health

Department:
Health
REPUBLIC OF SOUTH AFRICA

GUIDELINES FOR MONITORING

IRRADIATED FOODSTUFFS

in

SOUTH AFRICA

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GUIDELINES FOR MONITORING IRRADIATED FOODSTUFFS IN SOUTH AFRICA

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1. INTRODUCTION

The purpose of this document is to provide information and guidelines to all those persons that are involved in the administration and enforcement of regulations relating to food irradiation in South Africa.

Food irradiation is a modern technology that offers many benefits. It is however prudent that regulatory control be exercised to ensure that consumer confidence in the safety and wholesomeness of irradiated food products is maintained, as well as to ensure that consumers are able to exercise their right of choice when purchasing foods.

Regulations under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), stipulate that no foodstuff that has been irradiated may be sold unless the Minister of Health or the Director-General of Health has in writing, approved the sale of such irradiated foodstuff (Government Notice No. R.1600 of 22 July 1983). This authority has been delegated to the Director: Food Control of the national Department of Health (DoH).

The Minister of Health is responsible for the promulgation of regulations that govern food irradiation. The national DoH administers such regulations, while authorized local authorities are responsible for enforcing the regulations in their areas of jurisdiction.

In South Africa there are currently three facilities that irradiate food as well as commodities such as medical devices. These are located in Cape Town, Durban and Kempton Park. By far, the foodstuffs that are most frequently irradiated in South Africa are spices followed by honey and fresh garlic.

This document provides background information, and also explains the roles of the different sectors of government. Much attention is given to the role of local authorities. A checklist for the purpose of monitoring is included as a guide for Environmental Health Officers and other role players.

The principles on which the irradiation of foodstuffs rest should be noted very carefully, as the measures that are necessary for the control of food irradiation are dependent on the understanding of these principles.

It is trusted that careful adherence to these guidelines by all stakeholders will serve to uphold the current position whereby the South African food irradiation industry operates within a minimum of regulations but within the principles on Good Manufacturing Practice (GMP) and Good Irradiation Practice (GIP).

2. DEFINITIONS AND DESCRIPTIONS

Batch or lot: A quantity of food irradiated under the same conditions for an uninterrupted period.

Dosimetry system: A system that is used for determining absorbed dose consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use.

Good Irradiation Practices (GIP): Practices that specifically apply to food irradiation facilities and irradiated food products, to supplement those provisions of Good Manufacturing Practice (see definition) that would ordinarily apply to the approved activities of the irradiation facility. GIP would include:

- Treatment practices such as International Consultative Group on Food Irradiation Codes of GIP to be used as guidance;
- Product inventory and process parameters;
- Handling practices; and
- Record keeping.

Good Manufacturing Practice (GMP) where applicable: Practices applicable to methods of manufacture or handling or a procedure employed, taking into account the principles of hygiene so that food cannot be contaminated or spoiled during manufacturing or processing, which include:

- Specifications of every aspect of manufacturing, processing, packaging;
- Facilities, equipment, instruments;
- Prevention of contamination;
- Personnel – training, job descriptions;
- Production procedures; and
- Best available technology.

Gray (Gy): Is the unit of absorbed dose. One Gray is equal to the absorption of one joule per kg.

International Atomic Energy Agency (IAEA): An international body responsible for all relevant aspects of the peaceful utilization of atomic energy.

International Consultative Group on Food Irradiation (ICGFI): An international group of experts designated by governments to evaluate and advise on global activities in food irradiation. It was established under the aegis of the Food and Agriculture Organization (FAO), the IAEA and the World Health Organization (WHO).

Manager of the Irradiation Installation or his Delegate: The person officially in charge of or officially authorized to act.

Minimum Effective Absorbed Dose: Is the minimum absorbed dose to achieve the desired effect.

3. BACKGROUND / PURPOSE OF FOOD IRRADIATION

Food is *inter alia* irradiated for the same reasons it may be exposed to heat, refrigeration or freezing. Food irradiation should therefore be seen as one of an array of techniques that contribute to the same objectives. It combats food borne disease by attacking one of its main causes, namely harmful microorganisms such as *Salmonella, Campylobacter* and other pathogens. It also destroys insects and their larvae in food and fulfils a technological need by preventing sprouting, for example of onions, garlic and potatoes. In this way the shelf life of food is extended, the quality of food is improved and dissemination of organisms that are unacceptable to the agricultural sector is prevented. Irradiation therefore contributes to overcoming quarantine barriers and to extending the marketability of food.

Food irradiation is a physical process by which food is passed through a field of ionising energy. Some energy is absorbed but not enough to warm the food to a significant extent. The most common source of energy used for this purpose – also in South Africa – is Cobalt-60 (a radioactive form of cobalt). The energy applied to irradiate food is extremely low and does not induce radioactivity. Most foodstuffs are irradiated at doses between 0.1 and 10 kGy. An irradiation dose refers to the quantity of irradiation energy absorbed by the foodstuff as it passes through the irradiation field during the process of irradiation. It is measured using a unit called Gray (Gy) whereby 10 kGy is the equivalent of 10 000 Gy. Although it is important to ensure that the minimum irradiation dose is achieved in order to ensure the required quality and safety of the foodstuff being irradiated, a too high irradiation dose would spoil the food, similar to the over cooking of food.

Food safety, nutritional adequacy and microbial risks have been extensively evaluated over many years. According to the World Health Organization (WHO):

- An irradiation dose of up to 100 kGy is completely safe;
- Specifying upper dose limits is therefore superfluous;
- No particular nutritional problems are caused;
- There are no special microbiological risks; and
- Unlike chemicals or pesticides, the irradiation process does not leave any potentially harmful residues.

Because Cobalt-60 is a radioactive element, statutory provisions provide for the radiological safety of staff dealing with food irradiation and for the environment of the industrial facilities in which food is irradiated. Control measures to monitor these installations exist and are carried out by the Directorate: Radiation Control of the Department of Health that is located in Bellville, Cape Town.

Based on practical experience and in consideration of the safety aspects following from normal Good Manufacturing Practices, all irradiated foodstuffs have been divided into different classes. (Additional classes, specific for South African needs, were added to the suggested international list - **ANNEX B**). This list relates to the reason for irradiation of foodstuffs. For example, Class 2 refers to fresh fruits and vegetables which are irradiated for the purposes of delaying ripening or extending shelf-life. Applications for the irradiation of foods and the quarterly reports (**ANNEX C)** of irradiation of foodstuffs must be in accordance with these classes.

ANNEX D to this document also contains a checklist that identifies aspects to be taken into account during monitoring actions. The checklist however only serves as a guide. The concept of the Hazard Analysis and Critical Control Points System (HACCP) is also applicable and should eventually also determine points to control.

Labelling **(ANNEX E)** is an important means of identifying foodstuffs processed by irradiation. It provides consumers with the information needed to make a choice on whether or not to select irradiated foodstuffs for specific reasons. Industry also has an opportunity to make food safety or other claims by means of statements on labels.

4. REGULATORY ASPECTS AND PRINCIPLES OF FOOD IRRADIATION

4.1 REGULATORY ASPECTS:

The Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), makes provision for the control over the safety and quality aspects of the sale, manufacture and importation of foodstuffs, as well as of aspects such as labelling. Regulation No. R.1600 of 1983 of this Act governs the irradiation of food. The Hazardous Substances Act, 1973 (Act 15 of 1973), requires the licensing of irradiation facilities, training experience and qualification of the operators and prescribes the requirements for radiological safety.

4.1.1 Labelling of irradiated foodstuffs

The labelling of foodstuffs is regulated so as to ensure that consumers are not misled and that they are able to make informed choices. Specific references to the labelling of foodstuffs in terms of the Foodstuffs, Cosmetic and Disinfectants Act, 1972, are found in the Regulations Relating to the Labelling and Advertising of Foodstuffs (G.N. No. R.146 of 1 March 2010). - **(ANNEX E)**

4.1.2 Licensing of irradiation facilities

Requirements to ensure radiological safety are prerequisites for permission to proceed with the licensing of irradiation facilities, including those involved in the irradiation of food. In South Africa, a register of all irradiation facilities is maintained by the Department of Health's Directorate: Radiation Control in Bellville. These facilities must be operated and controlled by competent trained personnel. This requirement emphasizes the requirement in respect of the training of radiation personnel in general as laid down by the Hazardous Substances Act, 1973 (Act 15 of 1973). The Directorate: Radiation Control of the national Department of Health is responsible for the licensing and various other safety aspects in terms of the Act.

4.1.3 Regulations governing general hygiene requirements for food premises and the transport of food (No. R. 918 of 30 July 1999) under the Health Act, 1977 (Act No. 63 of 1977)

All premises upon which irradiated foods are to be handled, stored or sold must comply with the hygiene requirements indicated in these regulations. All vehicles used in the transportation of irradiated foods must also comply.

4.1.4 Occupational Health and Safety Act, 1993 (Act No. 85 of 1993)

4.2 PRINCIPLES:

4.2.1 Technological needs and food hygiene purpose

Irradiation is a process that, like other processes such as conventional cooking, microwave cooking, and freezing serves specific purposes in food preparation, for example the lengthening of shelf life. No food preparation method is intended to improve poor quality of food. **Irradiation is not a substitute for poor GMP. The irradiation of food is therefore justified only when it fulfils a technological need, or where it serves a food hygiene purpose due to unavoidable circumstances** (CODEX STAN 106-1983, (Rev.1-2003) - Section 4.1). Examples of the latter include the microbiological contamination of herbs and spices, as well as the contamination of poultry meat due to modern mass-slaughtering practices.

Compliance with GMP is the responsibility of both the food industry and of managers of food irradiation installations.

*4.2.2 **Kinds of foodstuffs***

Codex Alimentarius (CODEX STAN 106-1983, (Rev.1-2003) - Section 4.1) does not impose any restriction on the kinds of food that may be irradiated. For the sake of convenience the International Consultative Group on Food Irradiation (ICGFI) has divided foodstuffs to be irradiated into different classes based on:

- Similarities in kind and composition;
- The treatment intended (or has the potential) to achieve an identified technological need or food hygiene purpose; and
- Comparability to the radiation dosages which are necessary to achieve the objective and the similarity in sensorial quality after irradiation.

South Africa adapted the ICGFI classification by adding four additional classes, namely for:

- Foodstuffs irradiated at high doses;
- Phyto-sanitary requirements of the national Department of Agriculture, Forestry and Fisheries (DAFF);
- Integrated combination processes and;
- Imported foodstuffs not requiring phyto-sanitary clearance

*4.2.3 **Control***

Because of the difficulty in establishing whether a food has been irradiated, and the amount of radiation applied, the ***process*** of irradiation rather than the presence of radiolytic products are controlled.

A number of control measures must be in place to ensure that the correct foodstuff is irradiated with the correct dose. The following are required:

- Standard operating procedures and working instructions must be available. These must cover all aspects of the operations;
- An adequate product tracking system should be in place so that consignments can be traced back both to the irradiation facility and the client from whom they were obtained;
- A quality assurance system must be in place, to ensure that the treatment was consistently applied according to current procedures and criteria;
- A suitable and accurate dosimetry system must be in place. This should be calibrated and traceable to a national or international standard or system; and,
- The national DoH must be informed regularly of specific activities by means of quarterly reports from irradiators and quarterly monitoring reports from local authorities in whose areas of jurisdiction the irradiation facilities are located.

*4.2.4 **Importation***

The regulations do not directly address the importation of irradiated foodstuffs. Irradiated foodstuffs, including imported irradiated foodstuffs, may however not be sold without the approval of the Director-General of Health. Persons wishing to import irradiated foodstuffs into South Africa are advised to first contact the Directorate: Food Control in this regard.

4.2.5 ***Packaging***

Packaging is an important factor in the maintenance of acceptable standards of hygiene and must be appropriate for irradiation. **(ANNEX L)**

5. RESPONSIBILITY OF NATIONAL DEPARTMENT OF HEALTH (DOH)

5.1 FOOD IRRADIATION FACILITIES

The national DoH must receive the assurance that the irradiation facility is in compliance with the Regulations Governing General Hygiene Requirements for Food Premises and the Transport Food (G.N. No. R.918 of 30 July 1999) and is able to handle food in accordance with Good Irradiation Practices (GIP).

5.2 PROCESSING OF APPLICATIONS FOR INDIVIDUAL FOOD GROUPS

Application is made per food class according to the list in **ANNEX B.**

The application is made by the owner of the food (food producer, manufacturer or importer) in consultation with the manager or designated person of the irradiation facility. The application form (**ANNEX F - for irradiation of foodstuffs or ANNEX G – for imported irradiated foodstuffs)** must be completed in conjunction with the manager of the irradiation facility and then submitted to the Directorate: Food Control of the Department of Health. If approved, both the food owner and the manager of the food irradiation installation will receive letters indicating such approval (**ANNEX H - for irradiation of foodstuffs or ANNEX I – for imported irradiated foodstuffs)** and stipulating the conditions to which such approval may be subject. The conditions could be specific to the situation or case but would include items mentioned in the "Checklist for Monitoring by the National Department of Health" (**ANNEX J**). The provincial authority in whose area of jurisdiction the food irradiation facility is located will be notified in this respect, i.e. will receive copies of the letters of approval.

5.3 PRE APPROVAL ASSESSMENT OF FOOD MANUFACTURING FACILITIES

Circumstances may require an assessment of the premises or of the manufacturing procedures or of the reasons for irradiation before approval is granted. An example is where irradiated foodstuffs pose specific microbiological hazards. Such an assessment should be done in consultation with the various role players, depending on the specific case. The assessment should preferably be done by an expert with thorough knowledge and sufficient experience, as far as possible, in the application of Good Irradiation and Good Manufacturing Practices.

5.3.1 ***Special considerations***

Matters that may need special consideration during the pre-approval assessment of food to be irradiated include:

- Written methods of preparation of the food products;
- Reasons for the inclusion (or exclusion) of specific additives such as preservatives;
- Previous records of food processing and the results of bacterial counts;
- Reasons for specific steps in the processing;
- Determination of an expiry date where applicable;

- Instructions for refrigeration and maintenance of the cold chain where applicable. For some foodstuffs this is of the utmost importance. Assurance should be given of an acceptable procedure of cold chain maintenance during storage and transportation at any time during manufacture and irradiation.
- Records of the quality of stocks, especially bacterial counts; and
- Storage facilities.

5.3.2 Effectivity studies

The Department of Health may require studies to confirm the effectivity of the irradiation process. These studies should be conducted by a reputable independent organization with experience in food product development, in consultation with the Department.

5.4 MONITORING OF THE IRRADIATION PROCESS

The irradiation of food is a very specialized technology. Both the safety of the personnel and the achievement of the purpose of irradiating food must be addressed in monitoring of the process. Safety of personnel lies within the jurisdiction of the Directorate: Radiation Control of the Department of Health, whose headquarters is located in Bellville.

5.5 DAFF AND IRRADIATION OF FOODSTUFFS

Phyto-sanitary requirements are laid down by the Directorate: Plant Health and Quality of the national Department of Agriculture, Forestry and Fisheries (DAFF) for specific commodities such as:

- Honey that is to be irradiated to prevent dissemination of *Bacillus larvae*, and
- Fresh garlic and onions to prevent germination.

The importer must produce a permit signed by the national DAFF before the national DoH may proceed with processing of the application. There may also be other special circumstances where the irradiation of food will only be allowed after consultation between the national DoH and the national DAFF. The validity of the application for authorization is linked to the permit, as indicated in **ANNEX F**.

5.6 QUARTERLY AND ANNUAL REPORT ON FOOD IRRADIATION

The national Department of Health compiles an annual report on food irradiation in South Africa, based on the quarterly reports received from the three irradiation facilities, and submit updated information on South African food irradiation regulations and facilities to the IAEA Nucleus Database.

5.7 **AD HOC** *WORKING GROUP ON FOOD IRRADIATION OF THE FOOD LEGISLATION ADVISOY GROUP (FLAG)*

This Working Group reports to FLAG, who advises the Director: Food Control on matters concerning food irradiation and especially on irradiation legislation. Meetings are held biannually or when necessary.

6. RESPONSIBILITY OF PROVINCIAL HEALTH DEPARTMENTS

As mentioned previously, there are three food irradiation facilities in South Africa. These are located in three different provinces, namely Gauteng, KwaZulu/Natal, and the Western Cape. Based on the *White Paper* for Health and the National Health Act, 2003, (Act 61 of 2003) the role and responsibilities of the provincial health authorities towards these facilities rest within the broad scope of food control responsibilities that have been assigned to the provinces. They *inter alia* are:

- Support, monitor and evaluate the district (local) level services; and
- Coordinate health services within the province.
- Responsible for the control of imported foodstuffs

Provincial health departments execute food import control on behalf of the national Department. Foodstuffs irradiated outside South Africa may not be sold in South Africa without the written approval of the Minister or Director-General of Health. Such foodstuffs must be detained until written approval has been received from the provincial Port Health Authorities.

All irradiated foodstuffs must be correctly labelled in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).
Documentary evidence is required for food irradiated elsewhere and to be imported into South Africa. The importer must produce an authentic certificate with the following information:

- Name of the foodstuffs;
- Name and Address of the owner;
- Name of irradiation facility and address in the country of irradiation;
- Date of irradiation;
- Absorbed dose; and
- Verification of a governmental authority of exportation of foodstuffs.

Copies of the approvals to sell irradiated foodstuff are received from the national DoH. The provincial administration must send copies of such approvals to the local authorities in whose area of jurisdiction the foodstuffs that are destined for irradiation are sourced. The provincial authorities must liaise closely with the local authorities in whose area of jurisdiction the irradiated plant is located. Officers of provincial authorities should also visit irradiation plants from time to time in order to ensure a satisfactory level of control. They must also liaise with all the local authorities concerned in order to ensure that irradiated foods are labelled as such.

7. RESPONSIBILITY OF LOCAL AUTHORITIES

The local authorities in whose areas of jurisdiction the irradiation facilities are located are responsible for the enforcement of applicable regulations under the Health Act, 1977 (Act 63 of 1977) and the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) at such facilities. Their responsibility is to monitor within their area of jurisdiction certain activities and precautions that are to be taken by food irradiator managers and the food managers (see **ANNEX K** for address list).

The Regulations Governing General Hygiene Requirements for Food Premises and the Transport of Food (R. 918 of 30 July 1999) in particular are of importance. A certificate of acceptability in terms of these Regulations must accompany each application for irradiation to the national DoH. Local authorities must ensure that the irradiation facilities and all food premises from which food

destined for irradiation originated and/or is destined are in possession of a valid certificate of acceptability.

Local authorities of those areas from where foodstuffs are sent for irradiation, where they are irradiated and where they are sold must liaise closely in order to ensure effective control. The correct labelling of such irradiated foodstuff is of particular importance as the label on the foodstuff is the only indication of irradiation. The only way of monitoring is to trace the origin of the irradiation process by means of documentation, called the chain of custody.

It is also prudent for other aspects pertaining specifically to the irradiation of food to be monitored. In broad terms these are –

- Good Manufacturing Practice – before, during and after the process;
- Good Irradiation Practices – handling, treatment, product technology, labelling, physical barriers and record keeping.
- The monitoring of dosimetry must receive special attention.

In summary the purpose of communication with the managers of the food irradiation facilities would be to:

- Ensure Good Hygiene Practices and GMP;
- Ensure compliance with GIP;
- Trace labelling of irradiated food; and
- Ensure compliance with conditions for irradiation.

The following information should be made available by the irradiation facility.

- Name and address of the client;
- Type of foodstuff irradiated;
- Purpose of irradiation;
- Date of irradiation;
- Assurance of physical separation of irradiated from non-irradiated food (fence, visual colour change irradiation indicator);
- Each batch identified by a number;
- Records of at least five years after irradiation;
- Register containing – the type of food/ the date on which the irradiation took place/ the number of containers and identification of each batch / the dose applied versus the dose approved / the signature of the plant supervisor against the details of each batch treated. These records could also be recorded as electronic data such as an electronic signature;
- Storage facilities;
- Cold chain arrangements where necessary; and
- Records of microbial analysis of foodstuffs to be irradiated must be kept.

To initiate an investigation into the chain of custody to confirm labelling of irradiated foodstuffs, the following should be made available by the food managers:

- Names and addresses of retail/wholesale outlets;
- Labelling instructions and examples of labels/labelled food;
- Labelling instructions for distribution purposes (to distributors/retail outlets);
- Storage facilities; and

- Cold chain facilities where applicable.

8. OTHER ROLE PLAYERS

8.1 NATIONAL DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES (DAFF)

The role of the national DAFF consists of ensuring compliance to sanitary and phyto-sanitary (SPS) requirements at the port of entry. The purpose is to, among others, prevent plant and animal diseases and other pests from spreading into non infested areas.

Regarding foodstuffs of plant origin, a permit for the Importation of Controlled Goods is issued in terms of the provision of section 3 (1) of the Agricultural Pests Act, 1983 (Act 36 of 1983), whereby authorization is granted to import foodstuffs subject to conditions laid down by the authorities. Irradiation in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) may therefore be a phyto-sanitary condition with respect to the importation of certain commodities.

An irradiation dosage and sometimes the dimensions of the containers are prescribed by the Department of Agriculture and must be adhered to.

Imported meat and meat products can be irradiated on request of national DAFF.

8.2 MANAGER OF THE IRRADIATION FACILITY

The irradiation facility must comply with:

- The Hazardous Substances Act, 1973 (Act 15 of 1973);
- The Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972);
- Regulations Governing General Hygiene Requirements for Food Premises and Transport of Food (R 918 of 30 July 2002) under the Health Act, 1977 (Act 63 of 1977);
- Codex Alimentarius Standards **(ANNEX A);** and
- These Guidelines.

The manager must dedicate a person to be responsible for compliance with the above requirements. This manager must, apart from applying GMP, also convince the local authority that GIP is being applied. With respect to food irradiation the manager of the food irradiation facility must satisfy the authorities on the following matters.

- Suitability of the facility (use of proper type of source, suitability to handle food, ability to maintain the necessary environment, ability to treat the product within the legal limits, ability to segregate irradiated and non-irradiated products);
- Personnel competency (official qualifications, experience, job descriptions, documented training records, chain of command, responsibilities);
- Process control (operating procedures, product tracing system, quality assurance system, dosimetry system);
- Records (classification of foodstuff, batch number, quantity, name of company ordering and the company receiving the treated foodstuff, date of irradiation, packaging material

during treatment, reference to data control). The records must be kept for a period of five years.

The procedures followed to ensure the correct dose are described in detail by Codex Alimentarius Standards **(ANNEX A)**. The accepted practice in South Africa is to ensure a minimum dose, whereas the overall average absorbed dose is recommended by Codex Alimentarius. Exporters must adhere to the requirements of the country of importation. Specific requirements are:

- A record must be kept to illustrate routine dose measurements;
- Facility parameters such as transport speed or time spent in the radiation zone **(ANNEX A)**;
- Validation measurements for each new foodstuff irrespective of classification;
- Traceability to primary sources;
- Interlaboratory calibration.

The irradiation of a foodstuff should be done after consultation between the manager (and his delegate) of the irradiation facility and the owner of the food, having obtained the necessary approval. It is recommended that a contract to specify the responsibilities of each party, be signed by both parties. Upon completion of irradiation a certificate to confirm irradiation at the correct requested dose, should be issued by the manager of the irradiation facility.

The manager of the irradiation facility is responsible for labelling bulk containers of the irradiated product and must explain the importance of labelling to the food producer.

Quarterly reports stating quantities of food commodities irradiated according to classes must be submitted to the Director: Food Control of the national Department of Health, using the template provided in **ANNEX C** of the guidelines.

8.3 OWNER OF THE FOODSTUFF

The responsibilities of the owner of the foodstuffs are as follows:

8.3.1 In the case of imported foodstuffs that have not been irradiated,

- Apply for approval for the irradiation of the foodstuff to the Director: Food Control in consultation with the manager or designated of the proposed food irradiation installation, by submitting a completed application form **(ANNEX F)**, per irradiation class (**ANNEX B)** and per food irradiator **(ANNEX K).**
- Where applicable the necessary permit from the national DAFF must be submitted simultaneously with the application to the national DoH;
- Provide evidence of GMP;
- Provide evidence of GIP;
- Provide evidence of GHP; and
- Ensure compliance with applicable legislation including the provision of the certificate of acceptability with the application.

8.3.2 In the case of imported foodstuffs that have already been irradiated:

- Apply for aproval for the sale of such products by submitting a completed application form **(ANNEX G)** to the Director: Food Control. If approved, both the food owner and the manager of the food irradiation installation will receive letters indicating such approval (see **ANNEX I**) and stipulating the conditions to which such approval may be subject.
- Where applicable the necessary permit from the national DAFF must be submitted simultaneously with the application to the national DoH;
- Provide evidence of GMP;
- Provide evidence of GIP;
- Provide evidence of GHP; and
- Ensure compliance with applicable legislation including the provision of the certificate of acceptability with the application.
- In the case of imported foodstuffs that have already been irradiated, to supply the required certificate with the following information:
    - Name of the foodstuff/s;
    - Name and Address of the owner;
    - Name of irradiation facility and address in the country of irradiation;
    - Date of irradiation;
    - Absorbed dose; and
    - Verification by a governmental/Competent authority responsible for exportation of foodstuffs.

GIP in the case of the owner of the food would be:

- To keep records in order to ensure traceability of the irradiated foodstuffs as far as possible;
- To describe the foodstuff that is to be irradiated;
- To specify the minimum dose by doing the necessary research and providing documentation to confirm the dose;
- To apply microbiological criteria to determine if the product to be irradiated is in a suitable wholesome state and to record in this regard;
- To pre-pack the foodstuffs to be irradiated in packaging material appropriate for irradiation, of durable quality to prevent spilling or re contamination (**ANNEX K**);
- In the case of imported food, to supply proof of no previous irradiation of the foodstuff;
- Ensure correct labelling in terms of the Act.

9. CONCLUSION

The document attempts to address most of the activities when food is irradiated in South Africa. It should be considered as a guideline and should be applied as such. The guideline will need to be updated from time to time, as science and practices of food irradiation are developing continuously worldwide.

Due to better communication, a greater understanding of the valuable technology of food irradiation has developed. The advantages of irradiated food are acknowledged and accordingly irradiated foodstuffs are gaining increased acceptance by consumers. This document should therefore be another tool in increasing trust in the manner in which food irradiation is controlled in this country.

ANNEX A

CODEX ALIMENTARIUS STANDARDS

1. **GENERAL STANDARD FOR IRRADIATED FOODS** - CODEX STAN 106-1983, (Rev.1-2003)

2. **RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR THE OPERATION OF IRRADIATION FACILITIES USED FOR THE TREATMENT OF FOODS -** CAC/RCP 19-1979 (Rev. 1-1983)

ANNEX B

IRRADIATION CLASSES OF FOODSTUFFS

FOODSTUFF CLASS AND PURPOSE OF IRRADIATION	APPLICATION PROCEDURES
CLASS 1: BULBS, ROOTS, TUBERS ***Purpose of treatment:*** To inhibit sprouting during storage	Application from foodstuff owner per single food irradiation installation, renewable on a 12-month basis.
CLASS 2: FRESH FRUITS AND VEGETABLES (OTHER THAN CLASS 1) ***Purpose of treatment:*** a) To delay ripening b) Insect disinfestations c) Shelf-life extension d) Shelf-life extension	Application from foodstuff owner per single food irradiation installation and per purpose of treatment, renewable on a 12- month basis.
CLASS 3: CEREALS, MILLED CEREAL PRODUCTS, NUTS, OILSEEDS, PULSES, DRIED VEGETABLES, DRIED FRUITS and SUGAR ***Purpose of treatment*** a) Insect disinfestations b) Bacterial contamination	Application from foodstuff owner per single food irradiation installation, renewable on a 12- month basis.
CLASS 4 - RAW FISH AND SEAFOOD AND THEIR PRODUCTS (FRESH OR FROZEN), FROZEN FROG LEGS ***Purpose of treatment*** a) Reduction of certain pathogenic micro –organisms b) Shelf-life extension c) Control of infection by parasites	Every request from foodstuff owner for every purpose of treatment and every single food irradiating installation with justification for the minimum absorbed dose, accompanied by a written approval from the National Regulator for Compulsory Specifications (NRCS).
CLASS 5 - RAW POULTRY AND MEAT AND THEIR PRODUCTS (FRESH AND FROZEN) ***Purpose of treatment*** a) Reduction of certain pathogenic micro-organisms b) Shelf-life extension c) Control of infection by parasites	Every request from foodstuff owner for every purpose of treatment and every single food irradiating installation with justification for the minimum absorbed dose, accompanied by a written approval from the Department of Agriculture.
CLASS 6 - DRY VEGETABLES, SPICES, DRY HERBS AND HERBAL TEAS ***Purpose of treatment:*** a) Reduction of certain pathogenic micro - organisms b) Insect disinfestations	Application from foodstuff owner per single food irradiation installation and per purpose of treatment, renewable on a 12-month basis.

CLASS 7 – DRIED FOOD OF ANIMAL ORIGIN ***Purpose of treatment*** Insect disinfestations	Application from foodstuff owner per single food irradiation installation, renewable on a 12-months basis.
CLASS 8 – HIGH DOSE TREATMENT OF MEAT MEALS ***Purpose of treatment*** Shelf stable	Application from foodstuff owner per single food irradiation installation, renewable on a 12-month basis.
CLASS 9 – SPECIAL PHYTO SANITARY REQUIREMENTS ***Phyto-sanitary*** Honey / garlic / onions	Application from every foodstuff owner for every food irradiating installation, to be linked to the period indicated on the import permit, issued by Department of Agriculture, Fisheries & Forestry.
CLASS 10 – INTEGRATED COMBINATION PROCESSES ***Purpose of treatment:*** a) Irradiated food plus additional treatment where irradiation does not sterilize completely. b) Special microbiological concerns and where radiation does not sterilize completely. c) Radiated outside South Africa	Application from foodstuff owner per single food irradiation installation and per purpose of treatment, renewable on a 12-month basis.
CLASS 11 – IMPORTED FOODSTUFFS WITH NO SPECIAL PHYTO-SANITARY REQUIREMENTS a) Radiated outside South Africa	Application & Certificate from foodstuff owner for every consignment.

ANNEX C

QUARTERLEY REPORT OF FOODSTUFFS IRRADIATED IN TERMS OF THE REGULATION GOVERNING IRRADIATED FOODSTUFFS (R. 1600 OF 22 JULY 1993)

(TO BE COMPLETED BY THE IRRADIATION PROCESSOR)

To be send to

The Director: Food Control
Department of Health
Private Bag X828
PRETORIA
0001

Tel: 012 395 8794 / 8785
Fax: 0866321792 / 0866322942
E-mail: fouriy@health.gov.za
E- mail: dupless@health.gov.za

NAME OF IRRADIATION COMPANY	NAME OF FOODSTUFF	CLASS	QUARTER OF THE YEAR				TOTAL (KG)
			First	Second	Third	Fourth	

ANNEX D

CHECKLIST FOR MONITORING OF IRRADIATED FACILITY AND PREMISES OF FOOD OWNER BY ENVIRONMENTAL HEALTH PRACTITIONERS

The Director: Food Control
Department of Health
Private Bag X828
PRETORIA
0001

Tel: 012 395 8794 / 8785
Fax: 0866321792 / 0866322942
E-mail: fouriy@health.gov.za / dupless@health.gov.za

DETAILS OF INSPECTING OFFICER AND PREMISES	
Name of the irradiation facility	
Name of person in charge of the facility	
Name of monitoring officer (EHP)	
Name of responsible Local Authority	
Postal address of the Local Authority	
Telephone number of the Local Authority	
Fax number of the Local Authority	
E-mail address of the Local Authority	
ITEMS TO BE CHECKED	**DETAILS / COMMENTS**
1. Is the certificate of acceptability still valid?	YES / NO (if no provide reason why)
2. Number of approvals granted for irradiation since last visit.	(Provide total number)
3. List of food products for which approvals were granted since the last visit.	(Give only the type, eg. Fresh garlic, crushed garlic, honey, spices)

4. Is it possible to trace food products irradiated / to be irradiated on this day to product owner(s)?	YES / NO (if no, request written explanation from the person in charge and attach to this form
5. Are standard operating procedures still being adhered to? You will need to walk through the premises to determine this.	YES / NO (if no, request written explanation from the person in charge and attach to this form
6. On this visit, is the packaging of all food products to be irradiated in good condition (ie. not broken or torn)?	YES / NO (if no, request written explanation from the person in charge and attach to this form
7. Is the separation between un-irradiated and irradiated food products still intact and provides good separation?	YES / NO (if no, request written explanation from the person in charge and attach to this form
8. Is it easy to spot irradiated products and distinguish them from un-irradiated products?	YES / NO (if yes, describe method used for quick visual identification of irradiated products).
9. Any other comments?	
Signature of EHP conducting the inspection. Date:	Signature of person in charge Date:

ANNEX E

FOOD LABELLING REQUIREMENTS (G.N. No. R.146 of 1 March 2010)

Irradiation

Regulation 49 states that:

(1). The label of a foodstuff which has been treated with ionizing radiation shall carry a written statement indicating the treatment in close proximity to the name of the food.

(2). The use of the international recognised food irradiation symbol as illustrated by the Codex General Standard for the Labelling of Prepacked Foods, is optional, but when it is used, it shall be in close proximity to the name of the food.

(3). When an irradiated foodstuff is used as an ingredient in another foodstuff, this shall be so declared in the list of ingredients.

(4). When a single ingredient foodstuff is prepared from a raw material which has been irradiated, the label of the foodstuff shall contain a statement indicating the treatment.

ANNEX F

APPLICATION FOR THE IRRADIATION OF A FOODSTUFF IN TERMS OF THE REGULATION GOVERNING IRRADIATED FOODSTUFFS (R1600 OF 22 JULY 1993)

Application to be submitted to:

The Director: Food Control
Department of Health
Private Bag X828
PRETORIA
0001

Tel: 012 395 8794 / 8785
Fax: 0866321792 / 0866322942
E-mail: fouriy@health.gov.za
E- mail: dupless@health.gov.za

A. To be completed by the food owner (food manufacturer)

DETAILS	SECTION TO BE COMPLETED
Name of Applicant	
Physical Address of Applicant	
Postal Address of Applicant	
Telephone Number	
Facsimile Number	
E-mail Address	
Name of Contact Person	
Name of Foodstuff	
Foodstuff Class	
Purpose of Irradiation	
Copy of Phyto Sanitary Permit In Case of Class 9	
Proposed Minimum Dose	
Signature of Owner	
Date	
Copy of Certificate of Acceptability	

B. To be completed by the Manager of the Food Irradiation Installation

DETAILS	SECTION TO BE COMPLETED
Name of Food Irradiation Installation	
Foodstuff to be Irradiated	
Contact Name	
Name of Manager	
Signature of Manager	
Date	

FOR CONDITIONS, PLEASE CONSULT THE FOODSTUFFS, COSMETICS AND DISINFECTNATS ACT, 1972(ACT 54 OF 1972), THE REGULATIONS GOVERNING IRRADIATED FOODSTUFFS (R1600 OF 22 JULY 1993), THE REGULATIONS GOVERNING THE LABELLING AND ADVERTISING OF FOODSTUFFS (R 146 OF 1 MARCH 2010) AND THE GUIDELINES FOR MONITORING IRRADIATED FOODSTUFFS IN SOUTH AFRICA

ANNEX G

APPLICATION FOR THE IMPORT OF IRRADIATED FOODSTUFFS IN TERMS OF THE REGULATION GOVERNING IRRADIATED FOODSTUFFS (R1600 OF 22 JULY 1993)

Application to be submitted to:

The Director: Food Control
Department of Health
Private Bag X828
PRETORIA
0001

Tel: 012 395 8794 / 8785
Fax: 0866321792 / 0866322942
E-mail: fouriy@health.gov.za
E- mail: dupless@health.gov.za

C. To be completed by the food Importer

DETAILS	SECTION TO BE COMPLETED
Name of Applicant	
Physical Address of Applicant	
Postal Address of Applicant	
Telephone Number	
Facsimile Number	
E-mail Address	
Name of Contact Person	
Name of the Foodstuff	
Foodstuff Class	
Purpose of Irradiation	
Absorbed dose	
Copy of Certificate confirming irradiation from exporting country (Verification by a governmental/competent authority responsible for exportation of foodstuffs).	
Signature of Importer	
Date	
Copy of Certificate of Acceptability	

FOR CONDITIONS, PLEASE CONSULT THE FOODSTUFFS, COSMETICS AND DISINFECTNATS ACT, 1972(ACT 54 OF 1972), THE REGULATIONS GOVERNING IRRADIATED FOODSTUFFS (R1600 OF 22 JULY 1993), THE REGULATIONS GOVERNING THE LABELLING AND ADVEDRTISING OF FOODSTUFFS (R146 OF 1 MARCH 2010) AND THE GUIDELINES FOR MONITORING IRRADIATED FOODSTUFFS IN SOUTH AFRICA

ANNEX H

(On official letterhead of government only)

Import Permit Number (where applicable)	Date Issued	Expiry Date	Validity of Approval	Approval Number

FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, 1972 (ACT 54 OF 1972): APPLICATION FOR THE UNLIMITED SALE OF IRRADIATED FOODSTUFFS

Your application dated ……. refers.

Pursuant to Government Notice No. R.1600 of 22 July 1983, promulgated under section 15(1) of the Foodstuffs, Cosmetics and disinfectants Act (Act 54 of 1972), approval is granted to:
Foodstuff owner (Name and address): …….

to sell the foodstuff……..; irradiation Class…….

The approval is subject to the strict adherence to the following conditions:

1. The radiation shall be performed in the facility of …….
2. The purpose for the irradiation of the foodstuff is …….
3. The foodstuffs must comply with all the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), both before and after radiation.
4. Premises from which food is manufacture and prepared must comply with relevant provisions of the Health Act, (Act No. 63 of 1977).
5. Irradiation shall be conducted as described in the Guidelines for Monitoring Irradiated Foodstuffs in South Africa
6. The …….. must be irradiated at a D-min of at least …….. kGy
7. Additional conditions as deemed necessary.
8. In the case of foodstuffs falling under irradiation class 9, this approval is linked to validity of permit as indicated above.
9. Labelling: All packages must be labelled as depicted by the Regulations governing the Labelling and Advertising of Foodstuffs (GN. No. R.146 of 01 March 2010), promulgated under the Act.

DIRECTOR-GENERAL
DATE:

ANNEX I

(On official letterhead of government only)

Import Permit Number (where applicable)	Date Issued	Expiry Date	Validity of Approval	Approval Number

FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, 1972 (ACT 54 OF 1972): APPLICATION FOR THE UNLIMITED SALE OF IRRADIATED FOODSTUFFS

Your application dated ……. refers.

Pursuant to Government Notice No. R.1600 of 22 July 1983, promulgated under section 15(1) of the Foodstuffs, Cosmetics and disinfectants Act (Act 54 of 1972), approval is granted to:
Foodstuff owner (Name and address): …….

to sell the foodstuff……..; irradiation Class…….

The approval is subject to the strict adherence to the following conditions:

1. The radiation was performed in the facility of …… in …….(country)
2. The purpose for the irradiation of the foodstuff was ……
3. The foodstuffs must comply with all the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).
4. Premises to which food is transported/ prepared/ packaged/ stored, must comply with relevant provisions of the Health Act, (Act No. 63 of 1977).
5. Irradiation shall be conducted as described in the Guidelines for Monitoring Irradiated Foodstuffs in South Africa.
6. The ……. was irradiated at a D-min of at least …….. kGy
7. Additional conditions as deemed necessary.
8. In the case of foodstuffs falling under irradiation class 9, this approval is linked to validity of permit as indicated above.
9. Labelling: All packages must be labelled as depicted by the Regulations governing the Labelling and Advertising of Foodstuffs (GN. No. R.146 of 01 March 2010), promulgated under the Act.

DIRECTOR-GENERAL
DATE:

ANNEX J

CHECKLIST FOR MONITORING BY NATIONAL DEPARTMENT OF HEALTH

ITEMS TO BE CHECKED		RESPONSIBLE AUTHORITY
Owner of irradiating facility		**N**
License to operate an irradiation facility		**RC**
Permission to irradiate food		**FC**
Management: Line of command		**N**
Personnel:	Qualifications	**N**
	Experience	**N**
	In house training	**N**
Safety	Occupational	**RC**
	Radiation	**RC**
Facility Log book	Name of product	**N**
	Log book record number (Batch / lot / consignment identified by a unique reference number)	**N**
	Owner/Address of product	**FC**
	Requested dose	**N**
	Measured dose	**N**
	Dose measurement reference number	**N**
	Date and time of treatment	**N**
	Special observations including any deviation from standard operation	**N**
	Signature of personnel in charge (operator, dose measurer, loader)	**N**
Dosimetry	Dummy product (run/product itself)	**N**
	Routine dose measurement vs reference position	**N**

Dose distribution mapping	Dose pattern	Geometry (arrangement of product relative to the source, density and geometric shape of goods, kinds and composition of the goods)	**N**
		Loading pattern (conveyor, trays, carriers, pallets, tote boxes)	**N**
		Operation mode (inner/outer rail, repeated passes, turning of packages before second pass)	**N**
Dosimetry	Calibration of dose metre (product equivalence / type of radiation)		**N**
Dose meter selection	Trace ability (unbroken chain / national of international standard)		**N**
	Calibration (dose measurement instruments)		
	Maintenance of dose (measurement instrumentation)		
	Storage of dose metre stocks		
Actual dose measurements	Reference number of dose metres		**N**
	Raw data		
	Correction of raw data (thickness, temperature, outliers)		
	Conversion of raw data into dose values (calibration curve, statistical properties of data)		
Monitoring of approvals			**FC**

FC Food Control
N Both Food Control and Radiation Control
RC Radiation Control

ANNEX K

LIST OF FOOD IRRADIATION FACILITIES IN SOUTH AFRICA AND THE LOCAL AUTHORITIES IN WHOSE AREA OF JURISDICTION THE FACILITIES ARE LOCATED

HEPRO CAPE (PTY) LTD

CONTACT:	DR R BASSON	OR	CHERIN BALT
POSTAL ADDRESS:	SUITE 124		6 FERRULE AVENUE
	P/BAG X7		MONTAGUE GARDENS
	CHEMPET		CAPE TOWN
	7442		8001

TEL: (021) 555-8880
FAX: (021) 551-1766
hepro@iafrica.com

RELEVANT PROVINCIAL OFFICE

CONTACT:	MR E BONZET
POSTAL ADDRESS:	P O BOX 6489
	ROGGEBAAI
	8012

TEL: (021) 421 1124
FAX: (021) 418 5685
ebonzet@pgwc.gov.za

RELEVANT LOCAL AUTHORITY

CONTACT:	MR L CILLIE
POSTAL ADDRESS:	BLOUBERG ADMINISTRATION
	CITY OF CAPE TOWN
	P O BOX 35
	MILNERTON
	7441

TEL: (021) 550 7521
FAX: (021) 550 7537
leon.cillie@capetown.gov.za

ISOTRON (PTY) LTD

CONTACT:	MR G C V VON KETELHODT
POSTAL ADDRESS:	P O BOX 3219
	KEMPTON PARK
	1620

TEL: (011) 974-8851
FAX: (011) 974-8986
g.von.ketelhodt@gammaster.co.za

RELEVANT PROVINCIAL OFFICE

CONTACT: MR ALBERT MARUMO
POSTAL ADDRESS: ENVIRONMENTAL HEALTH SERVICES
GAUTENG PROVINCIAL HEALTH
PRIVATE BAG X62302
MARSHALLTOWN
2107
TEL: (011) 355 3479
FAX: (011) 355 3171

RELEVANT LOCAL AUTHORITY

CONTACT: MR J CHAKA
ADDRESS: EKURHULENI METROPOLITAN MUNICIPALITY
LEVEL 6 ALBERTON CIVIC CENTRE
ALWAYN TALJAARD STREET
ALBERTON
TEL: (011) 861 2291
FAX: (011) 421 4221
jerryc@ekurhuleni.com

CONTACT: MR B COETZEE
POSTAL ADDRESS: ENVIRONMENTAL HEALTH SERVICES
NORTHERN SERVICE DELIVERY REGION
EKURHULENI METROPOLITAN MUNICIPALITY
P O BOX 13
KEMPTON PARK
1620
TEL: (011) 921 2443/2475
FAX: (011) 394 0396
Braamc@ekurhuleni.com

GAMWAVE (PTY) LTD

CONTACT: MR D T GOVE
POSTAL ADDRESS: P O BOX 26406 PHYSICAL ADDRESS: 19 AVENUE EAST
ISIPINGO BEACH ISIPINGO BEACH
4115
TEL: (031) 902 8890
FAX: (031) 912 1704
Dale.gove@robertsons.co.za

RELEVANT PROVINCIAL OFFICE

CONTACT: MS AP HARGREAVES
POSTAL ADDRESS: PROVINCE OF KWAZULU-NATAL HEALTH SERVICES
Environmental Health Services
Private Bag X9052
Pietermaritzburg
3200

TEL: (033) 846 7510
FAX: (033) 846 7272
Antoinette.hargrieves@kznhealth.gov.za

RELEVANT LOCAL AUTHORITY

CONTACT: MR J GUMEDE
POSTAL ADDRESS: ETHEKWINI MUNICIPALITY
ENVIRONMENTAL HEALTH
Food Control

TEL: (031) 3113500
FAX: (031) 311 3576
gumedej@durban.gov.za OR salikrams@durban.gov.za

ANNEX L

PACKAGING MATERIALS APPROVED FOR USE IN THE IRRADIATION OF PREPACKAGED FOODS (SPICES AND CONDIMENTS)

Material	***Maximum overall average dose (kGy)***
Hessain sacks	**10**
Woven polypropylene sacks	**10**
Multiply paper sacks	**10**
Multiply paper sacks with polyethylene lining	**10**
Polyethylene coated multiply paper sacks	**10**
Cardboard cartons with polyethylene liners	**10**
Cardboard kegs	**10**

(Adapted from UK requirements)