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Perspectives / Perspectivas

Divergences between Portuguese and European Legislation on Radiological Protection of Pregnant and Lactating Women – Scientific Justification or Discrimination?

Divergências entre a Legislação Portuguesa e Europeia na Proteção Radiológica das Mulheres Grávidas e Lactantes - Justificação Científica ou Discriminação?

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Abstract

The legislation currently in force in Portugal, relating to the legal framework for the promotion of safety and health of workers at work, completely prohibits pregnant workers and workers who have recently given birth or are breastfeeding, regardless of the exposure level, from carrying out activities in which they may be exposed to ionizing radiation, contrary to other national and international legislation. as well as current scientific evidence. In fact, European diplomas relating to the radiological protection of workers, as well as related national diplomas, don't prevent the workers in question from continuing to work with ionizing radiation, despite paying special attention to the protection of the unborn child and requiring a rigorous risk analysis, with a clear definition of exposure limits. This work aims to present a historical perspective of European and national regulations and investigate the origin of this misalignment, also considering other legislative approaches and international practices, and highlighting the need to address and clarify the issue in our country.

Keywords

Radiation protection, Medical physics, Occupational exposure.

Resumo

A legislação atualmente em vigor em Portugal, relativa ao regime jurídico da promoção da segurança e saúde no trabalho, veda totalmente à trabalhadora grávida, puérpera ou lactante a realização de atividades em que possa estar exposta a radiações ionizantes, independentemente do nível de exposição, contrariando outros diplomas nacionais e internacionais, bem como todas a evidências científicas. De facto, os diplomas europeus relativos à proteção radiológica dos trabalhadores, bem como diplomas nacionais associados, não inviabilizam que as trabalhadoras em causa continuem a trabalhar num ambiente com radiação ionizante, não obstante terem especial atenção com a proteção do nascituro ou criança e exigirem uma análise rigorosa de riscos, com uma definição clara de limites de exposição. Com este trabalho pretende-se apresentar uma perspetiva histórica regulamentar europeia e nacional e investigar a origem deste desalinhamento, ponderando ainda acerca de outras abordagens legislativas e práticas internacionais, e destacando a necessidade da abordagem e clarificação do tema no nosso país.

Palavras-chave

Proteção radiológica, Física médica, Exposição ocupacional.

Context

The enormous medical benefits of ionizing radiation were recognized almost immediately after its discovery in the late 19th century by Wilhelm Röntgen in 1895.[1] The dangers and potential harmful effects of ionizing radiation also became obvious almost immediately, and in 1928, among other actions aimed at protecting the population against this new type of radiation, the ICRP (International X-Ray and Radiation Protection Committee in its original name) was established.[2]

Since then, at an international level, there has been exhaustive analysis and regulation in the field of radiological protection, with dose limits for exposed workers and the general public having long been established and periodically updated. In the particular case of pregnant workers and workers who have recently given birth or are breastfeeding (hereinafter referred to as PLW), special attention is paid to the protection of the unborn child or infant in international recommendations and, in particular, in European legislation, without preventing PLW from continuing to work in an environment with ionizing radiation, provided that a proper risk assessment is ensured and, if necessary, adjustments are made to the workplace to comply with the applicable limits.[3,4,5,16,23]

Contrary to this approach and also to national legislation relating to the legal framework for radiological protection (hereinafter referred to as RP), the legislation relating to the legal framework for the promotion of occupational safety and health (hereinafter referred to as OSH) currently in force in Portugal completely prohibits PLW from carrying out activities involving exposure to ionizing radiation.[5,6]

Through a non-exhaustive historical analysis of regulatory legislation relating to RP and OSH, we seek to determine the origin of the divergence in the national legislative approach to PLW. For time length reasons, we only consider a brief analysis of the Portuguese legislation in the pre-Community period (Figure 1) and, for the Community period we focus on the most relevant European and national legislation relating to PLW (Figure 2).

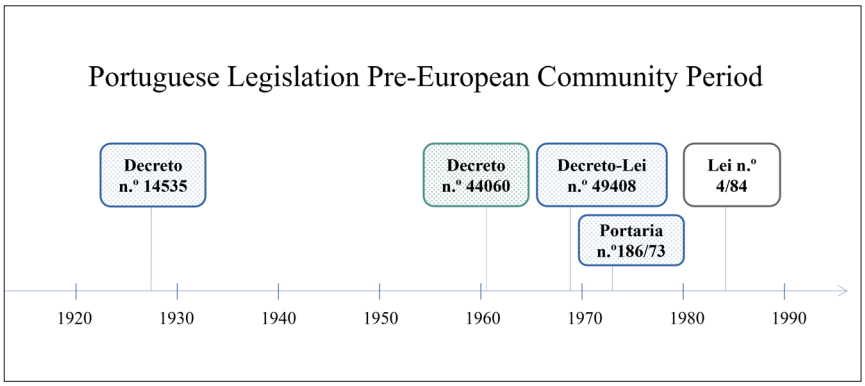

Figure 1 – Timeline of Portuguese legal diplomas relating to Occupational Safety and Health (in blue, already revoked), Radiological Protection (in green, already revoked) and Maternity and Paternity Protection (in grey) in the pre-Community period.

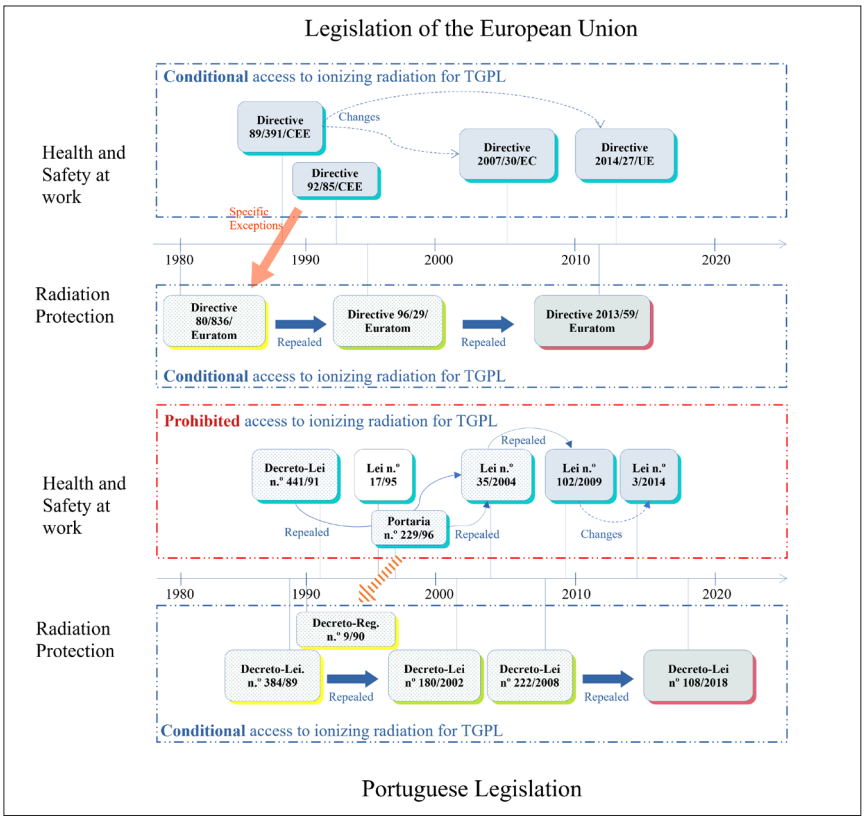

Figure 2 – Timeline of Community directives (above) and Portuguese legal acts (below) relating to Occupational Safety and Health (in blue; in the cases of revoked laws the box is shaded), Radiological Protection (in green; in the cases of revoked laws the box is shaded) and Maternity and Paternity Protection (in grey) during the Community period. The colored border shows the correlation between the European directives and the corresponding Portuguese legal instruments, which transpose them in whole or partially into the Portuguese legislation. In the particular case of the Euratom Directives, it should be noted that they derive from ICRP 26 (1977) (Directive 80/836/Euratom), ICPR 60 (1991) (Directive 96/29/Euratom) and ICRP 103 (2007) (Directive 2013/59/Euratom).

We then briefly address the international reality and specific cases when managing activities involving ionizing radiation for PLW. Finally, we make some considerations about the concerns that various groups have raised regarding the impact of these restrictions on PLW, as well as a brief conclusion.

Pre-Community period legislation

Labor Law had its origins in the protection of subordinate labor and there are records of this dating from the last years of the Monarchy.[7] During the First Republic, industrial work increased and the Government organized, for the first time, a hygiene, health and safety service in the workplace and legislated on the subject.[7]

During the Estado Novo, several restructurings were carried out in the organizations overseeing the Occupational Safety and Health (OSH) and associated formalities, and in 1927, through Decree No. 14535, a list of jobs prohibited to women was approved - a list that was kept in force by ministerial order of 15 September 1934.[7,8] Subsequent orders also established numerous prohibitions and constraints on women's access to certain professions, jobs or positions, with the prohibition (or limitation) of marriage for telephone operators, nurses, elementary school teachers and stewardesses for example.[8,10]

In 1961, this time in the field of RP, Decree-Law No. 44060 is worth mentioning as it dealt with the protection of people against ionizing radiation and defined for the first time the maximum admissible doses for people professionally exposed to such radiation, already considering the recommendations of the International Commission on Radiological Protection of 1958.[11] However, this diploma had no mention of PLW, perhaps because it was a prohibited activity, as the subsequent Ordinance No. 186/73 leads us to believe.[9]

In 1969, Decree Law No. 49408 approved a new legal regime for individual employment contracts which, although some of the previously mentioned limitations for women had already been overcome, continued to provide for the possibility of prohibiting or conditioning, by law or by means of an employment regulation order, women's access to certain activities in order to safeguard their health or morality or to protect their families.[12] Shortly afterwards, Ordinance No. 186/73 was published on the Regulation of Women's

Employment, highlighting the emergence of jobs whose risks affect women, particularly their "genetic function" and which make it imperative to reinforce the protection of maternity.[9] It is in this legal instrument that we find the explicit prohibition for women, during pregnancy and up to three months after giving birth, of "work that exposes them to ionizing radiation".[9]

In 1974, several changes occurred in the structure of the Portuguese Government, reflecting the social and political changes of the Revolution, but we could not find specific provisions relating to OSH and RP of the PLW.[7] Only in Law No. 4/84, which aims to protect maternity and paternity, is there an article relating to inadvisable tasks for the PLW, referring subsequent publication by the competent health central services of "the list of dangerous or toxic products, as well as environmental conditions harmful to health...".[13]

Legislation during the Community Period

When Portugal joined the European Economic Community (EEC) in 1985, a new stage in OSH emerged, particularly in the legislative field, with several new legal diplomas, some of which were already transposed from Community directives.[7] In 1989, Directive 89/391/EEC on the introduction of measures to encourage improvements in the OSH of workers, and in particular its ancillary directive, Directive 92/85/EEC, on the implementation of measures to encourage improvements in the OSH of PLW stood out.[3,14] The latter determines, in article no. 4, that for any activity likely to present a specific risk of exposure to agents, processes or working conditions to PPLW, the employer must assess all risks to safety and/or health, as well as the repercussions on pregnancy or breastfeeding, and determine the measures to be taken.[3] In Annex I, the referred Directive presents a non-exhaustive list of agents, processes and working conditions that must be assessed, among which are ionizing radiation, without ever classifying it as prohibited agents.[3] In fact, with regard to exposure to ionizing radiation, Directive 92/85/EEC refers to Directive 80/836/Euratom, which, in 1980, consolidated the basic safety standards for the health protection of the general public and workers against the dangers arising from ionizing radiation and established a dose limit to the fetus (applicable to pregnant workers) of 10 mSv from the declaration of pregnancy until the moment of delivery.[3,4] It should also be noted that Directive 89/391/EEC and its ancillary directives were subsequently amended in Directives 2007/30/EC and 2014/27/EU, but ionizing radiation remained a limiting agent and not prohibited to PLW.[14,15,16]

The Community directives on OSH were first transposed into national legislation in Decree-Law No. 441/91, which establishes the legal framework for occupational safety, hygiene and health, leaving the provisions on PLW to subsequent complementary legislation.[17] In 1995, with Law No. 17/95, the first amendment to Law No. 4/84 on the protection of maternity and paternity was registered and it established the obligation to prohibit PLW to exposure to agents and working conditions that endanger their safety or health, referring its determination to a subsequent joint order to be issued by the Ministers of Finance, Health and Employment and Social Security.[18] It was in 1996, with Ordinance No. 229/96, that the agents, processes and working conditions prohibited or limited to PLW were determined, defining in Annex II the radiation ionizing agents as physical agents prohibited to the PLW.[19] The aforementioned ordinance, which explicitly considers the transposition into Portuguese domestic law of Directive 92/85/EEC, reinforces that the new legislation for the protection of PLW in the workplace is based on the assessment of risks and the restriction or prohibition of performing certain activities, depending on the nature and degree of the existing risks, and recognizes that new scientific knowledge and technical means allow this adjustment, as well as elaborating on the limitations of the regulation determined by Ordinance No. 186/73.[3,9,19] However, contrary to the previous premises, Ordinance No. 229/96 maintains ionizing radiation on the list of physical agents prohibited to PLW, keeping in place, perhaps intentionally, normative and legislative practices of the past.[19]

In fact, at the date of publication of this ordinance, the guidelines of Directive 80/836/Euratom had already been transposed into national legislation in Decree-Law No. 348/89, which defines standards and directives for protection from ionizing radiation, and Regulatory Decree No. 9/90, which establishes the respective regulation, defining the dose limit to the fetus (applicable to pregnant workers) as 10 mSv from the declaration of pregnancy until the moment of delivery foreseen in the Directive.[4,20,21]

At Community level, also in 1996, Directive 96/29/Euratom was issued, revoking the previous Directive 80/836/Euratom within the scope of RP, revising the limit of equivalent dose received by the fetus (applicable to pregnant workers) to 1 mSv since the declaration of pregnancy to delivery and prohibiting breastfeeding women from performing jobs involving a significant risk of radioactive contamination of the body, but still failing to identify ionizing radiation as an agent prohibited to PLW.[4,22] These specific provisions for PLW were transposed into national legislation in Decree-Law No. 222/2008 and remain in force to this day, both at European level, in the subsequent Directive 2013/59/Euratom (in its latest amended version), and in Portuguese legislation, in Decree-Law No. 108/2018 (in its latest amended version).[23,24,25]

In 2004, Law No. 35/2004, which regulates the law approving the Labor Code and revoking Ordinance No. 229/96, incorporates the conditioned and prohibited activities to PLW without any changes regarding ionizing radiation (they remain as a prohibited physical agent for PLW).[26] New legislation appears at Community level, as mentioned above, with transposition into national legislation through Law No. 102/2009, but once again ionizing radiation appears as a prohibited agent.[27]

International legislation and specific cases

At an international level and in a transversal manner, we find the definition of specific dose limits for ionizing radiation for PLW in legal frameworks, despite some variability in the exposure limit value - from 1 mSv in Europe and Australia, to 4 mSv in Canada and 5 mSv in the United States.[24,28,29,30]

Specifically in the European Union, and despite the common regulatory framework, we find reference to different practical approaches in some specific cases depending on the risk involved. In urology procedures performed using ionizing radiation (fluoroscopy, where the doses received by workers can be significant), we register for PLW: i) The prohibition of presence in such procedures in Austria, Italy, Spain and Poland; ii) Optional presence, left to the discretion of the worker, in Germany (weekly monitoring of the dose to the fetus), the Netherlands, Norway and the United Kingdom; iii) No prohibition in the case of Belgium and Greece; we can possibly infer that the approach regarding other

procedures of increased risk using ionizing radiation will be similar in each country.[31] Specifically in Spain, the most recent ministerial recommendations prohibit the presence of PLW in surgical procedures using fluoroscopy, procedures in operating rooms and examinations performed with Portable X-ray units.[32]

In Portugal, in the National Occupational Health Program of the Directorate-General of Health, in the 2017 frequently asked questions, it is suggested that "… the activities prohibited or subject to limitation for pregnant workers, as indicated in Law No. 102/2009 of 10 September and its amendments, must be interpreted taking into account the legal limits admissible for the different agents, whenever these are present, as it is the case with ionizing radiation. Pregnant workers, in particular, are prohibited from being exposed to ionizing radiation "when the potential exposure is higher than the dose limit values established for the general public", but this understanding is not transversal.[33] In fact, the legal framework in force raises doubts and uncertainties and results in a heterogeneity of practices regarding the management of PLW activities which, in most of the cases we are aware of, leads to the adjustment of the workplace and the prohibition of their presence in controlled and supervised areas, even if unjustifiably and, possibly, against the will of the worker. One example is the relocation, in a radiology department, of a pregnant or breastfeeding radiographer from a job where exposure is practically zero (e.g. mammography) to a fixed job in magnetic resonance imaging, with inherent exposure to non-ionizing radiation and high magnetic fields (where the risk is also considered insignificant but where there is real exposure to electromagnetic fields of significant energy). And while in the case of pregnant workers it is always possible to consider the probability, even if insignificant, of an hypothetical negative impact on the fetus, in the case of external exposure for breastfeeding workers, this risk is physical and radiobiologically non-existent, although both situations are treated identically by law and, inherently, also often in practice.

Prohibition or Restriction?

With a growing number of women in the health field, the topic of protection and restrictions on PLW arises more and more frequently and has received special attention in different groups, particularly in medical-surgical specialties.

Several publications highlight the impact that this type of prohibition or unfounded restrictions, without scientific evidence to support them, could have on a worker's career choice and question whether this type of approach could not configure negative discrimination (not hiring women of childbearing age, with a consequent impact on their professional classification, training and professional promotion, and also salary; unjustified and unwanted job reallocation) for PLW.[28,31,32]

In fact, it is important to emphasize that at an international level, the definition of constraints based on the risk of the practice in question is transversal, but not the absolute prohibition of exposure to ionizing radiation. Multiple scientific evidence supports the feasibility of PLW being able to carry out various procedures and activities with controlled exposure to ionizing radiation without incurring significant risks to the fetus, as long as careful planning, understanding of the risks and adoption of appropriate measures to minimize the radiation dose are ensured.[2,28,31,34]

Conclusion

From the analysis carried out, we consider that the current legislation on the legal framework for the promotion of occupational safety and health is too restrictive in view of international standards, European guidelines and other national legislation, as well as the most recent scientific evidence, possibly transposing practices and points of view from the past. In other words, it is not consistent with European and international standards and can be seen as excessive protection that harms the worker instead of benefiting her.

It is therefore urgent to review legislation at the level of OSH that effectively integrates the radiological protection guidelines into the framework of the protection of occupational health and safety of pregnant, postpartum and lactating workers, already present in the Portuguese legislation, ensuring uniformity of practices in their protection and contributing to the dissemination of the best scientific evidence in the field and gender equality in the workplace.

Ethical Disclosures / Divulgações Éticas

Conflicts of interest: The authors have no conflicts of interest to declare.

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Protection of human and animal subjects: The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Protecção de pessoas e animais: Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pelos responsáveis da Comissão de Investigação Clínica e Ética e de acordo com a Declaração de Helsínquia da Associação Médica Mundial.

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