

# **GAMMA RADIATION FOR IMPROVEMENTS IN FOOD INDUSTRY, ENVIRONMENTAL QUALITY AND HEALTHCARE**

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*Abstract.* Recently published studies on the benefic applications of gamma radiation upon the environmental components, either natural or artificial ones, were summarized and discussed. Gamma irradiation is highly effective for inactivating or killing the microorganisms from various foods for microbiological safety ensuring, representing a properly method for sterilization; also radiation can induce chemical transformation of molecular compounds identified as most common pollutants of environment. This review is focused on the main beneficial applications of gamma radiation such as bioburden reduction, package medical materials, sterilization of pharmaceuticals and decomposing of toxic molecular substances from wastewater. Furthermore, administrative aspects related to risks and benefits of gamma irradiation were underlined.

*Key words:* gamma irradiation, sterilization, food, wastewater.

## **INTRODUCTION**

Gamma irradiation is known as a very widespread application of nuclear technology for peaceful purposes, like physical agent of sterilization or decontamination due to the deep penetration power and low dose rate, with high efficiency in killing microorganisms by breaking the covalent bonds of bacterial DNA and viruses [70, 72, 74]. Gamma radiation has been regarded as a safe, cost-competitive methodology for the sterilization of healthcare products, extension of shelf-life quality improvement, and reduction of bioburden in food products. Furthermore, exposure to gamma radiation can provide possible solutions for the treatment of contaminated waters (municipal, industrial wastewaters) aiming at the improvement of their chemical and biological quality. Although there are various different sterilization methods correlated with the purpose of sterilization and the

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material that will be sterilized [70], there are some common practical features in using of gamma radiation including: precise dosing, rapid processing, uniform dose distribution, system flexibility, dosimetric release, the immediate availability of product after processing [25, 52].

Water is known as an ubiquitous solvent highly beneficial for the living world, but when it is subjected to ionizing radiation in the presence of oxygen it produces highly reactive oxygen species (ROS) able to induce chemical instability further responsible for organic compound destruction with molecular fragments release. The schematic representation of the process can be seen in Fig. 1 where these short-lived radicals drive both oxidation and reduction reactions both at the same time [32].

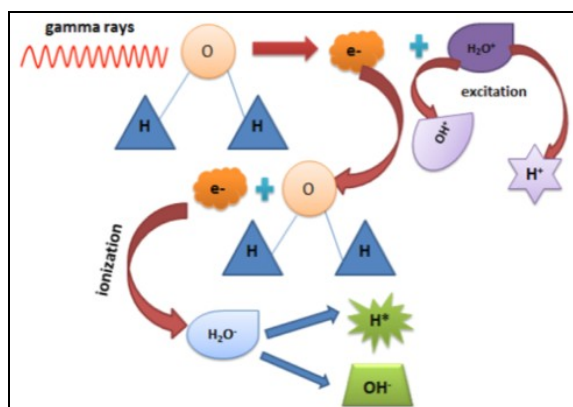


Fig. 1. Effect of gamma rays on water molecules (modified after Kátia Aparecida da Silva Aquino[18]).

This study will present and discuss the main applications of gamma irradiation in quality improvement of human life, and also few advantages and disadvantages of this method.

### THE MAIN APPLICATIONS OF GAMMA RAYS IN FOOD INDUSTRY

During past years innumerable studies on the main bio-effects of gamma radiation have been carried out with increased extent of those dedicated to environment and human nutrition sources.

Food irradiation consists in exposing food products to well established doses of ionizing radiation aiming to induce molecular changes in the microbial cell load. When the absorbed radiation energy breaks down the bonds in DNA molecules of

microorganisms which are present in the food and inactivates certain enzymes then their degrading action upon food products is much reduced. Not only microorganisms are inactivated or killed, but also parasite insect gametes are prevented from reproducing, leading to different preservative effects of food as a function of the absorbed radiation dose [23]; in frozen or fresh foods it takes larger radiation dose to kill microbes in the irradiated batches.

#### THE POSITIVE EFFECT OF IRRADIATION ON SHELF LIFE EXTENSION OF FRUITS

One of the main achievements in this field is that after irradiation of the fresh-cut fruits, microbiological and chemical changes occur which determine the extent of shelf-life, *i.e.* the period of time when the food product preserves acceptable quality for consumption. For example, Majeed has studied this aspect in some of the most appreciated, but also very perishable fruits all over the world: the strawberry (*Fragaria x ananassa*); exposure of strawberry batches to different radiation doses (0.5, 1.0 and 1.5 kGy) [33] resulted in considerable improvement of shelf-life from about three days to almost eight days for 1.5 kGy – which led to important material advantages for both consumers and distributors; also focus on fruits preserving, the authors of [62] succeeded shelf-life extension of citrus fruits and Shantag mandarin after radiation exposure from 0.2 up to 0.6 kGy; fruit juice was also found to improve its life time without changing the chemical properties as shown by Cheorun Jo *et al.* [14].

The shelf life of pre-climacteric mangoes fruits was found to be extended following low dose of gamma irradiation for 8–10 days at maximum dose 0.2 kGy; the irradiation was carried out under ambient storage conditions during 5–6 days [29].

Zaman *et al.* [61] investigated the shelf life extension of bananas with gamma irradiation method. The samples were irradiated with three doses 0.3 kGy, 0.4 kGy and 0.5 kGy, then stored in a dry place at ambient condition. The shelf life was found to be extended by 20 days in irradiated fruits compared to control ones, and more delaying ripening was obtained.

Wani *et al.* [58] studied the effects of gamma irradiation on pears for shelf life extension. Mature pears were irradiated with different doses (0.8–2.0 kGy) and stored at room temperature. After irradiation, it was found a significantly inhibited decay of pears up to 16 days, for 1.5–1.7 kGy applied doses.

Singh and Pal [48] found that the effect of 0.25 kGy dose gamma rays increased the postharvest life in guava fruit by 3–4 days. Ionizing radiation effects on shelf-life of fresh fruits are recapitulated in Table 1.

Table 1

Shelf life extension of irradiated fresh-fruits

Product	Radiation dose	Storage period/temp	Quality attributes	Shelf-life extension
Strawberry <i>Fragaria x ananassa</i>	1.0 and 1.5 kGy	3 days	growth inhibition of moulds, <i>Rhizopus</i> spp. and other spoilage fungi [33]	5.75 and 7.75 days
Fruit juices	5 kGy	7 days	2 decimal reductions in the microbial level [14]	
Mango	0.05–0.3 kGy	28–32°C	Delayed ripening, as indicated by higher retention of fruit color and reduction of physiological weight loss [29]	8–10 days
Bananas	0.30, 0.40 and 0.50 kGy	Dry place	Chemical constituents of the irradiated bananas were the same and no major changes were observed in the nutritional and organoleptic qualities except for a minor change in the ascorbic acid content [61]	20 days
Pears	1.5–1.7 kGy	(37±1°C, RH 80%)	delayed the physiological processes and inhibited microbial proliferation which resulted in delayed decaying of pears [58]	16 days
Guava fruits	0.25, 0.5, 1 kGy		maintained fruit quality, and reduced the decay incidence [48]	3–4 days

The control of spoilage microorganisms helps in increasing of shelf life of fresh produce. It was observed that radiation doses around 0.2–0.8 kGy could lead to a 1-log reduction in bacterial pathogens of fresh fruits. On the other way, fungi and pathogenic viruses are more resistant to radiation and require between 1–3 kGy completing 1-log reduction [41].

Furthermore, multiple studies have investigated that low doses of irradiation (up to 1 kGy) extend significantly the shelf life of fresh vegetables by inactivating the spoilage microorganisms and by inhibiting ripening technique [21].

#### BIOBURDEN REDUCTION IN FOOD PRODUCTS

Various germs are found sometimes in many natural and fabricated products such as *Escherichia coli* which is also part of human body microflora but can cause hemorrhagic diarrhea and hemolytic uremic syndrome when exceeding critical threshold; more dangerously, pathogenic bacteria species like *Campylobacter*, *Listeria*, *Salmonella*, *Shigella*, and *Staphylococcus* can be often found in many foods [53]; this is why microorganism inactivation by irradiation represents an

important alternative for limiting microbial loading with germs known to be harmful for human's health especially when thermal inactivation – or pasteurization – is not appropriate.

Feasible microbiological assay methods were applied to analyze food quality parameters of raw meat ball by I. Yildirim *et al.* [60] after gamma irradiation; bacteria as *Salmonella*, *Escherichia coli*, *Staphylococcus* were identified and counted in the gamma irradiated samples (2, 4, and 7 kGy) and non-irradiated controls; for 2 kGy dose the inactivation of *E. coli* was revealed, the 4 kGy dose was sufficient to eliminate the *Staphylococcus* bacteria and, furthermore, for the 7 kGy exposure, the ensuring of the microbiological safety of the food without changing the composition was noticed.

Also, microbiological qualities and color effects of red paprika were investigated – due to very appreciated nutritional content and spice properties [46]; following radiation exposure ranging between 0 and 12.5 kGy, microorganisms like *Enterobacteriaceae*, coliforms, sulfite-reducing clostridia, molds, and yeasts were found quantitatively diminished. Although molds, yeasts, and sulfite-reducing clostridia are known as the most resistant species, a 10 kGy dose of radiation leads to optimum decontamination even in their case with no significant changes in color properties in comparison to non-irradiated control, the results legitimating gamma irradiation as a proper procedure for minimization of the bioburden in this vegetable.

As well it was reported that radiation exposure could inactivate other parasites in meats and fish; it can reduce insect contamination of dried spices and grains as well as that of vegetables and fresh fruits resulting in shelf life prolong [55].

M. Arici *et al.* [4] studied the effects of gamma rays on oil properties in black cumin sample, reporting dose-effect response after irradiation with 2.5, 6, 8 and 10 kGy at the level of quantitative microbial loading.

#### RADIORESISTANCE OF VITAMINS AND ANTIOXIDANT

Special attention was paid to radiation effects on physical and chemical parameters of active biological compounds like vitamins from food products like bread, cereals and cookies. These products contain sources of vitamin E which is an essential compound in human nutrition; sources of vitamin E are extracted from oils, seeds, nuts and cereal grains [49, 73]; it is known as a main antioxidant which can be found together with vitamin A and C and minerals [59]. All antioxidants have an important role in preventing some very concerning diseases such as Alzheimer and cancer [63]. The effects of gamma irradiation on the vitamin E from

sunflower grain cookies were analyzed in [51] where after irradiation with 3 kGy dose no loss of vitamin E content was evidenced, which can show that gamma radiation is not harmful for these vitamins.

The influence of irradiation on antioxidants activity from spices and herbs was investigated in some studies. Murcia *et al.* [40] studied the antioxidant properties of seven dessert spices (anise, ginger, cinnamon, mint and nutmeg) reporting that in irradiated spices at 1, 3, 5 and 10 kGy no real changes in antioxidant activity were evidenced. Also, the antioxidant activity in anise, cumin and fennel essential oils extracted from the non-irradiated and gamma exposed samples were investigated in Farag and Khawas' paper [22]; they found that the irradiation of 10 kGy had no effect on antioxidant property of the essential oils. Calucci *et al.* [12] have studied the free radical formation and antioxidant contents of nine spices and aromatic herbs (black pepper, cinnamon, oregano, sage, rosemary, bird pepper, nutmeg, parsley and basil). After irradiation the increase of quinone radical content (which was assayed by electron paramagnetic resonance spectroscopy) was found in all samples. In some spices a decrease of the carotenoids content and total ascorbate was observed.

#### QUALITY IMPROVEMENT

According to FDA authority (Food and Drug Administration) [38] low dose range (< 2 kGy) is recommended for the spoilage of vegetables and fruits, the medium doses around 1 and 10 kGy are useful for removing the pathogenic bacteria and last but not least the higher doses (>10 kGy) can be used for the sterilization of products.

Vanamala *et al.* [56] have studied the impact of gamma radiation on quality of grapefruits. The samples were exposed to 0, 0.15 and 0.3 kGy gamma ray doses and then stored at 10 °C for 36 days, followed by additional 20 days storage at 20 °C. The results suggest that low-dose irradiation at 0.3 kGy did not have deleterious effects on the quality but enhanced or maintained the flavonoid concentration in the pulp during storage. Furthermore the irradiation at 0.3 kGy can be a viable quarantine treatment for grapefruit as it causes insignificant damage to the quality of grapefruit.

In [57], a study is reported on dehydration characteristics and quality of apples (Fuji apple) irradiated with gamma rays. As a result, they found that the vitamin C content of apples, the dehydration rate, and the rehydration ratio were significantly changed by applied radiation doses (1.5, 4.5, 5, and 6 kGy); it was concluded that the greater the dose, the higher the dehydration rate, the less the vitamin C content, and the lower the rehydration ratio.

Singh and Pal [48] studied the effects of ionizing radiation on improvement of physiological responses, storage time and quality of fruits. It was found that

irradiation can retard the process of fruit ripening due to the suppressed respiration and ethylene production rates. Furthermore, the biochemical and physical changes were retarded, correlated with ripening, for instance, soluble solids content, firmness, titratable acidity.

From historical viewpoint the application of ionizing radiation for food preservation began in 1920 and the interest in this technique has continuously grown ever since. Due to its proved efficacy it became an interesting perspective worldwide. According to Tamikazu [52], every year statistics for commercial products irradiation are published by the European Commission (Table 2).

Table 2

Quantities of irradiated food in Europe (adapted and simplified from Tamikazu Kume *et al.*) [52]

Country	Quantity (tons)		
	2005	2010	
Belgium	7.279	5.840	Frog legs, poultry, herb and spices, fish and shellfish, meat
Germany	472	127	Dried aromatic herbs, spices and vegetable seasoning
France	3.111	1.024	Frozen frog legs, poultry, gum arabic, herbs, spices and dried vegetables
Netherlands	3.299	1.539	Dehydrated vegetables, frog parts, spices, herbs, egg white, shrimps, poultry meat, others
Romania		17	Dried aromatic herbs

From all the above data, the decreasing of irradiation as biotechnological method of food preservation was noticed since 2005.

The Food Drug Administration (FDA) established a protective step on regulation of food irradiation compared with the rest of the world legislation, allowing doses only up to 1 kGy to be approved without toxicological tests. FDA deduced that each food irradiated up to 1 kGy dose or foods comprising no more than 0.01% of the daily irradiated up to 50 kGy dose are safe for human consumption [39]. Although, questions and uncertainties will remain concerning the food irradiation. The technology of food irradiation is the most intensely studied of all food processing [6]. The large scale of application of food irradiation would necessitate construction of irradiation facilities worldwide. The benefits and risks involved in this technology must be debated. Health care professionals should participate in the subject, so careful monitoring and continuous evaluation of all the food irradiation are prudent precautions [17].

## WASTEWATER STERILIZATION

Nowadays, because of the increasing pollutant levels in biosphere, the majority of scientists are facing the imperative need of wastewater monitoring. Since such waters have high concentration of toxic organic compounds – while natural water itself is a limited resource – the goal of wastewater treatment is to achieve improvements in the quality for eventual re-usage. Wastewater can originate from many activities, as it can be observed in Fig. 2, either municipal or agricultural and industrial processes [71], but the main issue concerns non-biodegradable chemical compounds most often originating from industry and agriculture.

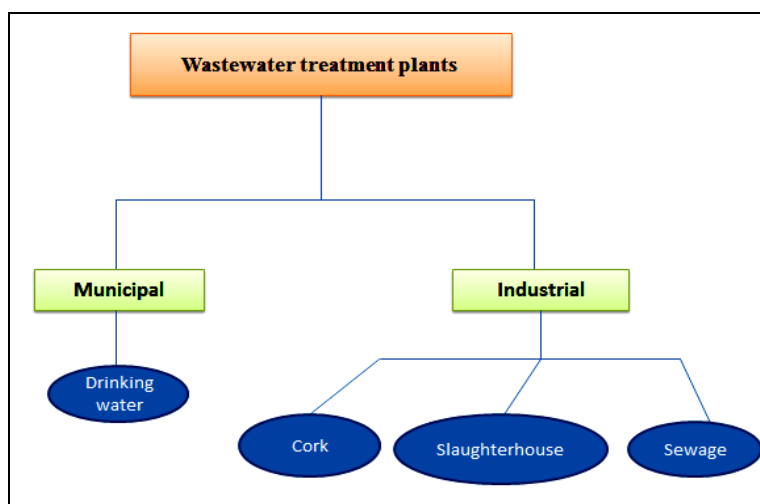


Fig. 2. Wastewater sampling places; modified after [9].

Biological wastewater treatment as a commonly biotechnological method is based on different types of cultivated microorganisms that are used in water processing and cleaning being an important part of wastewater treatment plants [66] while radiation exposure is developing also as an alternative method to diminish water pollution level.

## DRINKING WATER TREATMENT

The discharge of industrial effluents, sewage and sludge into environmental waters is responsible for infection risks, health effects caused by contaminated drinking water and offensive odors. In addition to disinfection there is an



increasing problem with the presence of toxic chemicals in water sources. Groundwater or surface waters are known as possible drinking water sources. The most common process used in the water disinfection has been the use of chlorine which leads to the formation of chemicals known as disinfection by-products. These disinfection by-products can be carcinogenic or have other toxicological effects associated with consumption. Besides chlorine, which has some disadvantage in the formation of by-products that have adverse health effects, another option is the use of gamma rays to destroy these by-products [75].

In [75] it was shown that the irradiation processing with gamma rays is efficient in the treatment and disinfection of microbiologically contaminated drinking water supplies. A radiation dose of 1 kGy was found to be optimal in controlling the microbiological content of raw drinking waters containing up to 1000 *E.coli* per 100 ml of sample.

According to [71], Myun-Joo Lee *et al.* have investigated the decomposition of chlorinated ethylenes and the behavior of the by-products which can be completely decomposed by gamma-rays or electron-beam irradiation. The radioactivity of the gamma source was around 100,000 Ci. They observed that the radiation treatment of chlorination by-products in the presence of O<sub>3</sub> removed the pollutants by nearly 100% [71].

#### CORK WASTEWATER

Cork is a product extracted from the trunk of *Quercus suber* L. (the botanical name for a slow growing oak tree) and it is the bark of the oak which, depending on the region, is periodically extracted in 9–12 years in order to produce a cork with a desirable thickness for industrial processing; it takes at least 25 years for a new tree to become profitable. The main country which is working on industrial cork wastewater, world-leading producer and exporter of cork is Portugal with about 70% of all the cork production in the world [73].

Biodegradation is viewed as a sustainable process of wastewater treatment, which under appropriate conditions, can promote an efficient reduction of the organic matter content with minimal energy requirements and, therefore, low costs [20].

For example, the study of acetovanillone, a toxic by-product of lignin which is one of the main components of cork industry wastewater was carried out by Rita Melo and her team [35]; acetovanillone solutions were gamma irradiated at five dose rates: 2, 5, 10, 20, and 50 kGy. They identified the degradation rate of acetovanillone and the main by-products as results of radiation action – an

advanced oxidation process. The scientists established that solution concentration affects acetovanillone radiolytic degradation: for 20 kGy dose, acetovanillone appears to be completely degraded in the low concentration solutions (0.1 mmol/dm<sup>3</sup>) while in higher concentration solutions (10 mmol/dm<sup>3</sup>) acetovanillone was still detected even following the action of maximum absorbed doses (50 kGy) [35, 42].

Another study that demonstrated the biodegradability of wastewater is the work of R. Melo *et al.* [35], where they tried to find out if radiolytic degradation based on gamma irradiation and followed by microbial degradation of gallic acid and esculetin – as models for phenolics, could increase the treatment efficiency of wastewater. Cork wastewater samples were irradiated at 9 kGy while for the radiolytic degradation of tested phenols samples were also irradiated with the dose rate of 2.5 kGy/h. The environmental microorganism strain selected from cork wastewater, biochemically identified as *S. maltophilia*, was not capable to degrade either gallic acid or esculetin (irradiated and nonirradiated) as sole carbon source. More, gallic acid irradiated solutions were found to have a lower biodegradability than non-irradiated solution [36]. Searching for molecular basis of wastewater processing by above mentioned procedures Dias-Machado *et al.* [20] demonstrated Fenton reactions role in gallic acid biodegradability.

Another interesting study is that of Gloria S.M.B. de Souza and her team [50] that investigated the inactivation of *Ascaris lumbricoides* eggs in domestic effluents by using gamma radiation from a <sup>60</sup>Co source. *A. lumbricoides* eggs are the most widely spread parasitic contaminants of wastewaters that are most resistant to adverse environmental changes. The bioeffects of 0.5 to 5 kGy suggest that gamma radiation affects the biomolecules and organelles of *A. lumbricoides* eggs, disturbing protein production [50] thus reducing the proliferation risk.

#### SLAUGHTERHOUSES WASTEWATER

Slaughterhouses generate large wastewater volumes and are very harmful to the environment [34]. One of the major pollutants dispersed in slaughterhouse wastewater is blood which degrades with difficulty being also accompanied by aliquots of fat, grease, hair, feathers, flesh, manure, grit, and undigested. Considering the strict legislation and control to protect health and the environment, precise and accurate tasks should be established to overcome this situation, including remediation [11] through new and detailed investigations that should be carried out to ensure the reuse of water [37].

R. Melo *et al.* investigated the impact of gamma radiation at a low dose rate, on slaughterhouse wastewater. Samples of slaughterhouse wastewater were irradiated with gamma rays at different doses from 7 up to 25 kGy [37]. It was

observed the decrease of some water parameters like COD (Chemical Oxygen Demand), BOD (Biochemical Oxygen Demand) and color – especially for high absorbed doses; the microbiological data sustained the BOD measurement ones so that all results highlighted the potential of this technology for wastewater treatment.

A huge amount of water is consumed in several stages to get finished products in the textile processing plant based on organic dyes which can set severe ecological problems [3]. The wastewater generated in textile processing plants is specifically contaminated with toxic synthetic colorants and various perilous chemicals with long degradation times in the environment since color of the textile wastewater is not removed efficiently by using typical techniques such as adsorption, coagulation, filtration and sedimentation [43, 44].

#### SEWAGE WASTEWATER

The advantages of wastewater and sewage sludge irradiation results from the method availability, with no additional chemicals involving, with no residual material yielded, with efficacy also on recalcitrant materials that can be degraded by indirect radiation action since hydroxyl radicals are easily yielded by water irradiation [8, 45].

Chu L. *et al.* reported the response of sewage sludge exposed to  $^{60}\text{Co}$  gamma irradiation at doses up to 25 kGy. The effects consisted in disintegration of sludge flocs and release of proteins, polysaccharides and extracellular enzymes into the bulk solution [16]; the microbial activity of cultivated bacteria in irradiated sludge gradually decreased with almost 91% at a dose of 5 kGy while 99% were inactivated at a dose of 25 kGy.

Rahman Bhuiyan M.A. *et al.* [43] presented a method for reducing the amount of freshwater used in the textile industry, by re-using of gamma irradiated textile wastewater. The samples were irradiated at different doses between 3–12 kGy. After irradiation the authors observed the diminution of pH value from 9 to nearly neutral 7–7.5, and color reduction percentage of 57–90%. The water can be used as freshwater in the scouring-bleaching stage of cotton fabric.

Jinho J. *et al.* [30] have investigated the influence of gamma-rays on sewage treatment plant. For the dose 15 kGy, it was found that the radiation treatment reduced BOD by 85% irrespective of absorbed dose, and the removals of COD, TOC and color were up to 64%, 34% and 88%, respectively. The microorganisms were effectively disinfected and completely removed at a dose of 0.3 kGy. The combination of gamma-rays and titanium dioxide significantly improved the treatment process. Furthermore the use of gamma rays on samples increased the COD, TOC and color removals were 40%, 10% and 20%. The increase was partly caused by the increase of hydroxyl radicals in the presence of titanium dioxide according to EPR and the spin-trapping method.

Some studies were focused on the effects of gamma-ray treatment on the biodegradability and toxicity of wastewaters from each unit process of a textile wastewater treatment plant to optimize textile wastewater treatment process [27]. After investigation the conclusion was that gamma-irradiation did not improve either the biodegradability of the raw wastewater or the wastewater after coagulation and flocculation, but it increased the biodegradability of the final effluent from 0.008 to 0.17 at a dose of 20 kGy. Another result was that gamma-rays improved the biodegradability of weight-loss wastewater from 0.72 to 0.91 at a specific dose of 1 kGy. It was done an acute toxicity test, which showed that the toxicity change induced by gamma-rays was dependent on the chemical properties of the wastewater.

#### **HEALTH CARE: STERILIZATION OF PHARMACEUTICALS AND MEDICAL SUPPLIES**

Radiation processing became a common treatment technique for the sterilization of medical devices, packages, and pharmaceuticals.

Gamma, electron beams, X-rays and hot steams are the main sterilization procedures used in biomedical object technology; all are safe and effective technologies for sterilization of medical products, having their own advantages and disadvantages. Radiation sterilization is a procedure which inactivates the microorganisms leading to microbial death or chemical reactions.

According to IAEA the value of sterile medical devices is estimated around €1000 million used in Europe [75]. Approximately 50% are sterilized by ionizing radiation. For radiation sterilization processing two complementary factors are involved: exposure to gamma rays from Cobalt-60 radioisotope and to accelerated electron beam.

It is well known that in medical field, the sterilization of medical devices is required and worldwide used but gamma sterilization can have a negative effect on polymer materials irradiation. Mostly plastics used for packages are: polyethylene (PE), polypropylene (PP), and polystyrene (PS). The topic concerning the polymers irradiation is largely discussed in many scientific articles and reports [13, 16, 17, 64].

Two pathways by which the effects of ionizing irradiation on polymeric materials can be explained: one could be the cross-linking where the polymer molecular weight increases and oppositely the chain scission – when molecular weight decreases. Gamma sterilization in the presence of oxygen can induce oxidation of polyethylene [5]. After gamma radiation gets in contact with oxygen

free radicals are formed leading to the deterioration of the material properties. According to IAEA, most natural polymers undergo degradation in cellulose, which shows a chain scission when it is irradiated. This fact is leading to the loss of evident mechanical properties [64].

Demertzis *et al.* [19] investigate the response of various polymer materials used in medical supplies packaging to radiation exposure: polyethylene (PE), polypropylene (PP), poly(ethylene terephthalate) (PET), polyamide (PA), polystyrene (PS), and poly(vinyl chloride) (PVC) irradiated with 44 kGy dose. After irradiation, it has been observed an increase of low volatile compounds in PE and PP. Also, the other packaging materials such as PET, PS and PA did not show any changes in their amount of solvent extractable compounds after 44 kGy irradiation. The result shows that PVC packaging material is not resistant to irradiation treatment at all. For general packaging legislative requirements and consumer protection for irradiated packaging materials, it is more and more important to evaluate the compositional changes of polymers during irradiation.

Komolprasert *et al.* [31], studied the effect of 10 and 20 kGy gamma irradiation on specific colorants (chromophthal yellow and irgalite blue) which were added to polystyrene (PS) material; the experimental data shows that irradiation did not generate any new chemicals compounds in the PS polymer.

In the FDA document 21CFR 179.45, Subpart C (USFDA, 2001) a list of approved packaging materials with gamma irradiation up to 10 kGy can be found.

Largely recognized and applied reference standards from USP (United State Pharmacopoeia) 30, BP (British Pharmacopoeia) and EP 5 (European Pharmacopoeia) have stated the industrial sterilization method and gave the definition of the sterilization of pharmaceuticals by gamma radiation [65, 69, 76].

Pharmaceutical products cover a variety of materials (*e.g.*, containers, closures, excipients) and processes. The following sections investigate the effect of gamma irradiation as a sterilization process on some pharmaceutical products [26].

Usually, solid-state systems show lower loss of activity after ionizing radiation supply than other systems, but in the case of aqueous solutions and suspensions of various organic compounds the use of radiation sterilization is not possible because of water radiolysis and its well-known biochemical consequences [1].

Jacobs [28] reported an investigation study of irradiation ampicillin and its esters at 25 and 50 kGy doses; the microbiological and chemical properties of ampicillin sodium, pivampicilin and talampicilin were examined and some changes in the drug radiolysis products were observed; it was concluded that only low doses must be used for decontamination.

Gopal reported [24] that the proteolytic activity of papain enzyme decreased with the increase in irradiation doses when the activity was assayed after 18 and 30 kGy.

Benchaabane H.S. *et al.* [7] found that the antibacterial drug sulphathiazole can be sterilized by 10 kGy irradiation dose. This comparative study was carried out by using physical, chemical, biological and microbiological assays; based on result arrays provided by all measurements carried out on sulphathiazole powder and its ophthalmic solutions following irradiation at different doses: 10, 25 and 40 kGy, the optimum radiation dose of 10 kGy was established for sterilization.

Sterilization of insulin by gamma rays *versus* accelerated electron beam was studied. The degradation of irradiated human insulin in aqueous solutions under the influence of the drug concentration, excipients and irradiation temperature has been analyzed in order to find how to protect the hypoglycemic protein hormone against ionizing radiation harmful effects during radiation sterilization. It was observed the loss of activity of insulin without radio-protector excipients irradiated at room temperature at doses of 10 kGy, when the pharmaceutical product was nearly destroyed. Radioprotector effects as well as irradiation temperature lowering were found efficient; ascorbic acid in aqueous solution and oxidized glutathione in frozen solution were found as the best degradation blocking agent caused by irradiation – enabling the fulfilling of corresponding European Pharmacopoeia standards [54].

### ADVANTAGES AND DISADVANTAGES

Gamma irradiation applications in human daily life present several evident advantages. The main one is related to useful materials sterilization: achieved due to the depth of gamma photon penetration which allows the sterilization of materials with different density levels.

Also, package material can be sterilized successfully because there is no risk for diffusion of sterilizing agent like in the case of sterilization with ethylene oxide.

Furthermore, the method based on gamma irradiation has a high SAL (Sterility Assurance Level), permits terminal sterilization and no addition requirements of heat. Method control can be made only by the parameter of applied dose [47].

Such as many radiation procedures, this method has some disadvantages; they consist in the fact that dose is not flexible and the dose rate is lower than for electron beam.

According to the above mentioned aspects, the gamma sterilization in open air affects the chemical and mechanical properties of polyethylene over time, leading to high subsurface oxidation, reduced strength and ductility.

Energy efficiency of irradiation processes is calculated as the cost of the energy required to treat a certain volume (Fig. 2).

In comparison with electron beam and X-ray radiation sterilization, gamma radiation is commonly used for sterilization technology because it is very penetrating and already a traditional method. Electron beam is by far the cheapest process sterilization [68], being very similar to gamma radiation sterilization as having an ionizing energy with different high dosage rates and low penetration.

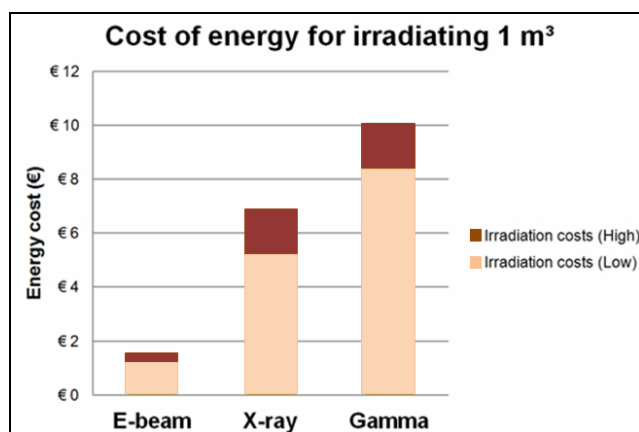


Fig. 3. Efficiency illustrations of the different radiation technologies costs (electron beam, X-ray, gamma rays); modified after Wikipedia [67].

Another difference consists in the fact that a source of electricity is needed to produce high charge of electrons needed for sterilization of the product [10]. But the electron beam sterilization is also approved by FDA process and is recognized and accepted by international standard organizations [10].

Comparing physical and geometrical features of X-rays and gamma-rays there is a significant difference that counts; gamma-rays are emitted in all directions, where high-energy X-ray photons are totally concentrated in the direction of the material sample.

In conclusion, there is no perfect sterilization process for all the types of samples because every method has various advantages and disadvantages.

## CONCLUSIONS

Gamma irradiation was found useful for various domestic and industrial applications; food storage for longer time durations with preserving of quality parameters is one of the earliest technological methods based on high energy

photon exposure but nowadays the trend is to limit such techniques as noticed also in official statistics. Rather wastewater irradiation seems to draw the attention of researchers for microbiological loading reducing but also for molecular pollutant decomposing aiming to protect environment and biosphere itself.

For the medical devices, it is essential to well-know the material for an efficient sterilization technology and the compatibility of all the components must be known before starting the sterilization. Regarding the pharmaceutical products, gamma rays present an important method for the sterilization taking into account the high ability to penetrate the sterile packaging of pharmaceutical and medical devices.

Gamma radiation processing is intensely studied and presents a large subject worldwide. Beside its efficient applications, it has been discussed the reduction of using the radiation sterilization technology, on a large scale, in products. Furthermore, careful monitoring and continuous evaluation of all the technology radiation are prudent precautions.

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