then could also be included in the Executive Summary. Scores assigned in the summary table should be more consistent with the underlying analysis. For instance the 'Overall impact' scores given to Option 2 (amendment of BSS and Medical Directives), Option 4 (amendment of BSS and covering natural radiation) and Option 5 (amendment of BSS and protection of non-human species) are equal, however the analysis in the report indicates that the health benefits of Options 2 and 4 are more significant than those of Option 5. Repetitions in the text, such as in sections 2.1/2.2, and 5.4/5.5/5.6, should be further reduced.

(E) IAB scrutiny process	
Reference number	2008/ENER/002
External expertise used	No
Date of Board Meeting	Written procedure The present opinion concerns a resubmitted draft IA report. The first opinion was issued on 17 December 2010.