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REPORT

on the proposal for a Council directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (COM(2012)0242 – C7-0151/2012 – 2011/0254(NLE))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Thomas Ulmer

Rapporteur for the opinion (*):

Anthea McIntyre, Committee on Employment and Social Affairs

(*) Associated committee – Rule 50 of the Rules of Procedure

Symbols for procedures

- * Consultation procedure
- *** Consent procedure
- ***I Ordinary legislative procedure (first reading)
- ***II Ordinary legislative procedure (second reading)
- ***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

In amendments by Parliament, amendments to draft acts are highlighted in bold italics. Highlighting in normal italics is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in bold. Any deletions that Parliament wishes to make in such passages are indicated thus: [...].

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(*) Associated committee – Rule 50 of the Rules of Procedure

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a Council directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation
(COM(2012)0242 – C7-0151/2012 – 2011/0254(NLE))**

(Consultation)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2012)0242),
 - having regard to Articles 31 and 32 of the Euratom Treaty pursuant to which the Council consulted Parliament (C7-0151/2012),
 - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
 - having regard to Rules 55 and 37 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Employment and Social Affairs (A7-0303/2013),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to alter its proposal accordingly, in accordance with Article 106a of the Euratom Treaty;
 3. Calls on the Commission to notify the Parliament how amendments from Parliament have been taken into due account in the final text of the directive as amended by the Council;
 4. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 5. Asks the Council to consult Parliament again if it intends to amend the Commission proposal substantially;
 6. Instructs its President to forward its position to the Council and the Commission.

Amendment 1

**Proposal for a directive
Citation 1**

Text proposed by the Commission

Having regard to *the Treaty establishing the European Atomic Energy Community*, and in *particular* Articles 31 and 32 thereof,

Amendment

Having regard to *the Treaty on the Functioning of the European Union*, and in *particular* Article 192(1) thereof,

Amendment 2

Proposal for a directive

Recital 1

Text proposed by the Commission

(1) Article 2(b) of the Treaty provides for the establishment of uniform safety standards to protect the health of workers and the general public and Article 30 of the Treaty defines ‘basic standards’ for the health protection of workers and the general public against the dangers arising from ionising radiations.

Amendment

(1) Article 191 of the Treaty on the Functioning of the European Union (TFEU) provides the legal basis for preserving, protecting and improving the quality of the environment and protecting human health, including against dangers arising from exposure to ionising radiation.

Amendment 3

Proposal for a directive

Recital 1 a (new)

Text proposed by the Commission

Amendment

(1a) Article 153 TFEU allows for the establishment of safety standards to protect the health of workers and of the general public.

Amendment 4

Proposal for a directive

Recital 1 b (new)

Text proposed by the Commission

Amendment

(1b) Article 168 TFEU allows for the establishment of basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.

Amendment 5

Proposal for a directive

Recital 7

Text proposed by the Commission

Amendment

(7) This Directive should follow the situation based approach introduced by ICRP Publication 103 and distinguish between existing, planned and emergency exposure situations. Taking into account this new framework the Directive should cover all exposure situations and all categories of exposure, namely occupational, public and medical exposures.

(7) This Directive should follow the situation based approach introduced by ICRP Publication 103 and distinguish between existing, planned and emergency exposure situations. ***With regard to the application of the standards and requirements, however, it should also draw a distinction between existing exposure situations attributable to natural radiation and existing anthropic exposure situations.*** Taking into account this new framework the Directive should cover all exposure situations and all categories of exposure, namely occupational, public and medical exposures.

Amendment 6

Proposal for a directive

Recital 13

Text proposed by the Commission

Amendment

(13) The new requirements on radioactivity in building materials should allow for the free circulation of building materials.

(13) The new requirements on ***natural*** radioactivity in building materials should allow for the free circulation of building materials ***while at the same time improving protection against radiological***

risks.

Amendment 7

Proposal for a directive Recital 15

Text proposed by the Commission

(15) The exposure of aircrew to cosmic radiation should be managed as a planned exposure situation. The operation of spacecraft should come under the scope of this Directive and should be managed as a specially authorised exposure.

Amendment

(15) The exposure of aircrew to cosmic radiation should be managed as a planned exposure situation. The operation of spacecraft should come under the scope of this Directive and should be managed as a specially authorised exposure. ***In addition, more attention should be paid to the potential risks of cosmic radiation for frequent air travellers. Like aircrew, who have the option of being registered and receiving health checks focusing on the risks from radiation, there should also be the option of registration for frequent air travellers – for example by calling on firms to register their employees who frequently travel by air.***

Amendment 8

Proposal for a directive Recital 16

Text proposed by the Commission

(16) ***The health protection of the general public allows for*** the presence of radioactive substances in the environment. In addition to direct environmental exposure pathways, consideration should be given to the protection of the environment as a whole, including the exposure of biota, within a comprehensive and coherent overall framework. As far as mankind is part of its environment, this policy benefits ***to*** long term health

Amendment

(16) The presence of radioactive substances in the environment ***has consequences for the health of the general public.*** In addition to direct environmental exposure pathways, consideration should be given to the protection of the environment as a whole, including the exposure of biota, within a comprehensive and coherent overall framework. As far as mankind is part of its environment, this policy benefits long term health protection. ***As organisms are***

protection.

susceptible to both internal and external radiation, more resources should go to examining in detail the impact that ionising radiation has on both mankind and the environment.

Amendment 9

Proposal for a directive Recital 27

Text proposed by the Commission

(27) The efficient management of a nuclear emergency with cross-border consequences calls for enhanced cooperation between Member States in emergency planning and response.

Amendment

(27) The efficient management of a nuclear emergency with cross-border consequences calls for enhanced cooperation **and transparency** between Member States in emergency planning and response.

Amendment 10

Proposal for a directive Recital 30

Text proposed by the Commission

(30) More precise requirements should be introduced for the issuing discharge authorisations and for the monitoring of discharges. Commission Recommendation 2004/2/Euratom of 18 December 2003 on standardised information on radioactive airborne and liquid discharges into the environment from nuclear power reactors and reprocessing plants in normal operation introduced standardised information for the reporting of data on discharges from nuclear power plants and reprocessing facilities.

Amendment

(30) More precise requirements **and appropriate sanctions** should be introduced for the issuing discharge authorisations and for the monitoring of discharges. Commission Recommendation 2004/2/Euratom of 18 December 2003 on standardised information on radioactive airborne and liquid discharges into the environment from nuclear power reactors and reprocessing plants in normal operation introduced standardised information for the reporting of data on discharges from nuclear power plants and reprocessing facilities.

Amendment 11

Proposal for a directive Recital 31

Text proposed by the Commission

(31) ***No major changes need to be made to the most recent*** Directive 2003/122/Euratom on the control of high-activity sealed radioactive sources and orphan sources, ***except to broaden some of*** the requirements to include any sealed radioactive source. However, there are still unresolved problems with orphan sources and there have been significant cases of contaminated metal being imported from third countries. Accordingly, a requirement should be introduced for the notification of incidents with orphan sources or the contamination of metal. With regard to international security, it is also important to harmonise the levels above which a source is regarded as a high-activity sealed source with those established by the IAEA.

Amendment

(31) Directive 2003/122/Euratom on the control of high-activity sealed radioactive sources and orphan sources ***should be broadened with regard to*** the requirements to include any sealed radioactive source. However, there are still unresolved problems with orphan sources, ***for example unexploded munition(s)***, and there have been significant cases of contaminated metal being imported from third countries. Accordingly, a requirement should be introduced for the notification of incidents with orphan sources or the contamination of metal. With regard to international security, it is also important to harmonise the levels above which a source is regarded as a high-activity sealed source with those established by the IAEA.

Amendment 12

Proposal for a directive Article 1 – paragraph 1

Text proposed by the Commission

1. This Directive establishes the basic safety standards for the protection of the health of workers, general public, patients and other individuals subject to medical exposure against the dangers arising from ionising radiation for the purpose of ***their uniform implementation by*** Member States.

Amendment

1. This Directive establishes the basic safety standards for the protection of the health of workers, general public, patients and other individuals subject to medical exposure against the dangers arising from ionising radiation for the purpose of ***guaranteeing a uniform threshold level of protection in the*** Member States.

Amendment 13

Proposal for a directive Article 1 – paragraph 3

Text proposed by the Commission

3. This Directive sets out requirements for the control of the safety and security of radioactive sources and the provisions of **appropriate** information in an emergency exposure situation.

Amendment

3. This Directive sets out requirements for the control of the safety and security of radioactive sources and the provisions of **mandatory** information in an emergency exposure situation.

Amendment 14

Proposal for a directive Article 2 – paragraph 1

Text proposed by the Commission

1. This Directive applies to any planned, existing or emergency exposure situation which involves a risk from exposure to ionising radiation **which cannot be disregarded from the radiation protection point of view** with regard to the health protection of workers, members of the public, or patients and other individuals subject to medical exposure or with regard to the protection of the environment.

Amendment

1. This Directive applies to any planned, existing, **accidental** or emergency exposure situation which involves a risk from exposure to ionising radiation with regard to the health protection of workers, members of the public, or patients and other individuals subject to medical exposure or with regard to the protection of the environment.

Amendment 15

Proposal for a directive Article 2 – paragraph 2 – point a

Text proposed by the Commission

(a) the production, processing, handling, use, storage, holding, transport, shipment, import to, and export from the Community **and the** disposal of radioactive material;

Amendment

(a) the production, processing, handling, use, storage, holding, transport, shipment, import to, and export from the Community, disposal of radioactive material **and temporary or final radioactive waste storage;**

Amendment 16

Proposal for a directive

Article 2 – paragraph 2 – point c – point i

Text proposed by the Commission

(i) the operation of aircraft and spacecraft;

Amendment

(i) ***practices exposing workers to cosmic radiation, including*** the operation of aircraft and spacecraft ***as well as frequent flying***;

Amendment 17

Proposal for a directive

Article 4 – point 3

Text proposed by the Commission

(3) Emergency means a ***non-routine*** situation ***or*** event that necessitates prompt action primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes nuclear and radiological emergencies;

Amendment

(3) Emergency means a situation ***resulting from an accident, malfunction, malicious act or conflict or from any other non-routine*** event that necessitates prompt action primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes nuclear and radiological emergencies;

Amendment 18

Proposal for a directive

Article 4 – point 10

Text proposed by the Commission

(10) Radioactive material means material incorporating radioactive substances;

Amendment

(10) Radioactive material means ***any*** material ***in a liquid, gaseous or solid form*** incorporating radioactive substances;

Amendment 19

Proposal for a directive Article 4 – point 22

Text proposed by the Commission

(22) Optimisation means a forward-looking iterative process to establish adequate protection measures taking into account the prevailing circumstances, the available options, and the nature of the exposure situation, with the aim of keeping the magnitude and likelihood of exposure and the number of people exposed as low as ***reasonably achievable***;

Amendment

(22) Optimisation means a forward-looking iterative process to establish adequate protection measures taking into account the prevailing circumstances, the available options, and the nature of the exposure situation, with the aim of keeping the magnitude and likelihood of exposure and the number of people exposed as low as ***possible***;

Amendment 20

Proposal for a directive Article 4 – point 24

Text proposed by the Commission

(24) Occupational exposure means exposure of workers incurred in the course of their work;

Amendment

(24) Occupational exposure means exposure of workers, ***including employees and self-employed as well as trainees and volunteers***, incurred in the course of their work;

Amendment 21

Proposal for a directive Article 4 – point 25

Text proposed by the Commission

(25) Health detriment means an estimate of the risk of reduction in length and quality of life occurring in a population following exposure. ***This includes*** loss arising from tissue effects, cancer and severe genetic disorder;

Amendment

(25) Health detriment means an estimate of the risk of reduction in length and quality of life occurring in a population following exposure. ***The definition used in ICRP Publication 103 delimits detriment as*** loss arising from tissue effects, cancer and

severe genetic disorder (*equivalent to a terminal illness*);

Amendment 22
Proposal for a directive
Article 4 – point 35

Text proposed by the Commission

(35) Exposed worker means a person, either self-employed or working under an employer, who is subject to exposure at work carried out within a practice regulated by this Directive and who is liable to receive doses exceeding one or other of the dose limits for public exposure;

Amendment

(35) Exposed worker means a person, either self-employed or working under an employer, ***including a trainee or volunteer***, who is subject to exposure at work carried out within a practice regulated by this Directive and who is liable to receive doses exceeding one or other of the dose limits for public exposure;

Amendment 23
Proposal for a directive
Article 4 – point 38

Text proposed by the Commission

(38) Apprentice means a person receiving training or instruction within an undertaking with a view to exercising a specific skill.

Amendment

(38) Apprentice means a person ***aged 16 years or over (including trainees and students)*** receiving training or instruction within an undertaking with a view to exercising a specific skill, ***which involves operations which would, in the case of an employee, be considered working with ionising radiation.***

Justification

The inclusion of trainees and students is important in order to bring this in line with the rest of the text.

Amendment 24

Proposal for a directive Article 4 – point 42 a (new)

Text proposed by the Commission

Amendment

(42a) Competent authority is any authority designated by a Member State.

Amendment 25

Proposal for a directive Article 4 – point 46

Text proposed by the Commission

Amendment

(46) Dosimetry service means a body or an individual having the competence for calibration, reading or interpretation of individual monitoring devices, or for measurement of radioactivity in the human body or in biological samples, or for assessment of doses, whose capacity to act in this respect is recognised by the competent authorities;

(46) Dosimetry service means a body or an individual having the competence for calibration, reading or interpretation of individual monitoring devices, or for measurement of radioactivity in the human body or in biological samples, or for assessment of doses, **whose status affords a guarantee of independence from the employer of the exposed workers and** whose capacity to act in this respect is recognised by the competent authorities;

Amendment 26

Proposal for a directive Article 4 – point 65

Text proposed by the Commission

Amendment

(65) Clearance levels means values established by the competent authority or in national legislation, and expressed in terms of activity concentrations, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of this Directive;

(65) Clearance levels means values established by the competent authority or in national legislation, and expressed in terms of activity concentrations **and of total activity**, at or below which materials arising from any practice subject to notification or authorisation may be released from the requirements of this

Directive;

Amendment 27

Proposal for a directive Article 4 – point 71

Text proposed by the Commission

(71) Radon-prone area means a geographic area or administrative region defined on the basis of surveys indicating that the percentage of dwellings expected to exceed the national reference level is significantly higher than in other parts of the country;

Amendment

(71) **Highly** radon-prone area means a geographic area or administrative region defined on the basis of surveys indicating that the percentage of dwellings expected to exceed the national reference level is significantly higher than in other parts of the country;

Amendment 28

Proposal for a directive Article 4 – point 74

Text proposed by the Commission

(74) Individual detriment means clinically observable deleterious effects in individuals or their descendants, the appearance of which is either immediate or delayed **and, in the latter case, implies a probability rather than a certainty of appearance**;

Amendment

(74) Individual detriment means clinically observable deleterious effects in individuals or their descendants, the appearance of which is either immediate or delayed;

Amendment 29

Proposal for a directive Artikel 4 – point 75

Text proposed by the Commission

(75) Interventional radiology means the use of X-ray imaging techniques, in addition to those involving ultrasound or magnetic resonance imaging or other non-ionising

Amendment

(75) Interventional radiology means the use of X-ray imaging techniques, in addition to those involving ultrasound or magnetic resonance imaging or other non-ionising

radiation techniques, to introduce and guide devices in the body for diagnostic or treatment purposes;

radiation techniques, to introduce and guide devices in the body for diagnostic or treatment purposes. **However, this Directive covers only high-dose radiological devices. This includes devices which employ a radiation dose higher than 100 Gy*cm².**

Justification

Gerätschaften die für die interventionelle Radiologie verwendet werden, gehören in den Bereich der Medizinprodukte. Da sie als Medizinprodukte schon weitreichender gesetzlicher Kontrolle unterliegen, erscheint eine weitere Kontrolle hier nur für solche Gerätschaften im hochdosierten Bereich als sinnvoll. Die International Electrotechnical Commission (IEC) hat hierzu Anforderungen veröffentlicht, die eine gute Grundlage für die Einordnung bieten (siehe IEC/EN 60601-2-43: Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures). Das IEC schlägt in diesem Bereich Anforderungen vor, die international beachtet werden, die Europäische Union sollte hier keinen eigenen Weg gehen.

Amendment 30

Proposal for a directive Article 4 – point 82

Text proposed by the Commission

(82) Representative person means an individual receiving a dose that is representative of the more highly exposed individuals in the population;

Amendment

(82) Representative person means an individual receiving **or liable to receive** a dose that is representative of the more highly exposed individuals in the population. **Evaluations shall take account of scenarios that are worse than the existing conditions unless it is demonstrated that such scenarios are not liable to arise or that their emergence would be identified and would trigger re-evaluation of the dosimetric impact;**

Amendment 31

Proposal for a directive Article 4 – point 83

Text proposed by the Commission

(83) Radiation protection officer means an individual who is technically competent in radiation protection matters relevant for a given type of practice and is designated by the undertaking to oversee the implementation of the radiation protection arrangements of the undertaking;

Amendment

(83) Radiation protection officer means an individual who is technically competent in radiation protection matters relevant for a given type of practice and is designated by the undertaking to oversee the implementation of the radiation protection arrangements of the undertaking; ***their capacity to act is recognised by the competent authorities;***

Amendment 32

**Proposal for a directive
Article 4 – point 91**

Text proposed by the Commission

(91) Residual dose means the dose expected to be incurred from all exposure pathways after protective measures have been fully implemented, ***or where a decision has been taken not to implement any protective measures;***

Amendment

(91) Residual dose means the dose expected to be incurred from all exposure pathways after protective measures have been fully implemented;

Amendment 33

**Proposal for a directive
Article 4 – point 97**

Text proposed by the Commission

(97) ***Normal*** exposure means exposure expected to occur under the normal operating conditions of a facility or activity (including maintenance, inspection, decommissioning), including possible minor mishaps that can be kept under control, i.e. during normal operation and anticipated operational occurrences;

Amendment

(97) Exposure ***in normal situations*** means exposure expected to occur under the normal operating conditions of a facility or activity (including maintenance, inspection, decommissioning), including possible minor mishaps that can be kept under control, i.e. during normal operation and anticipated operational occurrences;

Amendment 34

Proposal for a directive Article 5 – introductory part

Text proposed by the Commission

Member States shall establish legal requirements and an appropriate regime of regulatory control which, for all exposure situations reflect a system of radiation protection based on **the** following principles of justification, optimisation **and** dose limitation:

Amendment

Member States shall establish legal requirements and an appropriate regime of regulatory control which, for all exposure situations reflect a system of radiation protection based on **up-to-date, robust scientific evidence**, following principles of justification, optimisation, dose limitation **and reparation of damages**:

Justification

It is important that any new changes are based on up to date, robust scientific evidence.

Amendment 35

Proposal for a directive Article 5 – point a

Text proposed by the Commission

(a) justification: decisions **introducing or altering a radiation source, an exposure pathway or actual exposures** shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from them offsets the detriment that they may cause;

Amendment

(a) justification: decisions **which increase individuals' exposure to ionising radiation** shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from them offsets the detriment that they may cause;

Amendment 36

Proposal for a directive Article 5 – point b

Text proposed by the Commission

(b) optimisation: in all exposure situations, radiation protection shall be **optimised** with the aim of keeping the magnitude and likelihood of exposure and the number of individuals exposed as low as **reasonably achievable**, taking into account **economic and** societal factors, whereby optimisation of the protection of individuals undergoing medical exposure shall be commensurate with the medical purpose of the exposure as described in Article 55. This principle shall be applied in terms of effective dose as well as organ doses, as a precautionary measure to allow for uncertainties as to health detriment below the threshold, for deterministic effects;

Amendment

(b) optimisation: in all exposure situations, radiation protection shall be **minimised** with the aim of keeping the magnitude and likelihood of exposure and the number of individuals exposed as low as **possible**, taking into account societal factors, whereby optimisation of the protection of individuals undergoing medical exposure shall be commensurate with the medical purpose of the exposure as described in Article 55. This principle shall be applied in terms of effective dose as well as organ doses, as a precautionary measure to allow for uncertainties as to health detriment below the threshold, for deterministic effects;

Amendment 37

Proposal for a directive
Article 5 – point c

Text proposed by the Commission

(c) dose limitation: **in planned exposure situations**, the sum of doses to an **individual** from all regulated radiation sources may not exceed the dose limits laid down for occupational exposure **or public exposure**. Dose limits shall not apply to medical exposures.

Amendment

(c) dose limitation: **the sum of doses received by a member of the public from all regulated radiation sources and all existing anthropic exposure situations must not exceed the dose limits laid down for public exposure**.

The sum of doses to an **exposed worker** from all regulated radiation sources may not exceed the dose limits laid down for occupational exposure.

Dose limits shall not apply to medical exposures.

Amendment 38

Proposal for a directive Article 5 – point c a (new)

Text proposed by the Commission

Amendment

(ca) Reparation for damages: before authorising the construction of a nuclear installation or renewing its operating licence, Member States shall establish a mechanism which guarantees reparation for all physical damage and personal injury likely to be caused by an emergency at the installation.

Amendment 39

Proposal for a directive Article 5 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Information regarding justification and dose limitation should be made available to the general public.

Amendment 40

Proposal for a directive Article 6 – paragraph 1

Text proposed by the Commission

Amendment

1. For occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking ***under the general supervision of*** the competent authorities. In the case of outside workers the dose constraint shall be established in cooperation between the employer and the undertaking.

1. For occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking ***in consultation with workers' representatives. Their decision shall be supervised by*** the competent authorities. In the case of outside workers the dose constraint shall be established in cooperation between the employer and the

undertaking *in consultation with workers' representatives*.

Amendment 41

Proposal for a directive Article 6 – paragraph 2

Text proposed by the Commission

2. For public exposure, the dose constraint shall be set for the individual dose that members of the public receive from the planned operation of a specified radiation source. The competent authorities shall set the constraint so as to ensure compliance with the dose limit for the sum of doses to the same individual from all authorised practices.

Amendment

2. For public exposure, the dose constraint shall be set for the individual dose that members of the public receive from the planned operation of a specified radiation source ***or as a result of an existing anthropic exposure situation***. The competent authorities shall set the constraint so as to ensure ***the protection of health of the general public and*** compliance with the dose limit for the sum of doses to the same individual from all authorised practices, ***as well as from natural sources of radiation and residual contamination. The values chosen for the dose constraints shall be published, so that any member of the public can check that he or she has not received, as a result of aggregate planned and existing anthropic exposure situations, a dose in excess of the legal limit.***

Amendment 42

Proposal for a directive Article 8 – paragraph 2

Text proposed by the Commission

2. Optimised protective strategies shall be planned and implemented with the objective of reducing individual doses below the reference levels. The values chosen for reference levels shall depend

Amendment

2. Optimised protective strategies shall be planned and implemented with the objective of reducing individual doses ***to the lowest level*** below the reference levels ***which can reasonably be achieved***. The values chosen for reference levels shall

upon the type of exposure situation.

depend upon the type of exposure situation,
*the nature of the risk and the forms of
intervention and protective and remedial
measures available.*

Amendment 43

Proposal for a directive Article 8 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Levels of intervention shall be laid down for the various countermeasures applicable in emergency exposure situations; they shall correspond to a level of effective dose or organ dose above which protective measures must be taken to limit the risk incurred by the persons exposed.

Amendment 44

Proposal for a directive Article 8 – paragraph 4

Text proposed by the Commission

Amendment

4. The choice of reference levels for the effective dose shall take into account the three bands of reference levels set out in point 1 of Annex I.

4. The values corresponding to effective dose and equivalent organ dose set by the Member States for the reference and intervention levels shall be communicated to the Commission and published. Member States shall involve stakeholders in the process of setting these values.

Amendment 45

Proposal for a directive Article 11 – paragraph 1

Text proposed by the Commission

Amendment

1. As soon as a pregnant woman informs the undertaking of her condition, in accordance with national legislation or national practice, the protection of the unborn child shall be **comparable with** that provided for members of the public. The employment conditions for the pregnant woman shall be such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy.

1. As soon as a pregnant woman informs the undertaking of her condition, in accordance with national legislation or national practice, the protection of the unborn child shall be **equivalent to** that provided for members of the public. The employment conditions for the pregnant woman shall be such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy.

Amendment 46

Proposal for a directive

Article 12 – paragraph 2 – subparagraph 2 – point a

Text proposed by the Commission

Amendment

(a) the limit on the equivalent dose for the lens of the eye shall be **20** mSv in a year;

(a) the limit on the equivalent dose for the lens of the eye shall be **15** mSv in a year;

Amendment 47

Proposal for a directive

Article 12 – paragraph 2 – subparagraph 2 – point b

Text proposed by the Commission

Amendment

(b) the limit on the equivalent dose for the skin shall be **150** mSv in a year, averaged over any area of 1 cm², regardless of the area exposed;

(b) the limit on the equivalent dose for the skin shall be **50** mSv in a year, averaged over any area of 1 cm², regardless of the area exposed;

Amendment 48

Proposal for a directive

Article 12 – paragraph 2 – subparagraph 2 – point c

Text proposed by the Commission

(c) the limit on the equivalent dose for the hands, forearms, feet and ankles shall be **150** mSv in a year.

Amendment

(c) the limit on the equivalent dose for the hands, forearms, feet and ankles shall be **50** mSv in a year.

Amendment 49

Proposal for a directive

Article 13 – paragraph 1

Text proposed by the Commission

1. The limit on the effective dose for public exposure shall be 1 mSv in a year.

Amendment

1. The limit on the effective dose for public exposure shall be 1 mSv in a year. ***This limit shall be based on the aggregate doses received as a result of internal and external exposure linked to all regulated practices and existing anthropic exposure situations.***

Amendment 50

Proposal for a directive

Article 13 – paragraph 2 – point a

Text proposed by the Commission

(a) the limit on the equivalent dose for the lens of the eye shall be **15 mSv** in a year;

Amendment

(a) the limit on the equivalent dose for the lens of the eye shall be **3 mSv** in a year;

Amendment 51

Proposal for a directive

Article 15 – paragraph 2

Text proposed by the Commission

2. Member States shall establish education, training and retraining to **allow** the recognition of radiation protection experts, medical physics experts, occupational health services, and dosimetry services.

Amendment

2. Member States shall establish **continuous** education, training and retraining to **enable** the recognition of radiation protection experts, medical physics experts, **radiation protection officers**, occupational health and dosimetry services, and **to support the exchange of best practices between the Member States. All forms of education, training and up-to-date information shall enhance preparedness and enable swifter preventive and/or response actions in the field.**

Amendment 52

Proposal for a directive

Article 16 – paragraph 1 – introductory part

Text proposed by the Commission

1. Member States shall require the undertaking or the employer to inform exposed workers, apprentices and students who are subject to occupational exposure on:

Amendment

1. Member States shall require the undertaking or the employer to inform exposed workers **without exception**, apprentices and students who are subject to occupational exposure on:

Amendment 53

Proposal for a directive

Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(aa) safe working procedures minimizing the risks;

Amendment 54

Proposal for a directive

Article 16 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) the conditions under which workers are entitled to health surveillance;

Amendment 55

Proposal for a directive

Article 16 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Where appropriate, information on the risks connected with frequent flying shall also be provided.

Amendment 56

Proposal for a directive

Article 17 – point b

Text proposed by the Commission

Amendment

(b) advised and trained in the visual detection of sources ***and their containers;***

(b) advised and trained in the visual detection of sources ***and their containers as well as in how to report them;***

Amendment 57

Proposal for a directive

Article 18 – paragraph 1

Text proposed by the Commission

Amendment

1. Member States shall ensure that emergency workers and any other persons who might be involved in the organisation

1. Member States shall ensure that emergency workers and any other persons who might be involved in the organisation

of emergency assistance in the event of an emergency are *given adequate* and regularly updated information on the health risks their intervention might involve and on the precautionary measures to be taken in such an event. This information shall take into account the range of potential emergencies.

of emergency assistance in the event of an emergency are *promptly given complete* and regularly updated information on the health risks their intervention might involve and on the precautionary measures to be taken in such an event. This information shall take into account the range of potential emergencies.

Amendment 58

Proposal for a directive Article 19 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. As regards EU citizens, the information requirements laid down in this Directive shall be met in one of the official languages of the European Union in such a way that each citizen understands the information provided.

Amendment 59

Proposal for a directive Article 20 – paragraph 1

Text proposed by the Commission

Amendment

1. Member States shall ensure that new types of practices resulting in exposure to ionising radiation are justified before being approved.

1. Member States shall ensure that new types of practices resulting in exposure to ionising radiation are justified ***and pre-tested*** before being approved, ***and are regularly checked during implementation.***

Amendment 60

Proposal for a directive Article 20 – paragraph 1 – subparagraph 1 (new)

Text proposed by the Commission

Amendment

Member States shall ensure that all stakeholders, in particular the persons likely to be affected by the health impact of the practice, whether in normal operating circumstances or in an emergency, are involved in the decision-making process. That involvement must be arranged sufficiently far ahead of the deadline for a decision so that alternative solutions can be properly studied.

Amendment 61

Proposal for a directive Article 20 – paragraph 3

Text proposed by the Commission

Amendment

3. Existing types of practices shall be reviewed as to their justification whenever new and important evidence about their efficacy or potential consequences is acquired.

3. Existing types of practices shall be reviewed as to their justification whenever new and important evidence about their efficacy or potential consequences is acquired ***and/or where negative results have been registered. The Commission and the Member States shall lay down procedures for the revision of the justifications for existing practices at Union and national level. The arrangements shall in particular ensure that groups or individuals exposed to the dangers of ionising radiation as a result of these practices, and in particular members of the public and workers, can put forward proposals and take part in the decision-making process.***

Amendment 62

Proposal for a directive Article 21 – paragraph 1

Text proposed by the Commission

1. Member States shall require any undertaking intending to manufacture or import or export a new type of apparatus or product emitting ionising radiation to provide the competent authorities with relevant information as set out in Annex III, Section A, in order to enable the authorities, on the basis of assessment of information set out in Annex III, Section B, to decide whether the intended use of the apparatus or product can be justified.

Amendment

1. Member States shall require any undertaking intending to manufacture or import or export a new type of apparatus or product emitting ionising radiation to provide the competent authorities ***in the country in which the undertaking has its registered office*** with relevant information as set out in Annex III, Section A, in order to enable the authorities, on the basis of assessment of information set out in Annex III, Section B, to decide whether the intended use of the apparatus or product can be justified.

Justification

These checks should be carried out in only one Member State, in order to avoid duplication. The findings must then be recognised in all the other Member States. This stipulation is designed to ensure that the competent authorities and undertakings are not required to complete the same procedures twice.

Amendment 63

Proposal for a directive Article 21 – paragraph 2

Text proposed by the Commission

2. The competent authority shall share the information received in accordance with paragraph 1 with the competent authorities of the other Member States to ***allow*** them ***to take their own decision on the justification of*** the intended use of the apparatus or product.

Amendment

2. The competent authority shall share the information received in accordance with paragraph 1 with the competent authorities of the other Member States ***in order to inform*** them ***of its decision concerning*** the intended use of the apparatus or product. ***The competent authorities shall make this information available to all the other Member States.***

Justification

New type-approval requirements will make market access even more difficult without enhancing safety standards. There is a danger that Member States will introduce differing authorisation procedures. Information-sharing is therefore required at Member State level, in order to rule out any unnecessary requirement for the authorities or undertakings to complete the same procedures twice.

Amendment 64

Proposal for a directive Article 21 – paragraph 3

Text proposed by the Commission

3. The undertaking shall be informed on the decisions of the Member States' competent authorities within a period of **six** months.

Amendment

3. The undertaking shall be informed on the decisions of the Member States' competent authorities within a period of **four** months.

Justification

A six-month waiting period would impose a significant financial burden on an undertaking waiting to be granted type approval. This procedure is particularly onerous for small and medium-sized undertakings, and the deadline for taking a decision should therefore be shortened.

Amendment 65

Proposal for a directive Article 21 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. In accordance with Article 22, these types of apparatus and products shall be intended for use in controlled environments.

Amendment 66

Proposal for a directive Article 22

Text proposed by the Commission

Member States shall prohibit the **deliberate** addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, and shall prohibit the import or export of such products. Without prejudice to Directive 1999/2/EC of the European Parliament and of the Council, practices involving the activation of material resulting in an increase in activity in the associated products shall be deemed not to be justified.

Amendment

Member States shall prohibit **and sanction** the addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, **and, more generally, in consumer goods**, and shall prohibit the import or export of such products. Without prejudice to Directive 1999/2/EC of the European Parliament and of the Council, practices involving the activation of material resulting in an increase in activity in the associated products shall be deemed not to be justified.

Amendment 67

**Proposal for a directive
Article 23 – paragraph 1**

Text proposed by the Commission

1. Member States shall ensure the identification, by means of surveys or by any other appropriate means, of practices involving non-medical imaging exposure, as set out in Annex IV.

Amendment

1. Member States shall ensure the identification, by means of surveys or by any other appropriate means, of practices involving non-medical imaging exposure, as set out in Annex IV. **They shall assess each year the individual and collective doses associated with each of the practices listed, their impact and their development over time.**

Amendment 68

**Proposal for a directive
Article 23 – paragraph 2 – introductory part**

Text proposed by the Commission

2. Member States shall ensure that special attention is given to the justification of practices involving non-medical imaging

Amendment

2. Member States shall **monitor and** ensure that special attention is given to the justification of practices involving non-

exposure, in particular:

medical imaging exposure, in particular:

Amendment 69

Proposal for a directive Article 23 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Member States shall be responsible for researching, developing and implementing alternative technologies.

Amendment 70

Proposal for a directive Article 24

Text proposed by the Commission

Amendment

Member States shall ensure the identification of practices involving naturally occurring radioactive material and leading to exposure of workers or members of the public ***which cannot be disregarded from a radiation protection point of view***. Such identification shall be carried out by means of surveys or by any other appropriate means taking into account industrial sectors listed in Annex V.

Member States shall ensure the identification ***and publication*** of practices involving naturally occurring radioactive material and leading to exposure of workers or members of the public. Such identification shall be carried out by means of surveys or by any other appropriate means taking into account, ***in particular***, industrial sectors listed in Annex V.

Amendment 71

Proposal for a directive Article 25 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Member States shall specify the information which the undertaking is required to provide in order to enable the

competent authority to assess the levels of exposure of members of the public and workers and the radiological risks, in normal and emergency situations. On that basis, and drawing, where appropriate, on the findings of additional investigations, the competent authority shall determine which administrative arrangements are applicable and what regulatory control resources are required.

Amendment 72

Proposal for a directive Article 26 – paragraph 1

Text proposed by the Commission

1. Member States shall require any notified practice to be subject to regulatory control *commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the impact that regulatory control may have in reducing such exposures or improving the safety of installations.*

Amendment

1. Member States shall require any notified practice to be subject to regulatory control *by the competent authority.*

Amendment 73

Proposal for a directive Article 26 – paragraph 2

Text proposed by the Commission

2. Notified practices may be exempted from authorisation.

Amendment

deleted

Amendment 74

Proposal for a directive Article 27 – paragraph 1

Text proposed by the Commission

1. In cases where a limited risk of exposure does not necessitate the examination of individual cases and the practice is undertaken in accordance with conditions laid down in national legislation, competent authorities may limit regulatory control to registration of the practice and an appropriate frequency of inspections.

Amendment

1. In cases where ***a quantifiable dose limit can be established for a practice***, a limited risk of exposure does not necessitate the examination of individual cases and the practice is undertaken in accordance with conditions laid down in national legislation, competent authorities may limit regulatory control to registration of the practice and an appropriate frequency of inspections. ***Licensing should be requested where the authorisation is applied to the overall activities of an undertaking.***

Amendment 75

Proposal for a directive

Article 27 – paragraph 2 – introductory part

Text proposed by the Commission

2. Member States shall require licensing for the following practices:

Amendment

2. Member States shall require licensing ***for undertakings performing the following activities, or, where appropriate in accordance with paragraph 1, registration*** for the following practices:

Amendment 76

Proposal for a directive

Article 27 – paragraph 2 – point b

Text proposed by the Commission

(b) the deliberate addition of radioactive substances in the production and manufacture of consumer products or other products, including medicinal products, and the import or export of such products;

Amendment

deleted

Amendment 77

Proposal for a directive Article 27 – paragraph 3 – point f

Text proposed by the Commission

Amendment

(f) industries involving naturally occurring radioactive material identified by Member States as required in Article 24, and liable to lead to an effective dose to a member of the public equal to or exceeding 0.3 mSv per year. ***deleted***

Justification

Der in Artikel 13 festgelegte Wert von 1,0 mSv/a für die Exposition der Gesellschaft wird in diesem Artikel unterschritten. In der Praxis kann dies bedeuten, dass Deponien, welche eine Genehmigung für die Annahme- und Einlagerung für solche Stoffe in einer bestimmten Menge haben, ihr Potential nicht ausschöpfen und weniger annehmen als ihr Kapazität zuließe, um den Wert von 0,3 mSv/a nicht zu überschreiten. Daher müssten solche Stoffe, die beispielsweise in der Stahlindustrie anfallen, als radioaktive Abfälle entsorgt werden. Dabei würden die schon sehr begrenzten Kapazitäten für die Entsorgung radioaktiver Abfälle noch weiter belastet.

Amendment 78

Proposal for a directive Article 28 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) measures taken pursuant to this Directive;

Amendment 79

Proposal for a directive Article 28 – paragraph 5

Text proposed by the Commission

Amendment

5. Member States shall require the undertaking to promptly notify the occurrence of any significant event

5. Member States shall require the undertaking to promptly notify the occurrence of any significant event

resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in licensing requirements with regard to occupational or public exposure or as defined by the authorities for medical exposure.

resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in licensing requirements with regard to occupational or public exposure or as defined by the authorities for medical exposure. ***Random controls by the authorities shall be put in place.***

Medical devices which emit ionising radiation shall be dealt with in accordance with Directive 93/42/EEC¹. The arrangements for the exchange of information provided for under that Directive shall be exhausted and other competent authorities shall be informed.

¹ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 50).

Justification

Die vorliegende Richtlinie regelt die Anforderungen an die Auslegung und Herstellung von Produkten, die ionisierende Strahlungen abgeben. Jedoch werden Medizinprodukte auch bei der Zulassung dahingehend geprüft.

Die Medizinprodukterichtlinie und die vorliegende Richtlinie haben zwei unterschiedliche Schwerpunkte bei der Herangehensweisen an die Problematik der ionisierenden Strahlung. Gerade daher soll in diesem Feld die Doppelarbeit vermieden werden, weshalb Medizinprodukte unter der Medizinprodukterichtlinie behandelt werden sollen, da diese Richtlinie eine umfassende Kontrolle und Überwachung vorschreibt.

Amendment 80

Proposal for a directive Article 33 – paragraph 3 – point a

Text proposed by the Commission

(a) to assess the exposure of the crew concerned;

Amendment

(a) to assess the exposure of the crew ***or workers*** concerned;

Amendment 81

Proposal for a directive Article 38 – paragraph 1 – point a

Text proposed by the Commission

(a) category A: exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than **150** mSv per year for skin and extremities;

Amendment

(a) category A: exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than **50** mSv per year for skin and extremities;

Amendment 82

Proposal for a directive Article 39 – paragraph 2

Text proposed by the Commission

2. Monitoring for category B workers shall be at least sufficient to demonstrate that such workers are correctly classified in category B. Member States **may** require individual monitoring and if necessary individual measurements, performed by a dosimetry service, for category B workers.

Amendment

2. Monitoring for category B workers shall be at least sufficient to demonstrate that such workers are correctly classified in category B. Member States **should** require individual monitoring and if necessary individual measurements, performed by a dosimetry service, for category B workers.

Amendment 83

Proposal for a directive Article 41 – paragraph 3

Text proposed by the Commission

3. The information referred in paragraph 1 shall be retained during the period of their working life involving exposure to ionising radiation and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure.

Amendment

3. ***The dose record referred to in paragraph 1 shall be submitted to the data system for individual radiological monitoring established by the Member State in accordance with Annex VIII.*** The information referred in paragraph 1 shall be retained during the period of their working life involving exposure to ionising

radiation and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure.

Amendment 84

Proposal for a directive Article 43 – paragraph 1

Text proposed by the Commission

1. Member States shall require workers to have access at their request to the results of their individual monitoring, including the results of measurements which may have been used in estimating these results, or to the results of the assessment of their doses made as a result of workplace measurements.

Amendment

1. Member States shall require workers to have access at their request ***in a timely manner*** to the results of their individual monitoring, including the results of measurements which may have been used in estimating these results, or to the results of the assessment of their doses made as a result of workplace measurements.

Amendment 85

Proposal for a directive Article 44 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Examination of the workers will take place during working hours and without costs to them.

Amendment 86

Proposal for a directive Article 49 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Consultation and participation of workers and/or their representatives shall be

regulated by Article 11 of Directive 89/391/EEC¹.

¹ Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 193, 29.6.1989, p. 1).

Amendment 87

Proposal for a directive Article 50 – paragraph 1

Text proposed by the Commission

1. Member States shall ensure that the system for individual radiological monitoring affords outside workers equivalent protection to that for workers employed on a permanent basis by the undertaking.

Amendment

1. Member States shall ensure that the system for individual radiological monitoring affords outside workers equivalent protection *and medical care* to that for workers employed on a permanent basis by the undertaking.

Amendment 88

Proposal for a directive Article 54 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Staff shall be trained regularly and compliance with the applicable rules shall be monitored.

Amendment 89

Proposal for a directive Article 55 – paragraph 3 – point b

Text proposed by the Commission

(b) these individuals are **informed** about the risks of exposure;

Amendment

(b) these individuals are **given full information** about the risks of exposure;

Amendment 90

Proposal for a directive Article 55 – paragraph 4

Text proposed by the Commission

4. The optimisation shall include the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical exposure procedures, quality assurance, and the assessment and evaluation of patient and staff doses or administered activities, taking into account economic and social factors.

Amendment

4. The optimisation shall include the selection of equipment, the consistent production of adequate diagnostic information or therapeutic outcomes, the practical aspects of medical exposure procedures, quality assurance, **including appropriate staff training**, and the assessment and evaluation of patient and staff doses or administered activities, taking into account economic and social factors.

Amendment 91

Proposal for a directive Article 55 – paragraph 5 – point b

Text proposed by the Commission

(b) appropriate guidance is established for the exposure of carers and comforters;

Amendment

(b) appropriate guidance is established for the exposure of carers and comforters, **as well as for the proper use of the equipment**;

Amendment 92

Proposal for a directive Article 56 – paragraph 3

Text proposed by the Commission

3. The practitioner shall ensure that the patient or legal guardian is provided with **adequate** information relating to the benefits and risks associated with the radiation dose from the medical exposure to enable informed consent. Similar information as well as relevant guidance in accordance with Article 55(5)(b) shall be given to carers and comforters.

Amendment

3. The practitioner shall ensure that the patient or legal guardian is provided with **concise and easily understandable** information relating to the benefits and risks associated with the radiation dose from the medical exposure to enable informed consent. Similar information as well as relevant guidance in accordance with Article 55(5)(b) shall be given to carers and comforters.

Amendment 93

**Proposal for a directive
Article 59 – paragraph 2 – point a**

Text proposed by the Commission

(a) all medical radiological equipment in use is kept under strict surveillance regarding radiation protection;

Amendment

(a) all medical radiological equipment in use is kept under strict surveillance regarding radiation protection **and is disposed off in accordance with the appropriate legislation in force;**

Amendment 94

**Proposal for a directive
Article 59 – paragraph 2 – point d**

Text proposed by the Commission

(d) acceptance testing, involving the medical physics expert, is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any major maintenance procedure.

Amendment

(d) acceptance testing, involving the medical physics expert, is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any major maintenance procedure. **In performing such testing, Member States shall comply with the Commission guidelines (in particular RP162)¹ and European and international standards currently applicable to medical**

radiological equipment (IECTC62 on Electrical equipment in medical practice, IAEA Standards, ICRP Guidelines).

¹ Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy.

Justification

On the basis of this article Member States could develop their own approval testing procedures. This would generate additional costs in connection with acceptance and entry into service, but no added value as regards safety. For that reason, testing should be based on existing standards.

Amendment 95

Proposal for a directive

Article 62 – point d

Text proposed by the Commission

(d) the undertaking declares as soon as possible to the competent authorities the occurrence of significant events as defined by the authorities, including the results of the investigation and the corrective measures to avoid such events. The competent authorities ***shall share this information with the competent authorities*** for post-market surveillance established in Council Directive 93/42/EEC concerning medical devices.

Amendment

(d) the undertaking declares as soon as possible to the competent authorities the occurrence of significant events as defined by the authorities, including the results of the investigation and the corrective measures to avoid such events. ***In the case of medical devices, the undertaking or the user shall immediately forward all relevant information to*** the competent authorities for post-market surveillance established in Council Directive 93/42/EEC concerning medical devices. ***Where necessary those authorities shall notify other competent authorities.***

Justification

See the justification for Amendment 8.

Amendment 96

Proposal for a directive

Article 65 – paragraph 2 – introductory part

Text proposed by the Commission

2. The competent authority shall establish authorised limits for discharging radioactive effluents. These discharge authorisations shall

Amendment

2. The competent authority shall establish **and publish** authorised limits for discharging radioactive effluents. These discharge authorisations shall

Amendment 97

Proposal for a directive

Article 65 – paragraph 2 – point a

Text proposed by the Commission

(a) take into account the results of the optimisation of public exposure;

Amendment

(a) take into account ***the doses received by members of the public due to existing anthropogenic situations and other planned activities*** and the results of the optimisation of public exposure;

Amendment 98

Proposal for a directive

Article 68 – paragraph 1 – point a

Text proposed by the Commission

(a) achieving and maintaining ***an optimal*** level of protection;

Amendment

(a) achieving and maintaining ***the highest*** level of protection ***of public health and the environment***;

Amendment 99

Proposal for a directive

Article 70 – paragraph 1

Text proposed by the Commission

1. Member States shall require the undertaking responsible for a practice to notify the competent authorities immediately of any emergency occurring in its facility or related to its activities and to take all appropriate action to reduce the consequences.

Amendment

1. Member States shall require the undertaking responsible for a **licensed** practice to notify the competent authorities immediately of any emergency occurring in its facility or related to its activities and to take all appropriate action to reduce the consequences.

Justification

The provisions set out here refer to the practices falling under the categories which present high levels of risk and thus fall within the licensed category of practices.

Amendment 100

**Proposal for a directive
Article 70 – paragraph 2 a (new)**

Text proposed by the Commission

Amendment

2a. Member States should inform each other immediately about any radiation emergency that has occurred on their territory.

Amendment 101

**Proposal for a directive
Article 70 – paragraph 3 – point c**

Text proposed by the Commission

Amendment

(c) individuals, to reduce exposure.

(c) individuals, to reduce exposure ***and to be fully informed, as quickly as possible, of the risks and possible side effects of the emergency that has occurred***

Amendment 102

Proposal for a directive Article 71 – paragraph 1

Text proposed by the Commission

1. Member States shall ensure that members of the public likely to be affected in the event of an emergency are given information about the health protection measures applicable to them and about the action they should take in the event of such an emergency.

Amendment

1. Member States shall ensure that members of the public likely to be affected in the event of an emergency are given information about the health protection measures applicable to them and about the action they should take in the event of such an emergency. ***This shall concern, at the very least, people living within 50km of an installation at risk.***

Amendment 103

Proposal for a directive Article 72 a (new)

Text proposed by the Commission

Amendment

Article 72a

Informing the general public

As soon as news of an emergency situation is received, the Member States shall ensure that the general public is informed as soon as possible.

All information necessary for an assessment of the situation and its development – in particular weather data and forecasts, air movements and ground deposits, ambient dose rates and contamination levels of critical foodstuffs – shall be made public. The relevant authorities shall make public forecasts of the effective dose and equivalent dose for the vital organs, planned and completed interventions, and the expected and actual residual doses.

Amendment 104

Proposal for a directive Article 76 – paragraph 1

Text proposed by the Commission

Member States shall include, in their legal framework for radiation protection and in particular within the overall system of human health protection, provision for the radiation protection of non-human species in the environment. This legal framework shall introduce environmental criteria aiming to protect populations of vulnerable or representative non-human species in the light of their significance as part of the ecosystem. Where appropriate, types of practices shall be identified for which regulatory control is warranted in order to implement the requirements of this legal framework.

Amendment

Member States shall include, in their legal framework for radiation protection and in particular within the overall system of human health protection, provision for the radiation protection of non-human species in the environment. This legal framework shall introduce environmental criteria aiming to protect populations of vulnerable or representative non-human species in the light of their significance as part of the ecosystem. Where appropriate, types of practices shall be identified for which regulatory control is warranted in order to implement the requirements of this legal framework. ***To this end, Member States shall strengthen research in this area and update the legal framework to take account of any new findings accordingly.***

Amendment 105

Proposal for a directive Article 78

Text proposed by the Commission

Member States shall require undertakings to take appropriate technical measures to avoid significant environmental damage in the event of an accidental release or to mitigate the extent of such damage.

Amendment

Member States shall require undertakings to take appropriate technical measures to avoid significant environmental damage in the event of an accidental release or to mitigate the extent of such damage. ***National authorities shall provide for random periodic checks of sites or installations, as well as of the practices used by the undertakings, in order to ensure that such measures are being taken or are in place.***

Amendment 106

Proposal for a directive Article 79

Text proposed by the Commission

When establishing environmental monitoring programmes, or requiring such programmes to be carried out, Member States' competent authorities shall include representative non-human species, ***if necessary***, and also environmental media which constitute a pathway of exposure for members of the public.

Amendment

When establishing environmental monitoring programmes, or requiring such programmes to be carried out, Member States' competent authorities shall include representative non-human species and also environmental media which constitute a pathway of exposure for members of the public. ***In order to enhance the transparency and effectiveness of measures taken, Member States' national authorities shall regularly exchange data and information on environmental radioactivity monitoring, including the immediate dissemination of new data.***

Amendment 107

Proposal for a directive Article 80 – paragraph 1

Text proposed by the Commission

1. Member States shall designate the competent authority or authorities to carry out ***tasks*** provided for in this Directive.

Amendment

1. Member States shall designate the competent authority or authorities to carry out ***the regulatory control*** provided for in this Directive; ***the competent authority or authorities shall be functionally independent from any institution promoting or operating nuclear power.***

Amendment 108

Proposal for a directive Article 80 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Each Member State shall ensure that public participation is enforced according to national legislation by the competent authority of the Member State when dose limits are set or amended.

Amendment 109

**Proposal for a directive
Article 80 – paragraph 1 b (new)**

Text proposed by the Commission

Amendment

1b. The public participation procedures shall include reasonable time-frames for the different phases, allowing sufficient time for informing the public and for the public to prepare and participate effectively during the decision making.

Amendment 110

**Proposal for a directive
Article 80 – paragraph 1 c (new)**

Text proposed by the Commission

Amendment

1c. The competent authority shall ensure that in the decision for dose limits due account is taken of the outcome of public participation.

Amendment 111

**Proposal for a directive
Article 81 – paragraph 1 – subparagraph 1 – point c**

Text proposed by the Commission

Amendment

(c) radiation protection experts;

(c) radiation protection experts ***and radiation protection officers***;

Amendment 112

Proposal for a directive

Article 81 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

Member States shall lay down provisions to ensure the continuity of expertise of these services and experts.

Member States shall lay down provisions to ensure the continuity of expertise and ***independence*** of these services and experts.

Amendment 113

Proposal for a directive

Article 85 – paragraph 2 – subparagraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) establishing documented procedures for providing information to and training of exposed workers.

Amendment 114

Proposal for a directive

Article 86 – paragraph 2 – subparagraph 1 – point l a (new)

Text proposed by the Commission

Amendment

(la) establishing documented procedures for providing information to and training of exposed workers.

Amendment 115

Proposal for a directive Article 91 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Member States shall ensure that licence-holders mark containers and document the practices with high-activity sealed sources in a form not subject to weathering. The documentation shall comprise both the chemical, toxic and radiological composition of the inventory and an indication of whether it is solid, liquid or gaseous.

Amendment 116

Proposal for a directive Article 101 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) the objectives pursued by the strategy;

(a) the objectives pursued by the strategy,
in particular in terms of residual dose;

Amendment 117

Proposal for a directive Article 101 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) appropriate reference levels, taking into account the bands of reference levels laid down in Annex I.

deleted

Amendment 118

Proposal for a directive Article 107 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [00.00.0000] at the latest. The provisions laid down in Chapter IX with regard to the protection of the environment shall be transposed by [00.00.0000] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

Amendment

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [00.00.0000] at the latest. The provisions laid down in Chapter IX with regard to the protection of the environment shall be transposed by [00.00.0000] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive. ***The Commission shall report on those communications to the European Parliament.***

Amendment 119

Proposal for a directive

Article 107 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

Should a Member State plan to adopt standards stricter than those laid down by this Directive, it shall inform the Commission and the other Member States accordingly.

Amendment 120

Proposal for a directive

Article 107 – paragraph 2

Text proposed by the Commission

Amendment

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive. ***A summary of those communications shall be drawn up by the Commission, which shall forward it***

Amendment 121

**Proposal for a directive
Annex I**

Text proposed by the Commission

Amendment

ANNEX I

deleted

Bands of reference levels for public exposure

1. The optimisation of public exposures in emergency and existing exposure situations shall be based on a reference level to be established within the following bands, expressed in mSv effective dose (acute or annual):

(a) greater than 20 and less or equal to 100

(b) greater than 1 and less or equal to 20

(c) 1 or less.

The choice of the reference level shall fulfil the conditions set out in points 2-5.

2. Without prejudice to reference levels set for organ doses, reference levels expressed in effective doses shall be set in the range of 1 to 20 mSv per year for existing exposure situations and 20 to 100 mSv for emergency exposure situations.

3. In specific situations, a reference level below ranges referred to in point 1 may be considered, in particular:

(a) a reference level below 20 mSv may be set in an emergency exposure situation where appropriate protection can be provided without causing a disproportionate detriment from the corresponding countermeasures or an excessive cost;

(b) a reference level below 1 mSv per year

may be set, where appropriate, in an existing exposure situation for specific source-related exposures or pathways of exposure.

4. For the transition from an emergency exposure situation to an existing exposure situation, appropriate reference levels shall be set, in particular upon the termination of long-term countermeasures such as relocation.

5. The reference levels set shall take account of the features of prevailing situations as well as societal criteria, which may include the following:

(a) for exposures below 1 mSv or 1 mSv per year, general information on the level of exposure, without specific consideration of individual exposures;

(b) in the range up to 20 mSv or 20 mSv per year, specific information to enable individuals to manage their own exposure, if possible;

(c) in the range up to 100 mSv or 100 mSv per year, assessment of individual doses and specific information on radiation risks and on available actions to reduce exposures.

Amendment 122

Proposal for a directive Annex III – title

Text proposed by the Commission

Placing on the market of apparatus or products

Amendment

Placing on the market of apparatus or products ***emitting ionising radiation***

Amendment 123

Proposal for a directive

Annex III – part A – point 5 a (new)

Text proposed by the Commission

Amendment

(5a) the radiological risks associated with malfunctioning and accidents likely to affect the apparatus or product.

Amendment 124

**Proposal for a directive
Annex III – part B – point 5**

Text proposed by the Commission

Amendment

(5) whether the apparatus or product is appropriately labelled and suitable documentation is provided to the **customer** with instructions for proper use and disposal.

(5) whether the apparatus or product is appropriately labelled and suitable documentation is provided to the **user** with instructions for proper use and disposal.

Amendment 125

**Proposal for a directive
Annex III – part B a (new)**

Text proposed by the Commission

Amendment

Ba. The competent authorities shall give prior and full information to potential users of apparatuses and products and shall ensure that they are involved in the decision-taking process.

Amendment 126

**Proposal for a directive
Annex VI – point 3 – paragraph 1 – introductory part**

Text proposed by the Commission

Amendment

The general criteria for the exemption of

The general criteria for the exemption of

notified practices or the clearance of materials from authorised practices are as follows:

notified practices or the clearance of **radioactive** materials from authorised practices are as follows:

Amendment 127

Proposal for a directive Annex VI – point 3 – paragraph 5 – introductory part

Text proposed by the Commission

Amendment

For artificial radionuclides:

For artificial radionuclides **and natural radionuclides used for their fissile, fertile or radioactive properties**:

Amendment 128

Proposal for a directive Annex VIII – heading "General provisions" – paragraph 2

Text proposed by the Commission

Amendment

The data system for individual radiological monitoring established by a Member State may be realised either as a centralised national network or as a national dose register. These networks or registers **may** be supplemented by the issuance of individual radiological monitoring documents for every outside worker.

The data system for individual radiological monitoring established by a Member State may be realised either as a centralised national network or as a national dose register. These networks or registers **should** be supplemented by the issuance of individual radiological monitoring documents for every outside worker.

Amendment 129

Proposal for a directive Annex X – part A – point 4 a (new)

Text proposed by the Commission

Amendment

4a. Information on the nature and scale of harm liable to be caused by various emergency situations.

Amendment 130

Proposal for a directive Annex X – part A – point 4 b (new)

Text proposed by the Commission

Amendment

4b. Information on the terms for damages for personal injury and material loss following an emergency.

Amendment 131

Proposal for a directive Annex X – part A – point 4 c (new)

Text proposed by the Commission

Amendment

4c. Information on how to store and use stable iodine tablets provided by the competent authorities.

Amendment 132

Proposal for a directive Annex X – part B – point 1 – point a

Text proposed by the Commission

Amendment

(a) information on the type of emergency which has occurred and, ***where possible***, its characteristics (e.g. its origin, extent and probable development);

(a) information on the type of emergency which has occurred and its characteristics (e.g. its origin, extent and probable development);

EXPLANATORY MEMORANDUM

In your rapporteur's view, the proposal recasting the Council directive laying down basic safety standards represents a further step towards improving protection against exposure to ionising radiation. On the basis of Article 31 of the Euratom Treaty, the proposal combines the directive on medical exposure, the directive on the control of high-activity sealed radioactive sources, the directive on the operational exposure of outside workers and the directive on informing the general public with Directive 96/29/Euratom laying down basic safety standards.

One of the aims of the recast is to do away with contradictory provisions in the existing legislation. That objective has largely been achieved, so that in this respect there is little need for amendments. Many aspects of radiation protection which are dealt with in the directive laying down basic standards work very well in practice, so that once again few amendments are necessary.

A further aim of the proposal is to incorporate the latest scientific data concerning and experience gained with radiation protection into current legislation. In this respect the Euratom rules have always followed the scientific recommendations issued by the International Commission on Radiological Protection (ICRP). In Publication 103 (2007) that body recommended changes to the current radiological protection arrangements which have now been taken into account in the proposal for a directive.

In addition, for the first time provisions on natural sources of radiation are to be incorporated into the directive laying down basic standards, with a view to improving the protection of the public. This is a welcome step. In the area of dumping, however, the proposed registration requirements could lead to contradictory objectives being set as regards the disposal of different radioactive substances. With a view to preventing this, your rapporteur has tabled an amendment to the rules governing naturally occurring radioactive materials.

In the area of medical exposure your rapporteur has tabled a number of minor amendments designed to prevent duplication of work in connection with medical devices which give off ionising radiation. Here there is a danger that medical devices which work with ionising radiation may be covered by both the Medical Devices Directive and the relevant provisions of the directive laying down basic standards. Since the focus of the two directives is different, at first sight it would seem to make sense for the notification requirements to cover both directives. However, this may give rise to bureaucratic delays for manufacturers and operators of such devices. With a view to preventing this, your rapporteur is proposing that these medical devices should be dealt with under the Medical Devices Directive (93/42/EEC), which already lays down comprehensive monitoring and supervisory arrangements. Your rapporteur welcomes in principle the incorporation in the directive of a chapter on environmental protection. Here, however, there is a danger of provisions being introduced which at present cannot be enforced. The proposed provisions on environmental criteria seek to guarantee the protection of individuals by laying down rules on the protection of non-human species. However, as there is as yet no proven scientific basis for determining what impact radiation has on non-human species, rules of this kind will do nothing to protect people more effectively. The ICRP likewise has no data and values at its disposal which could be used as the scientific basis for introducing environmental criteria of this kind. For that reason, this chapter should be deleted from the proposal. Your rapporteur takes the view that a

separate legal act dealing with the protection of the environment against ionising radiation can be drawn up once a sufficient volume of reliable data is available. A corresponding proposal should then be put forward on the basis of the environmental objectives set in the Lisbon Treaty and considered under the codecision procedure.

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS ON THE LEGAL BASIS

Mr Matthias Groote
Chair
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on the legal basis on the proposal for a Council Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation [COM(2012)0242]

Dear Mr Chair,

By letter of 4 July 2013, you asked the Committee on Legal Affairs, pursuant to Rule 37 of the Rules of Procedure, to consider a possible change of legal basis for the above proposal for a Regulation.

The legal basis proposed by the Commission is Articles 31 and 32 of the Treaty establishing the European Atomic Energy Community (the "Euratom Treaty").

At its vote on the draft report in ENVI on 4 July 2013, an amendment was adopted which changes the legal basis to Article 192(1) of the Treaty on the Functioning of the European Union (TFEU).

I - Background

According to the Commission proposal there is a significant body of Euratom legislation addressing different radiation protection issues defined as basic safety standards in the Euratom Treaty. As these issues have developed over a long period of time, there are inevitably quite a few inconsistencies between different acts and also obsolete references as a result of updated legislation. The proposal therefore aims at resolving these inconsistencies, in line with the Commission's policy for simplification of European legislation.

The proposal therefore updates several pieces of existing Euratom legislation by adapting it to the latest scientific data and operational experience, by clarifying requirements and ensuring coherence within the acquis, by ensuring coherence with international recommendations and by covering the whole range of exposure situations and categories of exposure.

II - Relevant Treaty Articles

The following Articles of the Euratom Treaty, under Chapter 3 entitled "Health and safety" are presented as the legal basis in the Commission proposal (emphasis added):

Article 31

The basic 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. The Commission shall obtain the opinion of the Economic and Social Committee on these basic standards.

After consulting the European Parliament the Council shall, on a proposal from the Commission, which shall forward to it the opinions obtained from these Committees, establish the basic standards; the Council shall act by a qualified majority.

Article 32

At the request of the Commission or of a Member State, the basic standards may be revised or supplemented in accordance with the procedure laid down in Article 31.

The Commission shall examine any request made by a Member State.

The expression "basic standards" is defined in Article 30 of the Euratom Treaty (emphasis added):

Article 30

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.

The expression 'basic standards' means:

- (a) maximum permissible doses compatible with adequate safety;*
- (b) maximum permissible levels of exposure and contamination;*
- (c) the fundamental principles governing the health surveillance of workers.*

The legal basis adopted in the vote in ENVI has the following wording (emphasis added):

Article 192

1. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall decide what action is to be taken by the Union in order to achieve the objectives referred to in Article 191.

[...]

Article 191 TFEU has the following wording:

Article 191

1. Union policy on the environment shall contribute to pursuit of the following objectives:

- preserving, protecting and improving the quality of the environment,*
- protecting human health,*
- prudent and rational utilisation of natural resources,*
- promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change.*

2. Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a procedure of inspection by the Union.

[...]

III - The proposed legal bases

Article 31 of the Euratom Treaty provides the legal basis for the adoption of basic standards for the protection of the health of workers and the general public against radiation. Article 32 of the Euratom Treaty provides the legal basis for the revision of the basic standards and the provisions supplementing them. The Council acts unanimously and the Parliament is consulted.

Article 191 TFEU provides the legal basis for measures to be taken in order to achieve the objectives of the Union policy on the environment. Those measures are to be taken in accordance with the ordinary legislative procedure, and the Parliament is therefore co-legislator.

IV - Case-law on legal basis

It is settled case law of the Court of Justice that "the choice of legal basis for a Community measure must rest on objective factors amenable to judicial review, which include in particular the aim and content of the measure"¹. The choice of an incorrect legal basis may therefore justify the annulment of the act at stake.

In this case, it therefore has to be established whether the proposal either:

1. pursues a twofold purpose or has a twofold component, and one of those is identifiable as the main or predominant purpose or component, whereas the other is merely incidental; or
2. simultaneously pursues a number of objectives or has several components that are indissociably linked, without one being secondary and indirect in relation to the other.

According to the case law of the Court of Justice, in the first case the act must be based on a single legal basis, namely that required by the main or predominant purpose or component, and in the second case the act will have to be founded on the various corresponding legal bases.²

V. Aim and content of the proposed regulation

The aim of the proposal is to consolidate existing Euratom legislation in order to establish the basic safety standards for the protection of the health of workers, general public, patients and other individuals subject to medical exposure against the dangers arising from ionising radiation for the purpose of their uniform implementation by Member States.

The content of the proposal is very extensive, including chapters on general principles of radiation protection, education, regulatory control, protection of several categories of people, and a new chapter on the protection of the environment.

VI - Determination of the appropriate legal basis

As the Legal Service rightly points out, the legal acts being repealed by the proposal were all based on Articles 31 and 32 of the Euratom Treaty, and the fact that a new chapter on the environment has been added does therefore not alter the determination of the main or predominant aim or component of the proposal, as compared with the repealed legal acts, not least considering the extensive content of the body of the text, of which this chapter constitutes a minor part.

The predominant aim and component of the proposal is thus to establish basic safety

¹ Case C-45/86, *Commission v. Council* (Generalised Tariff Preferences) [1987] ECR 1439, para. 5; Case C-440/05 *Commission v. Council* [2007] E.C.R. I-9097; Case C-411/06 *Commission v. Parliament and Council* (8 September 2009) ([OJ C 267 of 07.11.2009, p.8](#)).

² See the above-referenced Case C-411/06, paras. 46-47.

standards against the dangers arising from ionising radiation under the Euratom system, whereas any aspects relating to the Union policy on the environment are merely incidental, and Articles 31 and 32 of the Euratom Treaty must therefore constitute the sole legal basis for the proposal.

VII - Conclusion

In light of the foregoing analysis Articles 31 and 32 of the Euratom Treaty constitute the appropriate legal basis for the proposal.

VIII - Recommendation

At its meeting of 17 September 2013 the Committee accordingly decided, by 13 votes in favour and 11 against¹, to recommend to you that the appropriate legal basis for the proposal for a Council Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation is Articles 31 and 32 of the Euratom Treaty.

Yours sincerely,

Klaus-Heiner Lehne

¹ The following were present for the final vote: Raffaele Baldassarre (Vice-Chair), Luigi Berlinguer, Sebastian Valentin Bodu (Vice-Chair), Françoise Castex (Vice-Chair), Christian Engström, Marielle Gallo, Giuseppe Gargani, Lidia Joanna Geringer de Oedenberg, Sajjad Karim, Klaus-Heiner Lehne (Chair), Eva Lichtenberger, Antonio López-Istúriz White, Jiří Maštálka, Alajos Mészáros, Angelika Niebler, Bernhard Rapkay, Evelyn Regner (Vice-Chair), Francesco Enrico Speroni, Dimitar Stoyanov, József Szájer, Alexandra Thein, Axel Voss, Cecilia Wikström, Tadeusz Zwiefka, Olle Schmidt(pursuant to Rule 187(2)).

25.3.2013

OPINION OF THE COMMITTEE ON EMPLOYMENT AND SOCIAL AFFAIRS (*)

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a Council directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (COM(2012)0242 – C7-0151/2012 – 2011/0254(NLE))

Rapporteure: Anthea McIntyre(*)

(*) Associated committees – Rule 50 of the Rules of Procedure

SHORT JUSTIFICATION

Ionising radiation occurs naturally, but can also be produced artificially. Workers, medical patients, and members of the public are liable to be exposed to emissions at levels which can cause organ damage.

On the other hand, the use of radioactive substances and radiation generators are an essential component for many industries throughout the EU, who in turn are also large sources of employment, and because of this, basic standards for the protection of workers and the general public have been laid down since 1959.

The measures currently in force are set out in Council Directive 96/29/Euratom which reflect the recommendations of the International Commission on Radiation Protection (ICRP), have been supplemented by more specific legislation in a number of areas, all of which have an impact on radiological protection.

In September, 2011, the Commission put forward a new draft Directive to simplify the existing arrangements for radiological protection, bringing all existing Directives into a new Basic Safety Standards Directive (BSSD). The BSSD seeks to incorporate the latest recommendations from the ICRP, and to harmonise the EU regime with the basic safety standards of the International Atomic Energy Agency (IAEA).

While broadly supporting the Commission's proposal for a more coherent approach, your Rapporteur remains convinced of the importance of ensuring a proportionate risk based approach is followed.

Your Rapporteur is concerned that while simplification is important, some of the proposed changes in the proposal do not provide additional benefits in terms of increased protection of

workers, but will impose disproportionate burdens on Member States in terms of implementation. It is important to note that Member States regulatory regimes differ significantly from each other and therefore a uniform approach is not appropriate. Member States need appropriate flexibility to implement the legislation in accordance with their own established practices.

Your Rapporteur believes that we must strike a balance between essential business usage, occupational risks and high levels of societal concern.

AMENDMENTS

The Committee on Employment and Social Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive Article 1 – paragraph 1

Text proposed by the Commission

1. This Directive establishes the basic safety standards for the protection of the health of workers, general public, patients and other individuals subject to medical exposure against the dangers arising from ionising radiation for the purpose of their **uniform** implementation by Member States.

Amendment

1. This Directive establishes the basic safety standards for the protection of the health of workers, general public, patients and other individuals subject to medical exposure against the dangers arising from ionising radiation for the purpose of their implementation by Member States.

Justification

The regulatory regime in each Member State differs significantly; therefore it is not realistic to expect uniform implementation by Member States. It is possible to achieve the desired objectives of this proposed legislation without the need for uniform implementation

Amendment 2

Proposal for a directive Article 2 – paragraph 2 – point c – point i

Text proposed by the Commission

i) the operation of aircraft and spacecraft;

Amendment

i) ***practices exposing workers to cosmic radiation, including*** the operation of aircraft and spacecraft ;

Amendment 3
Proposal for a directive
Article 4 – paragraph 1 – point 24

Text proposed by the Commission

(24) Occupational exposure means exposure of workers incurred in the course of their work;

Amendment

(24) Occupational exposure means exposure of workers, ***including employees and self-employed as well as trainees and volunteers,*** incurred in the course of their work;

Amendment 4
Proposal for a directive
Article 4 – paragraph 1 – point 35

Text proposed by the Commission

(35) Exposed worker means a person, either self-employed or working under an employer, who is subject to exposure at work carried out within a practice regulated by this Directive and who is liable to receive doses exceeding one or other of the dose limits for public exposure;

Amendment

(35) Exposed worker means a person, either self-employed or working under an employer, ***including a trainee or volunteer,*** who is subject to exposure at work carried out within a practice regulated by this Directive and who is liable to receive doses exceeding one or other of the dose limits for public exposure;

Amendment 5
Proposal for a directive
Article 4 – point (38)

Text proposed by the Commission

(38) Apprentice means a person receiving training or instruction within an undertaking with a view to exercising a

Amendment

(38) Apprentice means a person ***aged 16 years or over (including trainees and students)*** receiving training or instruction

specific skill.

within an undertaking with a view to exercising a specific skill, **which involves operations which would, in the case of an employee, be considered working with ionising radiation.**

Justification

The inclusion of trainees and students is important in order to bring this in line with the rest of the text.

Amendment 6

Proposal for a directive Article 5 – introductory part

Text proposed by the Commission

Member States shall establish legal requirements and an appropriate regime of regulatory control which, for all exposure situations reflect a system of radiation protection based on **the** following principles of justification, optimisation and dose limitation:

Amendment

Member States shall establish legal requirements and an appropriate regime of regulatory control which, for all exposure situations reflect a system of radiation protection based on **up-to-date, robust scientific evidence**, following principles of justification, optimisation and dose limitation:

Justification

It is important that any new changes are based on up to date, robust scientific evidence.

Amendment 7

Proposal for a directive Article 6 – paragraph 1

Text proposed by the Commission

1. For occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking **under the general supervision** of the competent authorities. In the case of outside workers the dose constraint shall be

Amendment

1. For occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking **in consultation with workers' representatives. Their decision shall be supervised by** the competent authorities. In

established in cooperation between the employer and the undertaking.

the case of outside workers the dose constraint shall be established in cooperation between the employer and the undertaking *in consultation with workers' representatives*.

Amendment 8

Proposal for a directive Article 11 – paragraph 1

Text proposed by the Commission

1. As soon as a pregnant woman informs the undertaking of her condition, in accordance with national legislation or national practice, the protection of the unborn child shall be *comparable with* that provided for members of the public. The employment conditions for the pregnant woman shall be such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy.

Amendment

1. As soon as a pregnant woman informs the undertaking of her condition, in accordance with national legislation or national practice, the protection of the unborn child shall be *equivalent to* that provided for members of the public. The employment conditions for the pregnant woman shall be such that the equivalent dose to the unborn child is as low as reasonably achievable and unlikely to exceed 1 mSv during at least the remainder of the pregnancy.

Amendment 9

Proposal for a directive Article 12 – paragraph 2 – subparagraph 2 – point a

Text proposed by the Commission

(a) the limit on the equivalent dose for the lens of the eye shall be **20** mSv in a year;

Amendment

(a) the limit on the equivalent dose for the lens of the eye shall be **15** mSv in a year;

Amendment 10

Proposal for a directive Article 12 – paragraph 2 – subparagraph 2 – point b

Text proposed by the Commission

(b) the limit on the equivalent dose for the skin shall be **150** mSv in a year, averaged

Amendment

(b) the limit on the equivalent dose for the skin shall be **50** mSv in a year, averaged

over any area of 1 cm², regardless of the area exposed;

over any area of 1 cm², regardless of the area exposed;

Amendment 11

Proposal for a directive

Article 12 – paragraph 2 – subparagraph 2 – point c

Text proposed by the Commission

Amendment

(c) the limit on the equivalent dose for the hands, forearms, feet and ankles shall be **150** mSv in a year.

(c) the limit on the equivalent dose for the hands, forearms, feet and ankles shall be **50** mSv in a year.

Amendment 12

Proposal for a directive

Article 16 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. Member States shall require the undertaking or the employer to inform exposed workers, apprentices and students who are subject to occupational exposure on:

1. Member States shall require the undertaking or the employer to inform exposed workers ***without exception***, apprentices and students who are subject to occupational exposure on:

Amendment 13

Proposal for a directive

Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(aa) safe working procedures minimizing the risks;

Amendment 14

Proposal for a directive

Article 16 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) the conditions under which workers are entitled to health surveillance;

Amendment 15

Proposal for a directive

Article 16 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Where appropriate, information on the risks connected with frequent flying shall also be provided.

Amendment 16

Proposal for a directive

Article 17 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) advised and trained in the visual detection of sources ***and their containers***;

(b) advised and trained in the visual detection of sources ***and their containers as well as in how to report them***;

Amendment 17

Proposal for a directive

Article 27 – paragraph 1

Text proposed by the Commission

Amendment

1. In cases where a limited risk of exposure does not necessitate the examination of individual cases and the practice is undertaken in accordance with conditions laid down in national legislation, competent authorities may limit regulatory control to registration of the practice and an appropriate frequency of inspections.

1. In cases where ***a quantifiable dose limit can be established for a practice***, a limited risk of exposure does not necessitate the examination of individual cases and the practice is undertaken in accordance with conditions laid down in national legislation, competent authorities may limit regulatory control to registration of the practice and an appropriate frequency of inspections. ***Licensing should be requested***

where the authorisation is applied to the overall activities of an undertaking.

Amendment 18

Proposal for a directive

Article 27 – paragraph 2 – introductory part

Text proposed by the Commission

2. Member States shall require licensing for the following practices:

Amendment

2. Member States shall require licensing ***for undertakings performing the following activities, or, where appropriate in accordance with paragraph 1, registration*** for the following practices:

Amendment 19

Proposal for a directive

Article 28 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) measures taken pursuant to this directive;

Amendment 20

Proposal for a directive

Article 33 – paragraph 3 – point a

Text proposed by the Commission

(a) to assess the exposure of the crew concerned;

Amendment

(a) to assess the exposure of the crew ***or workers*** concerned;

Amendment 21

Proposal for a directive

Article 38 – paragraph 1 – point a

Text proposed by the Commission

(a) category A: exposed workers who are

Amendment

(a) category A: exposed workers who are

liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than **150** mSv per year for skin and extremities;

liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than **50** mSv per year for skin and extremities;

Amendment 22

Proposal for a directive Article 39 – paragraph 2

Text proposed by the Commission

2. Monitoring for category B workers shall be at least sufficient to demonstrate that such workers are correctly classified in category B. Member States **may** require individual monitoring and if necessary individual measurements, performed by a dosimetry service, for category B workers.

Amendment

2. Monitoring for category B workers shall be at least sufficient to demonstrate that such workers are correctly classified in category B. Member States **should** require individual monitoring and if necessary individual measurements, performed by a dosimetry service, for category B workers.

Amendment 23

Proposal for a directive Article 41 – paragraph 3

Text proposed by the Commission

3. The information referred in paragraph 1 shall be retained during the period of their working life involving exposure to ionising radiation and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure.

Amendment

3. ***The dose record referred to in paragraph 1 shall be submitted to the data system for individual radiological monitoring established by the Member State in accordance with Annex VIII.*** The information referred in paragraph 1 shall be retained during the period of their working life involving exposure to ionising radiation and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure.

Amendment 24

Proposal for a directive Article 43 – paragraph 1

Text proposed by the Commission

1. Member States shall require workers to have access at their request to the results of their individual monitoring, including the results of measurements which may have been used in estimating these results, or to the results of the assessment of their doses made as a result of workplace measurements.

Amendment

1. Member States shall require workers to have access at their request ***in a timely manner*** to the results of their individual monitoring, including the results of measurements which may have been used in estimating these results, or to the results of the assessment of their doses made as a result of workplace measurements.

Amendment 25

Proposal for a directive Article 44 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Examination of the workers will take place during working hours and without costs to them.

Amendment 26

Proposal for a directive Article 49 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Consultation and participation of workers and/or their representatives shall be regulated by Article 11 of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work¹.

¹ OJ L 193, 29.6.1989, p. 1.

Amendment 27

Proposal for a directive Article 50 – paragraph 1

Text proposed by the Commission

1. Member States shall ensure that the system for individual radiological monitoring affords outside workers equivalent protection to that for workers employed on a permanent basis by the undertaking.

Amendment

1. Member States shall ensure that the system for individual radiological monitoring affords outside workers equivalent protection **and medical care** to that for workers employed on a permanent basis by the undertaking.

Amendment 28

Proposal for a directive Article 54 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Staff shall be trained regularly and compliance with the applicable rules shall be monitored.

Amendment 29

Proposal for a directive Article 70 – paragraph 1

Text proposed by the Commission

1. Member States shall require the undertaking responsible for a practice to notify the competent authorities immediately of any emergency occurring in its facility or related to its activities and to take all appropriate action to reduce the consequences.

Amendment

1. Member States shall require the undertaking responsible for a **licensed** practice to notify the competent authorities immediately of any emergency occurring in its facility or related to its activities and to take all appropriate action to reduce the consequences.

Justification

The provisions set out here refer to the practices falling under the categories which present high levels of risk and thus fall within the licensed category of practices.

Amendment 30

Proposal for a directive Article 85 – paragraph 2 – point f a (new)

Text proposed by the Commission

Amendment

(fa) establishing documented procedures for providing information to and training of exposed workers.

Amendment 31

Proposal for a directive Article 86 – paragraph 2 – point l a (new)

Text proposed by the Commission

Amendment

(la) establishing documented procedures for providing information to and training of exposed workers.

Amendment 32

Proposal for a directive Annex 8 – paragraph 2

Text proposed by the Commission

Amendment

The data system for individual radiological monitoring established by a Member State may be realised either as a centralised national network or as a national dose register. These networks or registers ***may*** be supplemented by the issuance of individual radiological monitoring documents for every outside worker.

The data system for individual radiological monitoring established by a Member State may be realised either as a centralised national network or as a national dose register. These networks or registers ***should*** be supplemented by the issuance of individual radiological monitoring documents for every outside worker.

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	21.3.2013
Result of final vote	+: 40 -: 1 0: 2
Members present for the final vote	Regina Bastos, Edit Bauer, Heinz K. Becker, Jean-Luc Bennahmias, Phil Bennion, Vilija Blinkevičiūtė, Philippe Boulland, Alejandro Cercas, Ole Christensen, Derek Roland Clark, Minodora Cliveti, Marije Cornelissen, Emer Costello, Andrea Cozzolino, Frédéric Daerden, Karima Delli, Richard Falbr, Thomas Händel, Danuta Jazłowiecka, Martin Kastler, Ádám Kósa, Jean Lambert, Patrick Le Hyaric, Verónica Lope Fontagné, Olle Ludvigsson, Thomas Mann, Elisabeth Morin-Chartier, Csaba Óry, Siiri Oviir, Konstantinos Poupakis, Sylvana Rapti, Elisabeth Schroedter, Nicole Sinclaire, Jutta Steinruck
Substitute(s) present for the final vote	Georges Bach, Jürgen Creutzmann, Edite Estrela, Sergio Gutiérrez Prieto, Anthea McIntyre, Ria Oomen-Ruijten, Csaba Sógor
Substitute(s) under Rule 187(2) present for the final vote	Fiona Hall, Angelika Werthmann

RESULT OF FINAL VOTE IN COMMITTEE

Date adopted	4.7.2013
Result of final vote	+: 53 -: 0 0: 4
Members present for the final vote	Martina Anderson, Elena Oana Antonescu, Kriton Arsenis, Sophie Auconie, Paolo Bartolozzi, Lajos Bokros, Franco Bonanini, Nessa Childers, Chris Davies, Anne Delvaux, Bas Eickhout, Jill Evans, Karl-Heinz Florenz, Elisabetta Gardini, Gerben-Jan Gerbrandy, Matthias Groote, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Jolanta Emilia Hibner, Karin Kadenbach, Christa Kläß, Eija-Riitta Korhola, Jo Leinen, Corinne Lepage, Linda McAvan, Vladko Todorov Panayotov, Gilles Pargneaux, Antonyia Parvanova, Andrés Perelló Rodríguez, Mario Pirillo, Pavel Poc, Anna Rosbach, Oreste Rossi, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Theodoros Skylakakis, Bogusław Sonik, Claudiu Ciprian Tănăsescu, Thomas Ulmer, Anja Weisgerber, Glenis Willmott, Sabine Wils, Marina Yannakoudakis
Substitute(s) present for the final vote	Erik Bánki, Esther de Lange, Gaston Franco, James Nicholson, Alojz Peterle, Vittorio Prodi, Kārlis Šadurskis, Alda Sousa, Struan Stevenson, Marita Ulvskog, Vladimir Urutchev, Anna Záborská