Basic safety standards for protection against the dangers arising from exposure to ionising radiation

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The Committee on the Environment, Public Health and Food Safety adopted the report by Thomas ULMER (EPP, DE) on the proposal for a Council directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

The Committee on Employment and Social Affairs, exercising its powers as an associated committee under Rule 50 of the Rules of Procedure, was also consulted on this report.

Legal basis: Members propose a different legal basis to the one proposed by the Commission. They would like the proposal to be based on Article 192(1) the Treaty on the Functioning of the European Union, rather than Articles 31 and 32 of the Treaty establishing the European Atomic Energy Community

They also note:

- 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.

- Article 153 TFEU allows for the establishment of safety standards to protect the health of workers and of the general public.

- 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.

Purpose of the directive: the 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 Member States**. It 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.

Scope: the 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.

New provisions are introduced on : i) disposal of radioactive material and temporary or final radioactive waste storage; ii) practices exposing workers to cosmic radiation, including the operation of aircraft and spacecraft as well as frequent flying.

Members specify that **occupational exposure** means exposure of workers, including employees and self-employed as well as trainees and volunteers, incurred in the course of their work as well as **apprentices** aged 16 years or over

Interventional radiology: the proposal aims to cover interventional radiology within its scope, meaning 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. However, the Directive covers only high-dose radiological devices. This includes devices which employ a radiation dose higher than 100 Gy*cm².

Medical devices: in the area of medical exposure, Members propose to prevent duplication of work in connection with medical devices which give off ionising radiation, and considered 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.

With regard to **testing of medical equipment**, 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).

Protection of the environment against ionising radiation: the presence of radioactive substances in the environment has consequences for the health of the general public. In addition to direct environmental exposure pathways, the aim is to protect the environment as a whole, including the exposure of biota, within a comprehensive and coherent overall framework. However, **more resources should go to examining in detail the impact that ionising radiation has on both mankind and the environment**. Accordingly, Members deleted the corresponding provisions.

Minimum requirement: Members want Member States to 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 for damages**. For each of these principles, new provisions are added in order to limit as much as possible the risk of exposure.

On **reparation for damages**, Members require the establishment of a mechanism which guarantees reparation for all physical damage and personal injury likely to be caused by an emergency at the installation before authorising the construction of a nuclear installation or renewing its operating licence.

Consultation with workers: for occupational exposure, the dose constraint shall be established in consultation with workers' representatives.

Organisational measures to minimise the risk of exposure: similarly, Members propose to strengthen the provision enabling better regulation of the procedures regarding exposure for workers so as to minimize risk as much as possible. The text provides for other measures regarding training and organisation.

Information for the public: Members feel that the public should be better informed of the risks and doses to which it is exposed. The values chosen for the dose constraints must 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.

There are also provisions regarding informing the public in **emergency situations**. In such cases, Member States must publish 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

Member States must 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**.

Stakeholders: the committee requires that Member States 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. This type of provisions also applies to revision of the relevant legislation.

Penalties: the report states that 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.

Monitoring by Member States: there are new provisions strengthening the level of monitoring for non-medical imaging exposure. In addition, Member States must 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.

Stricter provisions: should a Member State plan to adopt standards stricter than those laid down by this Directive, it must inform the Commission and the other Member States accordingly.

Annexes: lastly, the committee amended the annexes to the proposal to correspond to the amendments in the body of the text.