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**GUIDELINES FOR THE AUTHORIZATION
OF FOOD IRRADIATION
GENERALLY OR BY CLASSES OF FOOD**

***INTERNATIONAL CONSULTATIVE GROUP ON FOOD IRRADIATION
(ICGFI)***

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INTERNATIONAL CONSULTATIVE GROUP ON FOOD IRRADIATION
(ICGFI)

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ICGFI is an International group of experts designated by Governments to evaluate and advise on global activities in food irradiation

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GUIDELINES FOR THE AUTHORIZATION OF FOOD IRRADIATION GENERALLY OR BY CLASSES OF FOOD

1. Introduction

It is generally accepted that it is right and proper for the process of food irradiation to be under the control of national authorities; indeed, the licensing and registration of food irradiation facilities, the justification of the application of the process and the need to follow good irradiation practices are mandatory requirements of the Codex General Standard for Irradiated Foods (2).

Guidelines for Preparing Regulations for the Control of Food Irradiation Facilities (4) and an Inventory of Authorized Food Irradiation Facilities (21) were, therefore, published by the International Consultative Group on Food Irradiation (ICGFI) in 1991, together with several Codes of Good Irradiation Practices for a number of types of food (22).

The present Guidelines are focussed on authorization of the irradiation of *food*, whereas the ICGFI Guidelines for Preparing Regulations for the Control of Food Irradiation Facilities deals with the regulatory control and authorization of irradiation *facilities*. The two documents are intended to complement one another in achieving a sound framework of regulatory control over the food irradiation process.

The present Guidelines, like all ICGFI recommendations, take full account of the Codex General Standard for Irradiated Foods and the Recommended International Code of Practice for the Operation of Irradiation Facilities used for the Treatment of Food (1,2) and are based on the principle that "irradiation of any food up to an overall average dose of 10 kGy presents no toxicological hazard; hence toxicological testing of foods so treated is no longer required" (14) and that irradiation is justified only when it fulfils a technological need or when it serves a food hygiene purpose .

2. Purpose of the Guidelines

The purpose of the present Guidelines is to provide advice to governments on the regulatory control of foods subject to irradiation treatment (i.e. to grant authorizations to irradiate food or to allow the import and sale of irradiated food generally or on the basis of classes of food products, rather than on the basis of individual food items (see Annex 2).

It is hoped that compliance with the present Guidelines will help to eliminate or reduce non-tariff trade barriers resulting from regulatory disharmony, and will thus facilitate international trade in irradiated food products.

It is also anticipated that a general clearance or clearance of whole classes of foods will reduce the amount of scientific and administrative effort needed to process multiple applications, where closely related foods with similar chemical composition are treated to achieve the same technological objective, thus benefitting the industry, government and consumers.

The Guidelines are without prejudice to the nature of existing national and legal frameworks under which food irradiation is authorized, including those additional measures deemed to be necessary on a product-by-product or facility-by-facility basis in order to control the process.

3. General Authorization of Food Irradiation

One option for the regulatory control of food irradiation is to authorize the application of the process generally to any food up to an average absorbed dose of 10 kGy, which is the maximum dose of absorbed radiation recommended by the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food (14) and reflected in the Codex General Standard for Irradiated Foods (see Section 1).

This general approach allows for further controls to be exercised, according to national regulations, in order to enforce good irradiation practices and assure that irradiated products meet other applicable food law and quarantine requirements. These may include, among other, the issue of:

- (a) codes of good irradiation practices (eg. those issued under the ICGFI DOCUMENTS series, Ref. 22);
- (b) mandatory requirements for minimum absorbed doses by all parts of a consignment of food, where this is deemed necessary;
- (c) a detailed mandatory protocol for quarantine treatment and control procedures for groups of produce; and
- (d) advisory or mandatory microbiological product specifications for certain groups of food intended for irradiation treatment.

4. Authorization of Food Irradiation on the Basis of Food Classes

While a general authorization of food irradiation as outlined in Section 3, is the simplest regulatory approach, this may not be possible under the particular national legislative system of individual countries. In these cases, a more restrictive, but still flexible regulatory control based on the authorization of the irradiation of classes of food as outlined below may be possible. Annex 1 contains a list of information and conditions to be included in an authorization to irradiate classes of food.

4.1 Criteria for Authorization on the Basis of Food Classes

The following criteria have been used in drawing up the classes of food for the purpose of authorization:

- (a) There should be similarities, in kind and composition, between the food products included in each class, and the classification should take this into account.
- (b) Authorization of irradiation of classes of food is only possible where the treatment is intended or has the potential to achieve an identical technological or food hygiene purpose for all the foods in the class.
- (c) The radiation doses necessary to achieve the objective (e.g. shelf-life extension, reduction of certain pathogenic microorganisms, etc.) should be comparable for each food product included in the class, and the consequences of irradiation on sensoric quality should also be similar.

5 Associated Conditions for Authorization by Food Classes

5.1 The Principle of Justifiable Need

Even if the concept of general authorization or authorization on the basis of food classes is adopted generally, it is to be expected that countries will have different needs to irradiate the individual foods included in a food class, or to import them.

In order to ensure that irradiation is only used when there is a technological need to be fulfilled or a food hygiene purpose to be served, a provision to this effect can be included in national regulations based on a general clearance or authorizations by classes of foods.

Countries may also opt for additional administrative arrangements involving a more direct control of food irradiation and the importation of irradiated foods (eg. issue of specific licences). It is to be expected that, even though under the regulations the justification to irradiate a particular class of foods is recognized, commercial, technical and economic factors will influence the practical need for irradiation processing of individual food products. This is the case also with other methods of food processing.

5.2 Good Manufacturing and Irradiation Practices

Other conditions to be specified in regulations include the need to observe Good Manufacturing Practices before, during and after treatment, Good Irradiation Practices, as well as compliance with all relevant national or international food standards and hygiene regulations (e.g. Codex Standards, Codex Codes of Hygienic Practice and Codes of Good Irradiation Practice issued under the ICGFI Document Series). The Codex recommendations on re-irradiation should also be given statutory effect.

It should be recognized that the application of Good Manufacturing and Good Irradiation Practices is the responsibility of the food industry and of food irradiators under the control of

the competent national food control and inspection services. Regulatory approval (authorization) of the general application of irradiation or application to classes of food does not detract from this responsibility.

6. Dose Limits

6.1 General Requirements

Although only one statutory dose limit is sufficient for reasons of food safety (an overall average dose of 10 kGy) as outlined in Section 3, it is currently common practice for authorizations to limit the applied dose to that needed to achieve the desired technological objective. In some applications, e.g. food hygiene or plant quarantine, it also may be necessary to specify a minimum dose which the food must receive. Appropriate dose limits for such applications may also be included in general authorization of food irradiation or authorization by classes of food.

Maximum dose limits included in national authorizations are sometimes specified as "average" or "overall average" (with or without limitation of min/max ratios and without clearly specifying the size of the sample for the determination of such averages), or expressed as ranges. The exact meaning of dose limits is not always defined. It is necessary to ensure in the authorizations that the meaning of dose limits is clearly defined and is suitable for enforcement under official control. It is also desirable to harmonize dose limits in the interest of facilitation of international trade. It is expected that it would be more feasible to harmonize general limits rather than a multitude of individual limits.

It should be pointed out that the "overall average" dose limit of 10 kGy recommended by the Joint FAO/IAEA/WHO Expert Committee (WHO, TRS 659, Geneva 1981) and adopted by the Codex Alimentarius Commission (see Codex General Standard, Section 1). represents the maximum dose which has been found in wholesomeness and other studies to be acceptable. Dose limits set for technological purposes should be laid down on the basis of data from appropriate studies demonstrating the effectiveness of the process reflecting Good Irradiation Practices under practical conditions. Such limits should, therefore, facilitate the application of Good Irradiation Practices and should not be regarded as limits which, if exceeded, render the food unfit for consumption. They should only be advisory, except possibly for minimum doses specified in certain applications such as treatment for public health or for quarantine control purposes.

6.2 Advisory Limits in Annex 2

The maximum dose limits suggested in Annex 2 are advisory umbrella limits intended for the purposes of harmonization and, therefore, facilitation of international trade in irradiated food. In practice, the actual radiation doses employed will be determined by application of Good Irradiation Practice, and it will in many instances be possible or necessary to use doses lower than the maximum figures quoted. Exceeding these technological limits does not mean that the food is unsafe or unfit for human consumption; however, its quality may be partially impaired.

The advisory technological dose limits suggested in Annex 2 are not expressed as averages, i.e. they require that no part of the food should receive doses higher than that specified. However, the dose limit of 10 kGy for dried vegetable materials (Class 6) is being suggested as an average to reflect the maximum overall average dose of 10 kGy recommended in the Codex General Standard for Irradiated Foods (see Section 1 above) and to allow for an effective treatment, including doses up to 15 kGy for a portion of the food to be irradiated.

7. Classification of Foodstuffs for the Purpose of Authorizing Irradiation by Food Classes

One of the primary objectives of authorization by food classes is the facilitation of international trade in irradiated foods. It would, therefore, be desirable if every government which adopts the principle of authorization by food classes would follow the same system of classification.

The classes of food in Annex 2 by which irradiation is suggested to be authorized has been drawn up taking account of the criteria for grouping foods into classes referred to in Section 4.1 above. This classification is not intended for the harmonization of existing systems of food classification drawn up for trading or food standards purposes. The classification has been sub-divided according to the various technological needs within each class. For an explanation of the dose limits recommended for each type of application within each class see Section 4.2.

The classes of food included in Annex 2 are composed of groups of food which may require definition. A food classification developed by the Secretariat of ICGFI for the computerization of existing national authorizations of applications of food irradiation, could be used for this purpose.

**INFORMATION AND CONDITIONS TO BE INCLUDED
IN AN AUTHORIZATION
TO IRRADIATE A CLASS OF FOOD**
(see Sections 3 and 4)

1. Description of the class of food.
2. Purpose(s) for which irradiation is authorized.
3. Technological dose limits appropriate to each purpose, (maximum and, if appropriate, minimum, with indication whether average; and if average, reference to the size of the sample to be taken for verification), together with a statement that the overall average dose must not exceed 10 kGy.
4. Specification of the type or types of ionizing radiation which may be used.
5. Authorization of irradiation only in a facility licensed and registered for this purpose by the competent national authority.
6. Authorization of irradiation only to fulfil a technological need, or to serve a food hygiene purpose as appropriate.
7. Specification of initial quality of food to be irradiated and requirements to comply with Good Manufacturing Practices before, during, and after irradiation treatment and with Good Irradiation Practices (see also the report of the Consultation on Microbiological Criteria for Foods to be further processed, including by Irradiation (ref. 20).
8. Authorization of re-irradiation only under specified conditions (Ref. Codex General Standard).
9. Specification of packaging, labelling and documentation requirements.
10. Date and period of validity of authorization.
11. Name of issuing authority.
12. Specification of provisions for the importation of irradiated food.

**AUTHORIZATION OF IRRADIATION BY CLASSES OF FOOD
AND ADVISORY TECHNOLOGICAL DOSE LIMITS**
(see Section 6)

FOOD CLASS AND PURPOSE OF IRRADIATION	DOSE (kGy) minimum maximum
<p>CLASS 1 - BULBS, ROOTS AND TUBERS</p> <p><i>Purpose of treatment:</i> to inhibit sprouting during storage</p>	<p>0.2</p>
<p>CLASS 2 - FRESH FRUITS AND VEGETABLES (other than Class 1)</p> <p><i>Purpose of treatment:</i></p> <p>a) To delay ripening</p> <p>b) Insect disinfestation</p> <p>c) Shelf-life extension</p> <p>d) Quarantine control</p>	<p>1.0</p> <p>1.0</p> <p>2.5</p> <p>(*) 1.0</p>
<p>CLASS 3 - CEREALS, MILLED CEREAL PRODUCTS, NUTS, OILSEEDS, PULSES, DRIED VEGETABLES, AND DRIED FRUITS</p> <p><i>Purpose of treatment:</i></p> <p>Insect disinfestation</p>	<p>1.0</p>

<p>CLASS 4 - RAW FISH AND SEAFOOD AND THEIR PRODUCTS (FRESH OR FROZEN), FROZEN FROG LEGS</p> <p><i>Purpose of treatment:</i></p> <p>a) Reduction of certain pathogenic microorganisms</p> <p>b) Shelf-life extension</p> <p>c) Control of infection by parasites</p>	<p>(*) 5.0</p> <p>3.0</p> <p>(**) 2.0</p>
<p>CLASS 5 - RAW POULTRY AND MEAT AND THEIR PRODUCTS (FRESH AND FROZEN)</p> <p><i>Purpose of treatment:</i></p> <p>a) Reduction of certain pathogenic microorganisms</p> <p>b) Shelf-life extension</p> <p>c) Control of infection by parasites</p>	<p>(*) 7.0</p> <p>3.0</p> <p>(**) 3.0</p>

<p>CLASS 6 - DRY VEGETABLES, SPICES, DRY HERBS AND HERBAL TEAS</p> <p><i>Purpose of treatment:</i></p> <p>a) Reduction of certain pathogenic microorganisms</p> <p>b) Insect disinfestation</p>	<p>(*) 10.0(#)</p> <p>1.0</p>
<p>CLASS 7 - DRIED FOOD OF ANIMAL ORIGIN</p> <p><i>Purpose of treatment:</i></p> <p>Insect disinfestation</p>	<p>1.0</p>

(*) Minimum dose may be specified for particular pests. Generally fruit fly (0.15 kGy) (see ICGFI Document No. 7).

(**) Minimum dose may be specified bearing in mind the objective of the treatment to ensure the hygienic quality of the food (see ICGFI Document No. 4 and 5).

(#) Expressed as *overall average dose* as recommended and defined in the Codex General Standard for Irradiated Foods (ie. a mass fraction of at least 97.5% of the product should receive an absorbed dose of less than 15 kGy, when the overall average is 10 kGy). In practice, food irradiators will apply appropriate ranges of dose required by good irradiation practice in accordance with the principles of the Codex General Standard and its associated Code (see Section 1).

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