

ATOMIC ENERGY RADIATION PROCESSING OF FOOD AND ALLIED PRODUCTS RULES 2012

EXTRACT FROM THE GAZETTE OF INDIA : PART II SEC. 3. (i) Appearing on Page Nos. 968—983 3062012 DEPARTMENT OF ATOMIC ENERGY 26 2012 1962 14 17 qfaa 30 fizäq) 1996 2012 I (1962 (q) (q) (2) (2) 39-W (1) ga) 2004 3 (ii) (3) zq-fiz;q (1) (2) (4) zq-fnq (D 1 2370 AE/2012 (1) (2) (ii) 10 (iii) 7.5 BY RAD}ATION 3P{/Name Of the Product TAQFT/Purpose of Radiation Processing : qtéAvOperating Licence No. : Batch Identification No. (BIN) (as provided by facility) : of Processing (8) 2004 (Ä) 1954 7.) 17 zq-üz (4) f•Tqq 6 Oz,) (-a-q-a ; 03) (3) (3Ttqr€) (fiütrr : 2004 (71) fäq (PBq (kW) 3. 4. 5. 6. 7. 8. 9, (4) (i) 2(3) I Gi) 1962 (iii) (v) (Yi) Å, (ii) (iii) (iv) 10. 11. 13. 14. 15. 16. 17. 19. (5) (ii) (iii) (iii) (ii) (ÄR3 (ii) (102 1.0 (Kilo Gray) (12 1.0 1.0 2.5 1.0 .23 70 El)2- (6) 3

4. XfifrBi, faqvq, , Gi-Tai 3fr(fcfazü (izt-z- (gf2gfEF*1) (125 1.5 1.0 1.0 03 1.0 1.0 0.3 (13 0.3 1.0 20 0.25 2 5 0.25 50 0.25 5.0 IO 5.0 10 025 5.0 1.0 5.0 7.0 3.0 7.0 20 14.0 1.0 1.0 3.0 7.0 10 (Kilo Gray) 1.0 10.0 1.0 10.0 28 10.0 10 5-0 10 025 7. 3. 4. 5. 6. 7. 9. 10. 11. 12. 14. 16. 17. 18. fit.r;å (*frqq) atPRZ : \$8 , (*qfrs«) firq JOO 25 Iao 1.0 1.0 (Kao Gray) to 10 IO 10 10 10 10 10 10 10 10 10 10 19. 20. 21. 22. 23. 24. 26. 28 29. ZWZ Atta, (abd) ftFFq 3FQ utrrät 10 IO IO 30 30 60 6) 20 10 4 x IOS 105 4 x 102 0) Mumbai, the 26th Junc, 2012 (ZS.R. 158.— In exercise of the powers conferred by Section 30 read with Sections 14 and 17 of the Atomic I •nergy Act, (33 of 1962) and in supersession of the Atomic Energy (Control of Food) Rutß, 1996, except as respects things done or omitted to be done such supersession, the Central Government hereby makes following rules. namely : 1. Sion iitle, extent and These rules may be called the Atomic Energy (Radiation Processing or food and Allied Products) Rules, 2012. (2) -lbcy shall come into force on the date of their publication in the Official Gazette

2. In t}wse rules, the context otherwise requires,—(a) "Act" means the Atomic Energy Act, 1962 (33 Of 1962); (b) "applicant" means the person making an application for grant of licence under rule 3: (c) "certificate of radiation processing" means a certificate issued by the to the enect that the food and allied products have been processed by radiation; "dosimetry" means a system adopted measure the absorbed dose by the food and allied products; (c) "facility" means the radiation processing facility for food and allied products; products" means any food and allied products that could be processed by radiation and as notified by the Central Government; (g) "liccncc" means the licence issued under rule 3; (h) "radiation processing" means processing of food and allied prodtrts by radiation. (2) Words and expressions used in these rules and not but defined in the Act shall have the meanings assigned to tfwm in the Act- 3. Condition for operating a facility.—No person shall operate a facility without obtaining a licenec for radiation of food and allied products un&r these rules

4. Application far l) An application for liccncc to operate a Ecility shall be made to tlr Central (;overnment in Form-J.(2) Every application under sub-rule (I) shall be accompanied by (a} a liccncc fee of rupees ten thousand payable by bank draft; and (b) acertified copy of the licence issued under rule 3 or the Atomic Emrgy (Radiation Protection) Rules, S. I hcncc.H I) Where the Central Government, is satisfied that the application is complete in all respects; and (i) requirements ofruic 4 are complied with; shall, within a period of one month from the date of receipt and subject to the terms and conditions specified in rule 6, grant liccncc to applicant. (2) Where the Central Government is not satisfied, it may. after giving the applicant a reasonable opportunity of being heard. refuse to grant the licence by an order in writing setting forth the reasons for its refusal. (3) Every order undet sub-rule (I) or sub•rule (2) shall be communicated to the applicant within a period of one monLh from the date or order by sending a copy of such order by registered post on the address mentioned in the application. (4) The licence issued under sub-rule (I) shall be valid for a period of five years from the date of issue

6. Terms aru! conditions of licence.—The licensee shall- (a) operate the facility using one of the following sources; (i) Gamma (i) Electron beams from a machnncoperated at or below ten million electron volts: (iii) X-rays generated from a machine operated at or below seven and half million electron volts; (b) food and allied products within the absorbed dose limits as specified in Schedule I and Schedule II: (c) use packaging material suitable for radiation processing of food and allied products as specified in Schedule III; 23 (10) (d) carry out dosimetry as specified in Schedule IV; (e) affix the following label on the

package to indicate the product processed by radiation PROCESSED BY RADIATION NAME OF PRODUCT PURPOSE OF RADIATION PROCESSING OPERATING ICFNCE NO BAICH IDENTIFICATION NO. (BIN) (as provided by facility) DATE OF PROCESSING (t) appoint personnel having such qualification and have undergone such training as may be recognised by the Atomic Energy Regulatory Board for operation of the facility; (g) maintain product processing record in Form for a period of five years and issue a certificate of radiation processing; (h) provide security to the facility at all times; (i) hold a valid licence under Atomic Energy (Radiation Protection) Rules, 2004, as x1 (i) hold a valid licence under the Prevention of Food Adulteration Act, 1954. 7. I) Any person duly authorised under subsection (4) of section 17 of the Act may, for the purposes of enforcement of these rules, inspect the facility. (2) For the purpose of carrying out inspection, the person authorised under sub-rule (I) shall have access to any place within facility and to all documents and records relating to the radiation processing of food and allied products. (3) -I he person authorised under sub-rule (i) shall have powers to verify that the— (a) facility is operated using sources specified under clause (a) 6; (b) competent personnel are appointed by the licensee for the operation, quality control, safety and security of the facility; (c) specified packaging material is being used; (d) eefified dosimetry system is used; (e) srx•cified radiation doses are applied; (0 9ecified label is affixed; and (g) documents and records are properly maintained. (4) The Central Government shall have power to issue, to the licensee, such directions as it may deem fit, fog taking concetive actions. g. Cancellation of licence.—The Central Government may cancel the licence granted under rule 5 if the licensee has failed to comply with— (a) any of the terms and conditions of licence specified in rule 6; or (b) tix direcljns issued under sub-rule (4) of rule 7 • Provided that no licence shall be so canceled, unless a reasonable opportunity of being heard has been afforded to the licensee. (11) Fan 'I' (see rule 4) APPLICMON 1. Name Of the applicant in full (in capital letters) Designation of Qplicant Telephone No. No. Mobile No. Address of the Applicant : Detail of ur facility : (0) (R) 2. 3. 4. (a) Name aryl address of the facility withpin code: Telephorr Nos. (including Control Room) • (b) Identification (ID) number of the acility: [issued under Atomic Energy (Radiation Protection) Rules, 2004] (c) Proposed date of commissioning of the (d) Category of the Gcility: (e) Purpose for which Class of food and allied product the facility will be used: (f) Radiation source details: . Name of source Maximum designed activity (MeV)/Power (kW) (g) Name address of tip source supplier : Telephone No. Fax No. Details of the pyment of application fee: Demand Dranr%.• . Issuing bank branch: ITWe hereby undertake that— Date of issuance• Amount: Rs. (i) (iv) (v) No shall be carried out for purposes other than those specified under item 2(c) above All amAicable provisions of the Atomic Energy Act, 1962 and the rules mae thereunder shall be complied withs The raiiation processing facility shall not be transferred/decommissioned yitbout the prior permission of the authority issuing a license, Ail directions that may be made from time to time by the authority issuing license shall be complied with, Any change in the information furnished above shall be cornmunicated to tir authority issuing license within 30 days from the date of its occurrence. In case of any unforeseen circumstances resulting in threat to safety and security of the gamma radiation source, I will arrange to return the source to the supplier at my cost. Date: It is hereby declared that all statements made above are correct to the best of my knowledge and belief. Signature: Name and designation of tir applicant: (12) Form [scc clause (g) of rule 61 Product Processing Record Name of the facility : Identification Number : Sr. No. 2 3. 4. 5. 6. 8. 9. 10. n. 12. 13. 14. 15. 16 18. 19 Particulars Name of the product Dale and time of receipt Quantity (Metric •ron) Mode of transport (Vehicle Registration Number) Packaging material (i) Primary Secondary Batchil .ot Number Rc)narks on quality of received product Name and Address of the customer (i) Food and Drug Administration/ I .oan licence number issuing authority for loan licence (if applicable) (lii) Dale of issue (iv) Period of validity Purposc of radiation processing l)osc (i) (iO (iii) i)osc desired by customer Whether this dose is within the range notified by the Government of India If 'NC)' then provide country of destination Customer has provided information that the dose desired by him is acceptabk• as per the legal provisioem•s in the country mentioned (iii) Date and time of processing Dosimeter used Dose deli vcrd] .abelling details Serial number of certificate of radiation proecssing Remarks on processed product Date and time of delivery Io the customer l)estination (i) Shipping details/date of dispatch ('i) Mode of transport (vehicle Registration Number) (icnra) remarks, if any: and signature of (i) Quality Control Officer (iO Authorized signatory (J -icenscc or his authori•ad nominee) (13) Schedule - Iscc clause (b) of rule 61 Classes of Food Products and Dose Limits for Radiation Processing 'lass (• lass 2 ('lass 3 ('lass 4 Class 6 Class 7 Class 8 Food Bulbs,

stem and root tubers and rhizomes Fresh fruits and vegetables (other than Class J) Cereals and their milled products. pulses and their milled products. nuts, oil seeds. dried fruits and their products Fish, aquaculture, seafood and their products (fresh or frozen) and crustaceans Meat and meat products including poultry (fresh and frozen) and eggs Dry vegetables. seasonings, spices, condiments, dry herbs and their products, tea, coffee, cocoa and plant products Dried foods of animal origin and their products Ethnic foods, military rations, space foods. ready-to-eat, ready-to-cook minimally processed foods Purpose Inhibit sprouting Delay ripening Insect disinfection Shelf-life extension Quarantine application Insect disinfection Reduction of microbial load Elimination of pathogenic microorganisms Shelf-life extension Control of human parasites Elimination of pathogenic microorganisms Shelf-life extension Control of human parasites Microbial decontamination Insect disinfection Insect disinfection Control of moulds Elimination of pathogenic microorganisms Quarantine application Reduction of microorganisms Sterilization Dose limit (KiloGray) Minimum 0.02 0.2 0.2 11) 01 IS 10 03 10 1.0 03 6.0 03 03 10 C25 2 5 Maximum 0.2 2.5 10 50 71) 30 2.0 70 30 20 14.0 1.0 30 70 1 10 23 70 "E//2-9 (14) SCHEDULE-II [see clause (b) of rule 61] Dose Limits for Radiation Processing of Allied Products Sr.No. 4. 5. 6, Sr. No. 2. 3. 4. 5. 6. 7. 8, 9. 10 12 13. Allied product 2 Animal and Aged Ayurvedic herbs and their products, and medicines Packaging materials for foodstuffs Food additives Foodstuffs, dietary supplements and nutraceuticals Body care and cleansing products Cut flowers Purpose 3 insect disinfection Microbial decontamination insect disinfection Microbial decontamination Sterilization Microbial decontamination Sterilization insect disinfection Microbial decontamination Sterilization Microbial decontamination Quarantine application Shelf-life extension SCHEDULE-III [see clause (c) of rule 6] Dose limits (KiloGray) Minimum 4 0.25 5.0 0.25 10 5.0 10 0.25 5.0 10 0.25 5.0 10 0.25 0.25 Maximum 5 10.0 100 10.1) 100 1.0 10.0 100 1.0 Packaging Material for Radiation Processing of Food and Allied Products Packaging material 2 Kraft paper (flour pack aging only) Biaxially oriented polypropylene (BOPP) Cardboard cartons with polyethylene liners Cardboard kegs Glassine paper Paper sacks Polyethylene paper sacks Polyethylene paper sacks with polyethylene liners Nitrocellulose coated cellophane Nylon- 6 Polyethylene terephthalate film containing coatings comprising a vinylidene chloride co-polymer with one or more of the following co-monomers : acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate Polyethylene terephthalate film containing coatings of polyethylene Polyolefin film (e.g. Polyethylene. BOPP) Maximum tolerable dose KiloGray 3 0.5 10 10 10 to 10 10 10 to 10 10 10 14. 15. 16. 17. 18. 19. 20 21. 22. 23. 24. 26. 27. 28. 29. (15) 2 Polyolefin film containing coatings comprising a vinylidene chloride co-polymer with one or more of the following co-monomers : acrylic acid, acrylonitrile, itaconic acid, methyl acrylate, and methyl methacrylate Polystyrene film Rubber hydrochloride film Vinylidene chloride copolymer-coated cellophane Vinylidene chloride-vinyl chloride co-polymer Wax -coated paraffin Woven polypropylene sacks Polyethylene coated multiply paper sacks Ethylene vinyl acetate co-polymer film Polyethylene polyester laminates Nylon-6 film Polyethylene film Polyethylene terephthalate film parchment Vinyl chloride-vinyl acetate co-polymer Acrylonitrile Dacron Alanine Dyed polymethyl methacrylate Clear polymethyl methacrylate Cellulose acetate Lithium Yttrium, lithium fluoride Lithium fluoride (optical grade) Radiographic films, solution, optical waveguide (cerous sulfate solution) Ferric sulfate solution Potassium dichromate Ferric cupric sulfate solution Ferric solution Anionic acids Metal Oxide Semiconductor Field transistor MGIPRRNI) 2370 A1-JP Copies. SCHEDULE-IV [see clause (d) rule 61 Dosimetry for Food and Allied Products Readout system Electron Paramagnetic Resonance spectrometer Spectrophotometer Spectrophotometer Spectrophotometer Thermoluminescence reader Spectrophotometer Spectrophotometer Spectrophotometer or potentiometer Spectrophotometer Spectrophotometer Spectrophotometer, colour titration, high frequency conductivity Thermoluminescence reader 3 10 10 10 10 10 30 (0 Usable absorbed dose range Gray 1-10' 101-4 x 10' ICE-KY' I-tos 20-4* 10t 10-2 * 1-10' RAHULKULSI Jt. swy.