INDUSTRIAL SCALE APPLICATION OF IRRADIATION TECHNOLOGIES IN TURKEY

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Sufficient and safer foods, better healthcare, cleaner environment and higher life standards are the shared objectives and desires of the humankind. The rapid increase in the world population necessitates the development and application of new technologies in order to meet these desires. The need for such technologies is more important for developing countries, when it is thought that the major share of the population increase is originating from those regions. Irradiation technology, as a rather new one, may have a considerable contribution in this respect, providing that proper application. Although, a wide range of application areas, changing from flue gas treatment to polymer production, exists in this respect, transferring or developing new technologies requires time, trained personnel and equipment.

The energy sources used for irradiation process are:
- Gamma rays from radio-nuclides (in most case from Co-60)
- Accelerated electron beams
- X-Rays

Although, Gamma Irradiation is the most prominent within the market, the E. beams and X-Ray technologies have showed important developments during the last decade. Nevertheless these technologies have not been introduced in Turkey yet. Machine sources may become the alternatives according to the results of feasibility studies which will be carried out and the needs may arise in the market for higher dose rates.

It is almost 35 years that, Turkey has initiated laboratory studies on food irradiation. The studies related to the different foodstuffs have been carried out during that time span. But, the first industrial irradiation facility has been merely commissioned in 1993, in the Food Irradiation and Sterilization Department (FISD) of Ankara Nuclear Research Center of Agriculture and Animal Science (ANRCAAS), as a semi-commercial irradiation facility. The second one has started in Istanbul, almost simultaneously with the first one, by a private company.

The first intend of the both facilities was the radiation sterilization of the single use medical supplies, but the standards and regulations to arrange the process was not exist. Therefore, producers were uncertain to apply this process. The European Standard of “EN 552 Sterilization of Medical Devices - Validation And Routine Control of Sterilization by Irradiation” and the others, regulating industrial sterilization processes, like EN 550, EN 554 and EN 556 has been translated into Turkish with the collaboration of, Health Ministry, Turkish Standard Institution and FISD and approved as a national standard in 1996-1997.
Irradiation of food in industrial meaning was not regulated until November 1999. Therefore irradiation of any food for domestic consumption was not permitted. These two occasions have given impulse to the industrialization of the process. Irradiation technologies have a broad range of potential application areas such as:

- Sterilization and Bio-burden Reduction
- Polymer Modification
- De-polymerization of Cellulose
- Treatment of Waste-Water and Hospital Wastes
- Water treatment and sewage sludge treatment
- Removal of sulfur oxides and nitrogen oxides from flue gas
- Curing of Advanced Composites
- Curing of surface coatings
- Coloration of Glass and Gemstones
- Degradation of Fluoropolymers and Polypropylene
- Radiation Doping of Semi- Conductors
- Imparting Memory to Heat-Shrink Parts and Films

Turkey has made considerable progress in applying the irradiation method for sterilization of single use medicals and the irradiation of food. It seems possible that the share of radiation sterilization of disposable medicals can reach %45-%50 in 10 years if the correct technologies and policies can be chosen, for the facilities constructed in the near future.

It took long time and effort informing medical supply producers interested in the irradiation technology and encourage them to change their technologies from ethylene oxide to gamma. The Irradiation Facility mostly operated in order to cross-link the heater tubes produced by a private company until 1997. The demands related to the radiation sterilization of single use medical supplies emerged by the end of 1997 and showed a sharp increase (Fig1). The facility had trouble insupplying sufficient service to the customers during the last four years. Therefore the Co-60 source of the ANRCAAS-FISD Irradiation facility is not sufficient to have new contracts with customers, so that an increase in the strength of the Co-60 has been planned, and the purchase procedures are under process. The source delivery is being expected by the end of April 2001. The increase of the source strength will provide FISD new contracts with the companies having larger capacities production.

Most of the demand for radiation sterilization of medical supply has been received from the companies settled in Aegean Region, which means an additional cost for transportation from the companies’ point of view.
FOOD IRRADIATION AND STERILIZATION DEPARTMENT

The main objectives of the Department can be resumed as follows:

1. Setting up the infrastructure to fulfill the responsibilities of the Turkish Atomic Energy Authority (TAEA) related to the radiation processing.
2. Developing and transferring industrial irradiation processes to meet the needs of the domestic industry.
3. Setting up internationally accredited laboratories on the varied areas of the radiation process.
4. Close collaboration with the national and international organizations interested in the radiation processing.
5. Training of the companies on the irradiation processes.
6. Developing regulations and standards on the different aspects of radiation process.
7. Guiding private companies applying irradiation technologies, to carry out the process, as it should be.
8. Guiding private entrepreneurs in carrying out feasibility studies and selecting appropriate irradiation technology.
9. Carrying out researches on the different applications of irradiation process

Gamma Irradiation Facility and four laboratories are present today, Each has been carrying out studies on the different aspect of irradiation process and aimed to develop as reference laboratories to give high quality service to the industrialists.

High Dose Dosimetry Laboratory

Dosimetry is the most important tool of the radiation process being the main measurement point for every evaluation in laboratory or industrial level. Therefore, supplying an accurate and precise dose measurement service is one of the inevitable pre-requirement of the process.
The routine responsibilities of the laboratory are:

i) Establishing the process parameters of the Gamma Irradiation Facility,
ii) Establishing the process validation and the dose absorbed by the product in order to meet requirement for parametric release of the product,
iii) Determination of the dose rate, in certain periods, of the pilot scale Gamma Irradiation Chambers present in the Department
iv) Calibration of the commercially produced routine dosimeters, used in the laboratory

The future perspective of the laboratory:

v) Setting up traceability for the dosimetric systems used in the laboratory.
vi) Carrying out inter-comparisons with other laboratories studying on high dose measurement,
vii) Offering services on high dose Dosimetry calibration services national industry.

The laboratory is equipped with an UV-Visible Spectrophotometer with Temperature Control Unit, Oscillo-titrator, TLD Reader, Thickness Measurement Unit and Ultra Pure Water Treatment System. Fricke and dichromate solution are being used as reference dosimeter and PMMA, thin films, ECB and TLD are used in routine applications.

Radiation Microbiology Laboratory

The minimum sterilization dose to be applied to the medical supply is a function of the number and radio-resistance distribution of the bioburden existing on the product before sterilization. International standards require that the sterility assurance level (SAL) of medical supply must change between $10^{-6}$ and $10^{-3}$ according to their intended use.

The Association for the Advancement of Medical Instrumentation (AAMI) has developed procedures to allow determination of a radiation dose capable of delivering a specified level of sterility. This is based on product end-use and bioburden specifications, instead of requiring one fixed dose for all. The AAMI methods for dose setting have been successfully applied for over 15 years. AAMI dose setting methods have now been included in the international ISO 11137 standard for validating radiation processes. Harmonization of national and international standards provides an opportunity to validate sterilization doses below the 25 kGy dose usually used in Europe. Quarterly dose audits are required to verify the validity of the sterilizing dose selected.

The Radiation Microbiology Laboratory of FISD is the unique laboratory in the country applying the standard dose setting procedures of AAMI for the radiation sterilization of medical supplies. The laboratory is intended to serve as a reference laboratory on dose setting procedures. Instrumentation of the laboratory, in order to fulfill the international requirements, will be completed in the year 2001.
The studies related to the radiation sensitivity distribution of the microorganisms present on the medical supplies before sterilization are also being carried out in the laboratory.

**Material Compatibility Laboratory**

When polymer based materials are irradiated, the effect of radiation is observed as the following kind of behaviours,

- no effect
- degradation (chain scission)
- endurance increment (crosslinking)

To establish the desirable and undesirable changes, which will be induced by the irradiation process on the material, and to determine their suitability for the process are the main objective of the laboratory. The studies aiming this objective are carried out by preparing test samples with the suitable geometries by applying the identical conditions under which the medical supply produced and by performing different tests on the samples according to the intended use of the product.

The routine responsibilities of the laboratory are:

1. Applying standard tests to detect the changes, resulting from by irradiation, in the physical properties of materials forming medicals, including packaging and seals. These tests may change depend on the intended use of the product.
2. Evaluating changes, that could occur during the shelf life of the polymeric medical products and its packaging, by accelerated ageing tests.
3. Evaluating the packaging material of the foods to be irradiated.
4. Determination of the rough molecular size of the polymers before and after irradiation in order to decide whether the cross-link or scission effect is dominant for the polymer under investigation.

Mid term responsibility of the laboratory is to evaluate domestically produced polymers for the compatibility of the radiation process and support the commercial producers interested in the additives to produce radiation compatible polymers.

The Material Compatibility Laboratory is equipped with mechanical test instrument (Instron 1011), melt flow index (Ceast), hot-cold press (Ceast) and extruder (Friul Fliere) and a fresh air oven to carry out mentioned above studies.

**Food Irradiation Laboratory**

Turkey has an important share regarding the agricultural production in its geographical region and has the highest share in the world production of hazel nut and fig. Considerable proportion of the total agricultural products is exported. Chemical Fumigation is the preferred and very common disinfections method for the producer. The usage of the some chemical fumigants depleting ozone layer will be phased out by 2005, in accordance with Montreal Protocol, is known. Irradiation seems to be a potential alternative for the fumigation.
It is more than 30 years that, Turkey has dealt with the irradiation of food commodities. Studies related to the different foods changing from fish to potatoes. Feasibility studies also carried to figure out the potential benefits of the irradiation technology.

The declaration of Joint FAO/IAEA/WHO Joint Expert Committee on the Wholesomeness of Irradiated Foods (JECFI) in 1980 that “irradiation of any food commodity up to an overall average dose of 10 kGy causes no toxicological hazard; thus, toxicological testing of food so treated is no longer required” and “irradiation of food up to 10 kGy introduces no special nutritional and microbiological problems” caused an extra momentum for food irradiation studies.

Absence of the regulation arranging this issue caused these efforts unproductive for a long time. The regulation related to the food irradiation has been published on 6 November 1999, as a result of close collaboration of TAEA, Ministry of Agriculture and Rural Affairs and Health Ministry.

The main objectives of the laboratory are:

1. Carry out activities to fulfill responsibilities specified by the national Food Irradiation Regulation.
2. Determining the common inconveniences related to the foods produced, consumed or processed in the country,
3. Carry out researches to eliminate inconveniences which can not be overwhelmed by traditional food processes.
4. Supporting related governmental bodies responsible for the legislation of the food irradiation.

Total production, export and value of selected agricultural products suitable for irradiation (Turkey, 1997)*

<table>
<thead>
<tr>
<th>Crops</th>
<th>Total Production (Tons)</th>
<th>Export Quantity (Tons)</th>
<th>Value (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazelnut</td>
<td>410.000</td>
<td>144.018</td>
<td>444,375,113</td>
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<tr>
<td>Dried fig</td>
<td>243.000 (fresh)</td>
<td>35.467</td>
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<td>Raisin</td>
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<tr>
<td>Apricot</td>
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<tr>
<td>Pistachio</td>
<td>70.000</td>
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<tr>
<td>Walnut</td>
<td>115.000</td>
<td>330</td>
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<tr>
<td>Dry onions</td>
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<td>Potatoes</td>
<td>5,100.000</td>
<td>240.701</td>
<td>29,857,078</td>
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*“The summary of Agricultural Statistics” State Institute of Statistics Prime Ministry Republic of Turkey, 1997.
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<tr>
<td>Hazelnut</td>
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<tr>
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<tr>
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<td>Apricot</td>
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<tr>
<td>Pistachio</td>
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<td>Walnut</td>
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<tr>
<td>Dry onions</td>
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<tr>
<td>Potatoes</td>
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<td>58.185</td>
<td>15,586,574</td>
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*Statistical data is provided by State Institute of Statistics Prime Ministry Republic of Turkey, 1998. Figures are temporary, 14 May 1999.

Gamma Irradiation Facility

FISD Gamma Irradiation Facility (GIF) was designed by Hungarian Isotope Institute as a tote box irradiator with 1MCi source capacity. Tote boxes move around the source in 52 positions and 2 levels during the irradiation process. The starting source strength of GIF was 100 kCi. The technical specifications of the system can be resumed as follows:

Type: High Capacity TYPE-SVST-Co-60-1
Maximum Source Capacity: 1Mci
The Shielding of the System: 2 Mci
Operating Mode: Batch and Continuous Operation
Source: 46 piece active C-188 AECL Type Co-60
Source Size Dimension: 55 cm Wide, 95 cm High.
Storage Area for Product: 800 m²
Tote-Boxes Size: 45x45x90 cm
The Maximum Product Density (as bulk): 0.6 g/cm³
Dose Uniformity Ratio (for 0.2 g/cm³ density): 1.3
Water Pool: 280x320x600 cm, full With the De-ionized Water.
The Shielding of the Irradiation Room: Thickness of the Side Wall is 185 cm, Ceiling Thickness: 175 cm, normal concrete.

The Control Mechanism: The Irradiation Facility is operated and controlled by Electro-pneumatic - Mechanical System, Operation of the system is be controlled in every step by a computer program.

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CONCLUSION

Industrial Radiation application in sterilization of single use medical supplies and preservation of food commodities showed a rapid development during the last decade. Although a limited irradiation power, Country has a considerable potential for the new irradiation facilities to be built.

TAEA, and ANRCAAS Food Irradiation and Sterilization Department, as its sub organization, has enough experiences to apply this technology in accordance to the related World standards and to guide domestic industry.

The FISD has gained enough experience to apply the irradiation technology in accordance to the world standards through the laboratory facilities.

The power of Co-60 is not high to supply commercial irradiation.

The regulation regarding the food irradiation will enable implement this technology in a shorter period in Turkey.