FOOD IRRADIATION: SOME REGULATORY AND TECHNICAL ASPECTS

REPORT OF AN FAO/IAEA ADVISORY GROUP MEETING ON REGULATORY AND TECHNOLOGICAL REQUIREMENTS FOR AUTHORIZATION OF THE FOOD IRRADIATION PROCESS HELD IN VIENNA, 5–9 NOVEMBER 1984

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REPORT

1. INTRODUCTION

The adoption by the Codex Alimentarius Commission of a revised general standard for irradiated foods (Ref. 1) and of a code of practice for the operation of radiation facilities used in the treatment of foods (Ref. 2), their issue to Governments for implementation and the action by various Governments concerning the authorization of the food irradiation process has necessitated the convening of an Advisory Group by TAEA and FAO on Regulatory and Technological Requirements for Authorization of the Food Irradiation Process.

The Advisory Group was held at IAEA Headquarters in Vienna from 5 to 9 November 1984. The meeting was opened by Prof. M. Zifferero, Deputy Director General of the Department of Research and Isotopes, TAEA. Drs. L.G. Ladomery and J. Farkas represented the Food and Agriculture Organization of the United Nations (FAO) and the International Facility for Food Irradiation Technology (IFFIT), respectively. The Secretariat consisted of Messrs. J.G. van Kooij of IAEA and L.G. Ladomery of FAO. Prof. Dr. P.S. Elias and Mr. W.R. Bradford acted as rapporteurs. The meeting was chaired by Mr. R.H. McKay assisted by Messrs. F. Ley and Prof. Dr. E.H. Kampelmacher, acting as chairmen of working groups dealing with regulatory and technical questions respectively. A complete list of participants is attached.

2. BACKGROUND INFORMATION

In 1983 the Joint FAO/WHO Codex Alimentarius Commission adopted a revised General Standard for Irradiated Foods (Ref. 1) on the basis of the conclusions of the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Foods (Ref. 3) and following advice by a Consultation Group jointly organized by the Food and Agricultural Organization of the United Nations, the International Atomic Energy Agency and the World Health Organization (Ref. 4) and on the recommendation of the Codex Committee on Food Additives (Ref. 5). The Commission also adopted a revised Code of Practice for the Operation of Radiation Facilities (Ref. 2).
The Codex General Standard refers only to those aspects which relate to the processing of foods by ionizing energy. It incorporates the views of the Joint FAO/IAEA/WHO Expert Committee (Ref. 3) that the process of food irradiation has been established as safe for general application to food up to an overall average level of absorbed dose of 10 kGy. It also recognizes that irradiated food, like any other food, will be subject to general food regulations and standards relating to such aspects as quality, hygiene, weights and measures and chemical contaminants.

In the light of these developments and recognizing the utility of the food irradiation process, some Governments are taking action to regulate the process. However, such actions by Governments appear to be taken in a way which could lead to a lack of harmonization in the regulatory approach and, hence, to the establishment of barriers to trade. Other Governments are not taking action to regulate the use of ionizing energy in connection with food and the marketing of irradiated foods. It is in the light of these developments that the Advisory Group was convened.

3. TERMS OF REFERENCE

The task of the Advisory Group was to advise on the scientific and technological considerations affecting the implementation of the food irradiation process, with particular reference to the facilitation of international trade in irradiated foods and to develop guidance on how the various provisions of the Codex General Standard on Irradiated Foods could be incorporated into national legislation in order to facilitate international trade and avoid the occurrence of trade barriers.

4. TECHNOLOGICAL BENEFITS OF FOOD IRRADIATION

One benefit which would stem from the introduction of food irradiation lies in the field of public health and especially in the prevention of foodborne diseases. In many countries, economic considerations also favour introduction of the process for purposes such as extension of the keeping qualities of certain foods and the satisfaction of quarantine requirements for imported foods. There are further health implications
where irradiation is proposed as an alternative to the present use of chemicals such as ethylene dibromide, ethylene oxide, and methyl bromide.

The potential economic advantages of food irradiation to developing countries fall into two categories: firstly the reduction of post-harvest losses in food produced for home consumption, and secondly the opportunity which it would offer for increasing food exports to other countries with the consequent economic advantages which would ensue. These applications are likely to be considered worthy of support by national and international agencies.

In many developing countries, the obstacles towards progress in the full scale use of food irradiation are much more concerned with the lack of facilities and expertise than is the case with developed countries. The important contribution which can be made by regional coordinated research and development programmes was recognized in the establishment of technological procedures for irradiated food products common to a number of neighbouring countries. At the same time, maintenance of the role of IFFIT in providing a global service of information and training in irradiation technology was considered to be particularly desirable. In order to assist further in the introduction of sound irradiation practice in developing countries, it was considered that IAEA should continue the preparation and publication of technological guidelines for major food commodities. It was recognized that a necessary adjunct to the use of such guidelines would be the existence of an infrastructure supporting food control services.

5. IMPEDIMENTS TO APPLICATION OF THE PROCESS

The barriers which impede the implementation of the food irradiation process in the industrialized nations often differ in kind or importance from those which concern developing countries. This is due to the fact that the potentially most useful applications of the process tend to differ markedly between developed and developing nations, with the result that the resulting benefits are likewise different. Nevertheless, some important matters of principle are common to both groups of countries, and these are considered first.
The disharmony of existing legislation on food irradiation and the general absence of legislation which would permit the widespread introduction of food irradiation together constitute one of the most significant obstacles to be overcome.

Another major obstacle to the introduction of food irradiation in both developed and developing countries was considered to be the lack of knowledge about the process on the part of governments, processors and the public. There was, therefore, a vital need for the dissemination of factual information, and the role of various agencies in fulfilling this need was discussed.

It was noted that, while international organizations and some government agencies had adopted a policy of strict impartiality, other national authorities had a statutory duty to encourage the adoption of this beneficial technology. It was also recognized that commercial interests had an important part to play in educating the consumer, either individually or collectively through trade associations. Achievement of cooperation between governmental agencies, processors and consumers associations was considered to represent the ideal situation.

The proposed initiative by the World Health Organization (WHO), supported by FAO and IAEA, to publish an information booklet on the subject of food irradiation was noted with approval. The Advisory Group also considered that the preparation of an educational film along similar lines would be of great value, and expressed the hope that means would be found to produce such a film.

6. REGULATORY APPROACHES

6.1. Introduction

Irradiated foods do not differ from other foods except that they have been subjected to a physical treatment for preservation, plant quarantine or for public health purposes. The Advisory Group emphasized that other standards and regulations relevant to food were also applicable to irradiated food, although this fact was not explicitly stated in the Codex General Standard. This was considered particularly important because the irradiation treatment is, by its very nature, not discernable to the consumer from the appearance of the treated food.
6.2 Essential Features of the Codex General Standard for Irradiated Foods

Two main features were considered of importance in the Codex General Standard: (a) the limitation on the choice of the radiation source and (b) the limitation on the dose to be applied to the food.

(a) Source of Radiation

The selection of the four sources in the Codex General Standard is governed by the necessity that there be no induced radioactivity in the treated food. The Group recommended that this provision of the General Standard be made a mandatory part of any governmental regulation.

(b) Irradiation Dose to be applied

The Codex General Standard also recommends that the overall average dose of radiation absorbed by the food should not exceed 10 kGy. This value was recommended by the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Foods (JECFI) (Ref. 3) because adequate nutritional, microbiological and toxicological data existed to judge food so treated to be wholesome. This does not imply that irradiation at higher doses would necessarily render the food toxic. In order to facilitate the practical application of the process and the enforcement of compliance, the Advisory Group felt that the overall average absorbed dose, as stated in the Codex General Standard, should be made mandatory supplemented also by stating a maximum limiting dose. The Advisory Group, therefore, recommended that a dose of 15 kGy be regarded as a mandatory maximum radiation dose which any part of the food should be allowed to receive. The choice of this maximum limiting dose is based on the recommendations of JECFI regarding the acceptable dose ratios in food irradiation processing.

In the opinion of the Advisory Group, opportunities must be provided for the amendment of the source selection and of the overall average and maximum limiting doses, in the light of future developments in the field of radiation source technology and the appraisal of further wholesomeness data.
(c) Application of the Process - Specification of Irradiation Parameters

The Advisory Group was of the opinion that the specific doses would be chosen in the light of the technical effects intended to be achieved. Any process would have to comply with existing national or international requirements. In practice, doses higher than technically necessary would be unlikely to be used since they would be uneconomical and sometimes detrimental to the organoleptic or technological properties of the treated foods.

Consideration was, therefore, given to the need, or otherwise, for a mandatory specification of the technological objectives of food irradiation, and of the parameters for irradiation of individual food commodities. It was concluded that the existence of such specifications would neither assist materially the implementation of the process, nor would it be feasible to define these parameters in ways that would be universally applicable. Nevertheless, it would be appropriate to include practical advice on the establishment of irradiation parameters in the guideline documents referred to in paragraph 4 above. The Advisory Group recommended that both the overall average absorbed dose and the maximum absorbed dose be recorded in the documents relating to the irradiated food.

(d) Definition of acceptable hygienic conditions

It was noted that the Codex General Standard for Irradiated Foods included a requirement (see Section 4.2) that food to be irradiated shall be of acceptable hygienic condition before irradiation. The Advisory Group considered that the intention of this requirement was that the general quality of the food should be acceptable and in accordance with good manufacturing practice prior to irradiation, so that irradiation would not be used to make a food acceptable which had been of an overall poor quality initially. This topic could be further elaborated in the guideline document referred to in paragraph 4 above.

(e) Detection of irradiated foods

The Advisory Group discussed the question of detecting whether a food had been irradiated, particularly in the light of the fact that a universal method, or group of methods, for detecting irradiated
foods was not at present available. It was agreed that the existence of a reliable and comprehensive method of detection would be of assistance in establishing a system of legislative control, and would, therefore, overcome some of the obstacles to the introduction of the process.

On the other hand, it was considered that the current absence of such a detection method should not prejudice progress towards wider implementation, since methods of certification and licensing are available to control the process.

(f) Control of the Process

The Advisory Group explored the possibility of an international authority being set up for the coordination of inspection of food irradiation facilities for the purpose of licensing and registration of facilities and proper application of the process. It concluded that such an international mechanism would not be practicable, except in relation to regional multilateral agreements, and suggested that IAEA look into the question of issuing a register of facilities licensed for the irradiation of food.

As regards the control of the process of irradiation, it was considered desirable for the FAO Manuals on Food Control to include appropriate information on food irradiation, to be supplied by IAEA, with reference to existing IAEA publications, such as manuals and technical guidelines.

(g) Licensing Food Irradiation Facilities - Technological Requirements

The question was raised as to whether there were any technological requirements for food irradiation facilities which should be made conditional for licensing. The Advisory Group felt that such considerations would be adequately covered by a requirement to comply with the provisions of the Codex General Standard for Irradiated Foods. Existing standards for food processing facilities would also be applicable and would be sufficient to ensure the hygienic quality of food passing through the irradiation facility.
(h) Labelling

The Advisory Group discussed the Codex General Standard on Irradiated Foods and the draft Codex General Standard for the Labelling of Prepackaged Foods. It noted the view of the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Foods that it was not necessary, for scientific reasons, to envisage special labelling requirements for irradiated foods. The Advisory Group saw no reason to differ from this conclusion. However, the Advisory Group agreed that there were sound technological grounds that manufacturers be informed when raw materials and other ingredients had been irradiated. Moreover, the Advisory Group noted that it was a matter of fact that governments may require a special declaration on the label of prepackaged foods as a response to consumer demand for information, or in analogy with the declaration of other forms of processing, such as drying, freezing, concentration or smoking. Nevertheless, such labelling declarations should not be made mandatory as a condition of acceptance of the General Standard for the Labelling of Prepackaged Foods (in the process of revision) (Ref. 7). A decision on the need to label such food should be left to national authorities rather than be made a mandatory consequence of irradiation.

The Advisory Group was of the opinion that irradiated foods present in processed food products should not be so declared on the label, unless such foods were present in amounts which would characterise the product. Considering the difficulties of enforcement, the Advisory Group also noted that labelling provisions relating to irradiated ingredients would be of little value.

(i) Clearance of the Irradiation Process

The Advisory Group recommended that governments should be encouraged to accept and implement the Codex General Standard for Irradiated Foods with its particular reference to a broad clearance of the application of ionizing energy to food up to an overall average dose of 10 kGy. Clearances based on specific foods treated at specific doses was no longer a recommended approach, in the light of the broad clearance of the process of food irradiation recommended by JECFI for foods which have absorbed an overall average dose not exceeding 10 kGy. This change in approach arose from advances in knowledge of the wholesomeness of
irradiated foods and was in the interest of international harmonization and hence trade.

The Advisory Group, however, recommended that Appendix B to the Codex Recommended International Code of Practice for the operation of Radiation Facilities used in the Treatment of Foods (Ref. 2) should be removed, since it caused confusion with respect to the acceptance of the Codex General Standard. This was so since Appendix B gave the wrong impression that the Codex General Standard suggested a method of clearance on a food-by-food basis.

Governments were advised that, in implementing the Codex General Standard in legislation, they should ensure that the overall average dose of 10 kGy, as well as a maximum limiting dose of 15 kGy, which no part of the food would be allowed to exceed, would be enforced. Both the overall average dose and the maximum limiting dose applied to any irradiated food should be recorded on the documents relating to that food.

As regards the acceptance of the Codex General Standard for Irradiated Foods, countries were advised to consider accepting the General Standard whether or not they operate irradiation facilities, in order to facilitate trade in irradiated food.

(j) Model Regulations

The Advisory Group recommended that the "Model Regulations for the Control of and Trade in Irradiated Foods", issued by IAEA in 1979 (Ref. 6), should be revised to reflect the provisions of the Codex General Standard and should be presented as a general analysis and description of the possible legal issues and their respective juridical and practical implications.
7. RECOMMENDATIONS

1. Irradiated foods should be subject to regulations covering foods generally and to standards covering the corresponding non-irradiated foods. The Advisory Group recommends, therefore, that no special requirements for the quality, wholesomeness and labelling of irradiated foods should be introduced into national legislation other than those included in the Codex General Standard for Irradiated Foods.

2. The acceptability of irradiated foods in international trade depends very much on confidence that such foods have been treated in facilities registered with and licensed by competent national authorities. It is, therefore, necessary for a list of such facilities to be widely available. The Advisory Group recommends that the IAEA, in consultation with the International Consultative Group on Food Irradiation, should be responsible for the preparation and circulation of such a list.

3. It is stressed that the proper implementation of food irradiation requires the application of good irradiation practice. The Advisory Group recommends that the Joint FAO/IAEA Division of Isotope and Radiation Applications of Atomic Energy for Food and Agricultural Development should disseminate advice on the efficacy of the process and on the technological and economical application of the process. Such advice should take the form of guidelines of technological practice.

4. The Advisory Group recommends that IAEA and other interested UN Agencies should take such steps as will promote the acceptance and implementation by Governments of the Codex General Standard for Irradiated Foods. This should include consideration of ways of permitting the importation and marketing of irradiated foods even though the countries concerned do not have facilities for the irradiation of foods.

5. The Advisory Group recommends that its conclusions which relate to the Codex General Standard and Code of Practice should be brought to the attention of the appropriate Codex Committees.

6. As a follow-up to the adoption of the Codex Standard for Irradiated Foods by the Codex Alimentarius Commission in 1983 and its distribution to Member States in 1984, the Advisory Group recommends that the Joint FAO/IAEA Division disseminate information to national administrative
authorities on the application of the provisions of the Codex General Standard in national legislation for the purpose of control of food irradiation.

7. National efforts on research and development in food irradiation have much contributed to attain involvement of national authorities in preliminary pilot-scale and commercial projects. However, the Advisory Group recommends the stimulation of the development of regional research programmes and the establishment of regional centers in order to guide the implementation of the food irradiation process in an expeditious manner.

8. Considerable data on the wholesomeness of irradiated food have been compiled by the former International Project in the Field of Food Irradiation (IFIP) and exist at the Federal Research Institute on Nutrition, Karlsruhe, Federal Republic of Germany. Data in this field are also available in the USA, at the International Facility for Food Irradiation Technology (IFFIT) in Wageningen, The Netherlands, and elsewhere. The Advisory Group recommends that efforts should be made and means found to maintain these valuable data in a centralized source for the benefit and use of Member States.

9. The part played by IFFIT in the promotion of food irradiation technology is thought to be exceedingly valuable. The Advisory Group recommends that the sponsoring Organizations should seriously consider the continuation of IFFIT's activities beyond 1985.
REFERENCES


(2) Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods, Codex Alimentarius, Volume XV [(CAC/RCP 19-1979 (Rev.1)].


(5) Report of the 16th Session of the Codex Committee on Food Additives (ALINORM 83/12A, Appendix VIII, and Appendix IX)


(7) Report of the Seventeenth Session of the Codex Committee on Food Labelling, Ref., ALINORM 85/22, Appendix III.
Annex 1

ACCEPTANCE OF THE FOOD IRRADIATION PROCESS
An examination of some impediments

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Introduction

The technological usefulness of the process of food irradiation as a viable alternative to other traditional methods of food preservation has been investigated for almost 40 years. The availability of sufficiently powerful machine sources and isotope sources of radiation has been a determining factor in affirming the feasibility of the practical application of food irradiation for the preservation of food. To these facts must be added the scientific recognition of the wholesomeness of irradiated foods, provided the process is carried out on the appropriate foods and within properly defined technical limits. However, the general acceptance of the process, and of national and international trade in irradiated foods, is largely lacking throughout the world. It is therefore important to consider the possible modes to overcome the reluctance of governments to grant the necessary legal recognition of the process and of irradiated foods, and to gain broader acceptance of the wholesomeness of irradiated foods by the food industries and the consumers worldwide.

Before any useful suggestions can be made to achieve the above-mentioned objectives, it is necessary to discover the likely reasons underlying the reluctance of many governments to make appropriate legislative provisions for the establishment of irradiation facilities and for the free marketing and trading in irradiated foods. The reservations of governments may be considered under the following headings:

a) public health considerations,
b) legal/administrative considerations,
c) political considerations.

Public health considerations

It is a function of all governments to ensure an adequate, nutritious and safe food supply for their populations. Legislation exists therefore in almost all countries, which regulates the wholesomeness of any food manufactured or offered for sale to the consumer. Implicit in this regulatory supervision is also the exercise of proper control over imports of food into the country and health control of the chains of distribution and storage. Since adequacy of food supplies to the general population is an essential task of any government, a very cogent argument for permitting food to be processed by irradiation is the beneficial effect of this technology on increasing the food supply. The prolongation of the shelf life of food by destruction of insect pests and the delaying of the deterioration process through inhibition of germination or elimination of the microorganisms responsible for food spoilage makes a very obvious contribution to this
goal. If safety questions are not involved, the mere political or emotional objections to the application of this technology are not acceptable, if irradiated foods can fill a serious gap in the existing food supply of the population.

Before the introduction of this new technology of food processing can be proposed, positive evidence must be obtained of the absence of any hazardous effects to the health of the consumer. Without such assurance it would be pointless to recommend the use of this process to governments. Sufficient adequate data have now been generated over many years and have been culled from national and international sources by FAO, IAEA and WHO. These data were reviewed periodically by Expert Committees jointly organized by FAO, IAEA and WHO and these Committees met in 1969, 1976 and 1980.

At the last meeting in 1980 the Joint Expert Committee (JECFI) concluded that the irradiation of any food commodity up to an overall average absorbed dose of 10 K Gy presented no toxicological hazard; hence toxicological testing of foods so treated was no longer required or necessary. The Committee also stated that the irradiation of food up to 10 K Gy average overall dose introduced no special nutritional or microbiological problems. It emphasized, however, the need to pay particular attention to the known changes in micronutrient content in relation to the role in the national diet played by each particular irradiated food.

These conclusions clearly established the wholesomeness of any irradiated food treated with an overall average dose of 10 K Gy. The data, on which these evaluations are based, are available to any government for appraisal by its own national expert bodies, if considered necessary. Questions of safety are thus no longer acceptable as an excuse for delaying or denying the legal clearance of the irradiation process, and of the marketing of irradiated foods in comparison to thermal processing, deep freezing, freeze drying, smoking, and dehydration, which are accepted alternative methods of food preservation and hygienisation.

Concerns have often been expressed regarding the microbiological safety and hygiene of irradiated foods. These questions had already been addressed by the Joint Expert Committees but additional assurances were demanded by many governments. The Joint FAO/WHO Secretariat of the Codex Alimentarius Commission therefore approached the Board of the International Committee on Food Microbiology and Hygiene for a second opinion on these specific matters.

This Board met in 1982 to analyse all available microbiological information on irradiated foods and concluded, that there was no cause at all for concern. Irradiation-induced mutations of pathogens or other microorganisms resident on food, if produced, were inherently less viable in competition with the normal flora and pathogenicity had never been induced as a result of genetic mutation by irradiation. Therefore, no increased hazard to health existed. In the Board's opinion no qualitative differences could be demonstrated between the kind of mutations induced by ionising radiation and those induced by any other pasteurisation or partial preservation process, such as thermal treatment or vacuum drying.

Radiation-resistant organisms, which may survive, were equally handicapped as regards survival vis à vis the normal spoilage flora of foodstuffs. All this information is also available for review by nationally appointed expert
bodies and should therefore provide additional reassurance to governments regarding the absence of any microbiological hazards associated with the consumption of irradiated foods. This may be an important factor to be emphasised, if governmental reluctance to permit the application of irradiation to food is to be overcome.

Food contamination by chemical preservatives or pesticides is an important element in food safety considerations. Irradiation of food at doses up to 10KgY probably creates no more than 30-40 mg/kg food of radiolysis products. Almost all of these are qualitatively of the same nature as those produced by thermal processing and their toxicological innocuousness is known. Irradiation therefore has the enormous advantage of leaving no residues of toxicological significance in the treated food. If this fact is set against the need for governments to prescribe legal tolerances for many of the pesticides and preservatives in use today which may be detected on foodstuffs, another persuasive argument exists to overcoming governmental reluctance.

One of the essential elements in primary health care of a nation is the provision by governments of a safe food supply. Foodstuffs are unfortunately one of the media for transmitting human disease with its attendant toll of morbidity and mortality. Moreover the treatment of foodborne disease requires a considerable expenditure of public money and the disease represents an economic burden in terms of lost earnings, lost production, costs of treatment and expenditure on sickness pay and social services. Any public hygiene measure which contributes to a reduction or elimination of this economic burden should be regarded as a powerful and persuasive argument against undue governmental opposition to the recognition of the value of food irradiation.

The irradiation of food with doses up to 10 KgY is highly beneficial to the health and well being of the population because of the destruction of certain foodborne pathogens, such as Salmonella, E. Coli, Campylobacter and Yersinia, which are found on fresh, raw and cooked foods, even when prepacked or refrigerated. Irradiation of fresh meat and poultry may become one of the important measures in making food safe for handling in domestic and public catering environments. Since the essential elements of primary health care include the promotion of a safe food supply and better nutrition, it is a clear duty of governments to employ any measure which will help to achieve what WHO has termed "health for all by the year 2000". Any member nation of WHO, pledged to achieve this goal, should seriously consider revising their negative attitude towards the introduction of food irradiation.

Another hygiene aspect of importance in countries where veterinary control of meat for sale to the public is not fully established, is the use of irradiation, at comparatively low doses, for inactivation of parasites carried by food animals as intermediate hosts. Thus the irradiation of raw meat will inactivate the larvae of Trichinella spiralis and Cysticercus bovi, thereby contributing to improving the public health in those countries where these parasitic infections are endemic. The availability of such a simple public health measure should provide another convincing argument to remove governmental reluctance.

Legal/administrative considerations

Most of the early work on the technology and safety of food irradiation was carried out in the USA. An unfortunate legal consequence of this situation was the initial classification of the process of food irradiation
as a food additive under the US Federal Food Drugs and Cosmetics Act. This legal interpretation was based on the consideration, that irradiation added something to food, which was not present there previously, i.e. the products of radiolysis.

Consequently the clearance of irradiated foods under the US food regulations could proceed only on a food by food basis. Moreover each irradiated food had to be tested according to the provisions laid down for a chemical food additive, i.e. the whole gamut of extensive feeding tests in laboratory animals had to be performed. The insistence by the FDA on such an approach patently ignored the methodological difficulties arising from testing a complex food instead of a defined single chemical in animal feeding tests. This view was still embraced by the Joint Expert Committees held in 1964 and 1969.

The enormous costs involved in carrying out the required tests and the uncertainties regarding eventual approval, together with the large capital investment required for setting up an irradiation facility, specifically for food treatment, acted as a considerable deterrent to industry to use this new technology. Hence most of the technological and toxicological work was carried out through government-sponsored research; in the USA it was part of the US Army Research and Development Programme.

Progress was made only after the 1976 Joint Expert Committee, which clearly stated that food irradiation was a food process akin to other accepted food processing techniques. The necessary legal changes in the USA are only now being proposed in 1984 in the Federal Food Irradiation and Control Act (H.R. 5605), which defines food irradiation as a "food process". Powerful support has been given to this proposal by the American Medical Association. This body considered that irradiation makes no more changes in the food than do other traditional processing techniques, such as heating and freezing. Moreover irradiation is regarded by the AMA as an important substitution for pesticides and can prevent bacterial contamination in meats, poultry, and fish. Considering that irradiation has been used for many years in certain national markets, the process should be considered as safe. Obviously a suitable mode for overcoming governmental reluctance to legalising the process is to encourage the equivalent medical bodies in other countries to follow the lead of the AMA and advise their governments accordingly.

In almost all countries other than the USA the processing of food by ionizing radiation is forbidden under the existing national food laws. Exemptions for the application of the process can and have been given in some 24 countries for specific foods. However most of the exemptions are concerned with foods destined for national markets or specific purposes.

There is as yet no international trade in irradiated foods because of the differences in legislation in the various importing countries. A vital step to improve this situation was taken by the Joint FAO/WHO Codex Alimentarius Commission at its 14th Session in 1981. The Commission accepted the opinions of the 1980 Joint Expert Committee and of the Board of the International Committee regarding the safety of low dose irradiation of foods. It therefore adopted the Codex General Standard for Irradiated Food and the Recommended International Code of Practice for the Operation of Radiation Facilities for the treatment of food.

There now exist internationally agreed instruments which can be adopted by the member countries of the Codex Alimentarius Commission and
introduced into their national legislation for the benefit of their people regardless of their stage of development. It is an urgent task of FAO, IAEA and WHO, as participating organisations of the Codex Alimentarius Commission, to continue to urge the adoption of the Codex General Standard of the Recommended International Code of Practice in pursuance of the aims of the UN agencies to ensure freedom from hunger and health for all. There is the additional advantage of reducing the dependence on chemical treatment of food to promote adequate supplies of safe food for the world. It would also provide an important economic help to developing countries by allowing otherwise perishable commodities to be transported and imported into developed countries.

A point often raised in connection with the enforcement of controls over irradiated foods is the absence of any satisfactory test method to prove, that the food has in fact been irradiated. Ionizing radiation at doses up to an average 10KGY does not produce a marker compound in the treated food, which allows unequivocal recognition of the processing both in marketed and in imported goods.

There are several arguments why this fact should not inhibit the legal clearance of the process. Firstly, the technology involved is of such complexity as to require special facilities. Moreover the use of radioactive materials is controlled everywhere by very strict regulations and safety measures, so that the establishment of uncontrolled or illicit facilities is not possible. Furthermore the only useful radioactive isotopes for food irradiation are byproducts of the operation of nuclear reactors and thus under strict national and international control as to disposal, transport and acquisition. X-ray machines and electron accelerators with the necessary power require special siting and building protection against the scattered radiation produced during their operation.

Thus governments have absolute control over the siting and operation of irradiation facilities, as well as means of inspecting the proper running of these establishments. An important mode of overcoming the reluctance of governments to legalise food irradiation is the establishment of a register of internationally recognized licensed facilities, backed by the assurance of the national government, that adequate inspection and control of these facilities is being exercised. It might well be considered useful for IAEA to act as the international focus for keeping such an up-to-date register of all licensed food irradiation facilities in the world. Only food irradiated in these registered facilities would then be regarded as safe for national and international trade.

Just as there exists an international warning symbol for radioactivity, a similar symbol might be developed to indicate bulk goods of irradiated foods in transit. This would avoid the inadvertent repeated irradiation of foods. There is however an additional safeguard which operates automatically. If foods are treated at ambient temperature with excessive doses of radiation beyond those needed for the technological purpose and in toto exceeding the overall average dose of 10KGY, the quality of the excessively treated food would deteriorate considerably. It would thus not be technologically useful or economical to apply a comparatively expensive treatment unnecessarily and end up with a product of inferior quality, rejected for that reason by the consumer. Conversely irradiation cannot improve poor quality food. It may make it safe for consumption but would not deceive the consumer as to the nature and quality of the foodstuff.
**Political considerations**

In certain countries political considerations play an important role in preventing the passage of legislation permitting the use of ionising radiation to treat foodstuffs. If there is considerable antagonism in the population to anything related to atomic energy, nuclear power or radioactivity, including radiation, it is often politically unacceptable for a government to be seen to embrace, recommend or permit the use of radiation, particularly in the food field.

Public protests against the use of atomic energy in any form are based usually on emotional attitudes rather than scientific reasoning. They are often fostered by the communication media, which use sensationalism for commercial gain, and by political parties for their own political ends. Public attitudes are likely to play a major role in determining the policy of governments towards the legal introduction of food irradiation, a fact which cannot be ignored.

It is clearly impossible for UN agencies to assume a political role in trying to overcome the reluctance of governments to establish the necessary legal framework for allowing the process of food irradiation. This is not to say that FAO, IAEA and WHO could not assume an educational role in this field by providing some authentic literature or booklets, setting out the scientific arguments and evidence for the safety of the process and of the irradiated foods, as well as the importance of this new technology for the health and nutrition of the people.

A second useful role of these agencies could be to provide model legislation, particularly for those countries that require help in setting up the appropriate legal and administrative machinery to control the adequacy and safety of their food supply, both nationally and in relation to food imports and exports.
EFFICACY OF FOOD IRRADIATION IN THE FIELD OF FOOD HYGIENE

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It is quite evident, that cancer and cardio-vascular diseases are in our century of much greater importance than infectious diseases, which have threatened human health and life so seriously in previous centuries. There are, however, two quite important human activities, namely sexual intercourse and food consumption, in which infectious diseases still not only play an important role, but even show an alarming increase in recent decennia. Foodborne diseases and venereal infections are at present serious health problems in nearly all parts of the world (1, 2). As far as food infections and intoxications are concerned their increase is due to a complexity of factors.

Since the Second World War there has been an explosive growth of mass-breeding and mass-fattening of animals, mass-production and -processing of foods, mainly of animal origin, together with a still increasing international trade in foods and feeds. Moreover, migration of millions of people (tourists, immigrant-labourers) as never seen before in history took place, which resulted frequently in the importation of human enteric pathogens. Food habits have significantly changed in recent decennia both in the autochthonous population and under the influence of newly immigrated ethnical groups. Last but not least the increasing environmental pollution has resulted in transmission cycles and the built-up of a microbial environmental contamination pressure and hence the contamination of high percentages of food and feed lots.

Which are the important pathogens causing foodborne disease? Salmonella is at present the most important causal agent of food infections in most countries. Data on the occurrence of salmonellosis in man in various countries show a significant
increase during the last 30 years. In the U.S. 20-30,000 cases are officially reported, whereas over 2 million morbidity is estimated, resulting in medical payments and lost working days amounting approximately $300.- millions per year (3, 4). Research in various countries has demonstrated, that poultry and red meats play a major causative role in human salmonellosis (5, 6). Contamination of animal feeds has been recognized as a primary source of infection in animals and has led to great numbers of clinically healthy, Salmonella-carriers and hence to a considerable degree of contaminated food of animal origin (7, 8, 9, 10, 11).

In recent years campylobacteriosis has been recognized as an emerging diarrhoeal disease (12). There are numerous recent publications in which enteritis in man caused by Campylobacter fetus subsp. jejuni is reported. Indications point to food of animal origin, especially poultry, but also meat- and milk-products being frequent sources of this infection (13, 14, 15).

Intoxications caused by the heat-stable toxin of many Staph.aureus strains play an important role in certain parts of the world, particularly on the North-American continent. Especially where large numbers of meals or large size items such as turkeys are prepared, cooking and cooling facilities are often inadequate to eliminate, resp. prevent multiplication of, staphylococci and production of toxins. In recent years special attention was paid to this potential health hazard in mass-catering, particularly in aviation (16, 17).

Clostridium perfingens infections, which have occured regularly in Great-Britain since many years, are of increasing importance in the U.S. (18, 19). The organism can be found frequently in faeces of man and animals hence in food of animal origin, especially in meat and meat-products.

Finally, parasitic infections, such as hydatidosis, taeniasis, which are still a wide-spread health problem in man and animals in Africa and South-America, as well as toxoplasmosis and trichinosis should be mentioned. Meat and meat-products play a mayor role as sources for these, often serious, infections in man (20). Freezing of carcasses is an effective way of prevention of these parasitic diseases, but cannot always be applied, due to lack of technological facilities or shortage of energy.
Only in recent months we were confronted with a number of food-borne disease outbreaks, which have involved several hundreds of persons and have resulted in a relative high number of death cases. These incidents were widely published by press, television and broadcasting and have again startled the general public, which especially in the so-called high developed countries believes, that food is safe as far as pathogenic microorganisms and parasites are concerned.

What control and prevention measures are possible?

From the foregoing it is clear, that one has to face a high and frequently occurring contamination of pathogenic organisms in food, especially from animal origin. For the control of this contamination and hence the hazard of human disease three lines of defence are available.

1. Rearing of food animals free from pathogens.
   On a small scale this has been applied and proved to be succesful, i.e. with pigs in the case of *Salmonella* infections. On a larger scale application of this approach is costly and therefore for the time being economically not feasible.

2. Decontaminations of foods.
   Decontaminations by processing, i.e. by heat-treatment, addition of chemical substances and irradiation, is the second line of defence against pathogens in food.

3. Self-protection by the consumer.
   Adequate cold storage in order to prevent microbial proliferation and adequate heating before consumption in order to kill pathogens could prevent nearly all food-borne diseases.
   Education and information should be exercised whenever and wherever possible, but due to what has just been said quick results are not to be expected. It is for this reason and due to their responsibility, that governmental and industrial agencies concerned with health protection emphasize the significance of processing procedures, such as pasteurization. It is also in this field, that the use of radiation comes in.

For what purposes can irradiation be applied?

Extensive research has shown, that radicidation, defined as a treatment with ionizing radiation at doses up to approximately 5 kGy (0.5 Mrad) suffices to adequately reduce the number of viable
non-sporing pathogenic microorganisms in food and, therefore, is an attractive decontamination method (21).

It has been demonstrated, that radiolytic processes cannot be considered a health hazard, because most of the products formed in this way can also be found in non-irradiated foods, as a result of other processing procedures (21). The induction of radiation resistance in pathogens often leveled as a drawback seems to be a phenomenon occurring virtually only under laboratory conditions (22). Development of radiation resistant micro-organisms under normal conditions, including adherence to Good Manufacturing Practices as currently applied in the food industry, has so far not been observed (23). Few, if any, other food processing methods have been so thoroughly investigated toxicologically as food radicidation. Sophisticated animal feeding studies have failed to show any harmful effects (24, 25).

Specific advantages of food irradiation are (i) the unique possibility of treatment of foods after packaging, which in view of the frequency of cross-contamination in the food industry is of utmost importance; (ii) the low costs of the process, which has been estimated at 0.5-1 dollar cent per pound of irradiated foodstuff (26) and (iii) the low energy required for radicidation, especially in comparison with conventional heat and freezing processing methods.

The irradiation of poultry has the highest priority, due to the high contamination rates with pathogens, nearly all over the world and hence the possibility of cross-contamination in the kitchen (23).

Most data applying to poultry irradiation are also valid for red meat. Fresh meats, including poultry create a public health hazard mainly due to surface contamination and hence cross-contamination in food preparation. This is especially true for frozen meats, where, upon thawing, drip water is released. Frozen meats, being imported in large quantities into various countries, have proved to be contaminated with pathogenic organisms in relatively high percentages (27).

Low dose irradiation in the range of 2-7 kGy will reduce the level of pathogens considerably, especially after pre-packaging. Particularly in countries like The Netherlands, Switzerland, Belgium and Germany, where raw or insufficiently heated meat products are consumed, radicidation may help in controlling meat-borne food diseases - not only of bacterial - but also of parasitic origin.
Another group of foods suitable for irradiation is fish and shell-fish, especially shrimps, prawns, crab-meat, oysters and mussels which frequently harbour bacterial pathogens and parasites (28, 29) and are therefore to be considered as a public health hazard (30, 31).

Also frog-legs, originating from the (polluted) aquatic environment, should be mentioned in this respect. Radicidation of frozen sea-food products with dosis of 1-2 kGy have been applied in various countries with excellent results.

Irradiation of teleost fish and fish products with doses of 1-2.2 kGy has been cleared by a joint FAO/IAEA/WHO expert group (32).

Other commodities for which irradiation may be of great advantage are in the first place spices, which are important additives in meat and dairy products. Spices are known to be highly contaminated with microorganisms, including pathogens, which already have resulted in, for example, Salmonella outbreaks. Irradiation with doses between 5-10 kGy results in a considerable reduction of the total colony count and in the elimination of potentially present, non-sporing cells of pathogenic organisms (33).

Epicrisis

Food-borne infections and intoxications have been an important public health hazard in recent decennia and risks in this field are expected to continue or even to increase in future. Several outbreaks during recent months, resulting in thousands of patients and in a relatively considerable number of death cases underline this expectation. On a short term control and significant elimination of pathogens in food could be realized by applying processing methods, especially for decontamination purposes. Pasteurization and canning of food have in this respect shown to be of significant importance in protecting the consumer with regard to health risks. Radiation processing could in this field also be of great value in reducing and probably eliminating pathogens, which occur regular in high percentages in poultry, raw meats, sea-food, spices and other food items.
THE ADVANTAGES AND DISADVANTAGES OF OPTIONAL INFORMATION FOR THE CONSUMER ABOUT THE POSITIVE EFFECTS OF FOOD IRRADIATION VERSUS MANDATORY LABELLING OF THE PROCESS

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1. INTRODUCTION

This short paper is being submitted at the request of the Food Preservation Section of the Joint FAO/IAEA Division to facilitate the preparation of the programs for the Advisory Group Meeting scheduled for November 5-9, 1984, Vienna, Austria. The views, opinions and comments expressed are those of the author and draw upon his experience in the roles of Chairman, Food Labelling Committee, Codex Alimentarius and Director, Consumer Products, Department of Consumer and Corporate Affairs, Government of Canada. This paper does not reflect the positions of either the Government of Canada or the Food Labelling Committee of Codex Alimentarius with respect to either the use of ionizing radiation energy as a process or the labelling proposals being considered for treated products.

In order to make an assessment of the assigned title, "The Pros and Cons of Optional Information for the Consumer About the Positive Effects of Food Irradiation versus the Mandatory Labelling of the Process", one must establish through a number of assumptions those conditions under which such a comparison can be made.

1.0. The following are the assumptions made relative to requiring mandatory labelling:

1.1. The Joint Expert Committee Report on the Wholesomeness of Irradiated Foods is valid in that foods treated within recommended dosage levels up to a maximum of 10K Gy presents no toxicological hazards(1).

1.2. Irradiation is to be considered to be a treatment or process to be applied to foods and does not become classified as a food additive. [Note: This approach is consistent with the definition of terms as found in Appendix III, Codex Alimentarius Commission Report, ALINORM 85/22(2), and the current proposal of the Canadian Government as found in Information Letter No. 651 "Proposed Revised Regulations for the Control of Food Irradiation(3)."]
1.3. Products treated by ionizing energy would require the following statement to appear on the label "treated by ionizing energy." [Para. 5.2.1 of Appendix III, Codex Alimentarius Commission Report, ALINORM 85/22(1).]

1.4. That other mandatory labelling information such as the showing of symbols, logos or other descriptive terms would only serve to identify treated products without referring to either the positive or negative effects that may be perceived to result from the treatment.

2.0. The following assumptions are being made relative to the provision of meaningful information to the consumer about the positive effects of food irradiation:

2.1. Information would only be meaningful and made available when irradiated products are on the market and consumers are aware of their availability.

2.2. There must be a noticeable or visible difference that consumers can see in either the product presentation or its labelling which distinguishes between treated and non-treated products.

2.3. Consumers should be able to experience some difference through the use of irradiated products either through having available new products not otherwise obtainable that would allow for the expansion of menus or diets (or) by noting the extended shelf-life of treated products.

3.0. Content of Consumer Information - The information provided becomes optional in that its provision would not be required by legislation.

3.1. The benefits derived from the radiation treatment must be linked to a marketing strategy with emphasis directed to the consumer. Note could be made of increased shelf-life of products and/or more product availability and/or reduced prices due to minimized wastage.

3.2. The health concerns should be covered by pointing out that the dosage levels at time of treatment will be rigidly controlled. Furthermore, it should be noted that, based on WHO/FAO Expert Committee Reports, there are no toxicological hazards or special nutritional or microbiological problems created by foods treated at the recommended dosage levels and further toxicological testing is not considered necessary(1).

3.3. Additional points that are worthy of mention in support of the radiation treatment process are:

- it has been used extensively on foods in several countries with no reported adverse effects(1);

- it leaves no contamination as may be found with fumigants and no residual radiation is left with the product;
- it is a cost-effective means of controlling and inhibiting the reproduction of living cells as may be found in food contaminants such as moulds, salmonella and other bacteria, insect eggs and larva and controls product maturation as found in the sprouting of potatoes and onions;

- it has many commercial applications in the sterilization and sanitization of non-foods.

Consideration should be given to the need to dispel any misconception that could arise from believing that treated products have an induced energy level and are superior as a result of receiving treatments of "ionizing energy."

In creating the conditions under which consumer information should be provided, one must not be misled into believing that mandatory labelling would make the informational requirement optional. It would be possible to consider information for consumers if no mandatory labelling requirements exist, however, it should be noted that mandatory labelling would probably create a requirement for information to consumers that would include all the elements listed above. In recognition of the link which would exist between the provision of information and mandatory labelling, the true question becomes, "What are the pros and cons of providing information to consumers on the positive effects of foods treated by ionizing radiation whether or not mandatory labelling is required."

4.0. Pros of providing information where mandatory labelling is not required

4.1. More processors would likely use the radiation treatment process without consumers, through fear or lack of information, discriminating against products that are identified as being irradiated.

4.2. The provision of positive information would become a defense mechanism against the advertising and promotion by manufacturers of non-treated products using negative claims to promote their products.

4.3. A possible lower cost for products, as new labels and packages would not be required to facilitate the changeover in the marketing from non-treated to treated products.

5.0. Pros of providing information whether or not mandatory labelling is required

5.1. Increased acceptance through product satisfaction by consumers could result in increased demands for products having notably longer shelf-life and longer periods of usage in the home.

5.2. Increased shelf-life could result in less wastage of food supplies and perhaps lower prices.

5.3. Consumers in market areas remote from production or supply could benefit from an increased food supply that would otherwise rapidly deteriorate in transportation.
6.0. Cons to providing consumer information

There could be no disadvantage to providing consumers with information unless the message was found to be inaccurate and was misleading consumers as to either the health and/or safety aspects of irradiated foods. Furthermore, it must be recognized that withholding information from consumers about the use of the process on foods available would be denying them of their "right to know" and the "right of choice" in the selection of products in the marketplace.


(2) Codex Alimentarius Commission ALINORM 85/22 - Report of the Seventeenth Session of the Codex Committee on Food Labelling, Canada, 12-21 October, 1983.

(3) Health and Welfare Canada
    Information Letter
    Health Protection Branch
    July 28, 1983      Information Letter No. 651
The U.S. Food and Drug Administration has been closely involved with the problem of how to regulate the irradiation of foods for many years. An early major step was the 1958 amendment to the Food Drug & Cosmetic Act, which defined the source of irradiation as a food additive, rather than considering the source and process as a system like heating, canning or freezing. A number of other countries, and several international health and regulatory agencies, took a different approach and classified irradiation and its sources as a process.

Regulatory progress for the next two decades was very uneven. Irradiated bacon, for example, was approved by FDA in 1963, but in 1968 this approval was rescinded. During these years, however, much research on food irradiation was being conducted, both in the U.S. and other countries. Much of it was devoted to establishing the safety of irradiated foods. FDA established an internal Irradiated Food Committee, which in 1980 submitted a final report which was used as the basis of the FDA Notice of Proposed Rule Making of March 1981.

On February 14, 1984, FDA made its long awaited proposal to expand the use of food irradiation. The proposal would permit irradiation of fresh fruits and vegetables to inhibit maturation
and growth, and to disinfest food of insects, both at doses not to exceed 100 kilorads (1 kilogray). Spices could be irradiated up to 3 megarads (currently allowed at 1 megarad).

Many advocates of food irradiation were, of course, disappointed with the very limited FDA proposal, but others considered it to be an important first step in more widespread use of this long-delayed technology.

A closer look at FDA's activities leading up to the proposal may provide a guide to how and when FDA will permit expanded use of food irradiation in the future.

As you are well aware, food irradiation is a much researched technology, and much of this research covers the safety of the process. The safety issue is not, of course, radioactive food, a concern laid to rest many years ago, although still a consumer education problem. The safety issue concerns material produced in foods when it is irradiated, called radiolytic products. Of particular concern are products not normally encountered in foods and referred to as unique radiolytic products (URP's). The potential danger to human health of exposure to very small amounts of substances known to be toxic in vastly greater amounts is not peculiar to radiolytic products. It is the primary reason why so many food additives in the United States, such as saccharin, cyclamates, food colors, nitrites, plastic packaging, contaminants in drinking water, and literally hundreds of others, have been the subject of so much controversy, and in many instances, the target of severe restrictions or bans.
Attempts in the U.S. to resolve this dilemma with certain other additives have included moves to change the Delaney Clause, the use of risk assessment to balance risks from a variety of sources, and a number of legislative and regulatory maneuvers. Incidentally, there has been much discussion about the FDA regulatory definition of irradiation as a food additive, and there have been legislative attempts to define it as a process. FDA would have the same concerns, however, about both safety and labeling regardless of how food irradiation is defined.

Establishing the safety of irradiated foods is more difficult than for typical food additives. Concern about the toxicological significance of the latter can often be resolved with appropriate scientific tests, notably feeding studies, generally with exaggerated exposure levels. The purpose of such exaggeration is to identify those toxicities which are a consequence of overexposure. The toxicologist then knows what to look for in assuring absence of toxicity at lower exposure levels. The latter is not possible with irradiated foods, since overexposure would cause nutritional unbalances that could mask more subtle evidence of toxicity. The expensive alternative is to conduct many feeding studies with a very large number of animals. The FDA has reviewed literally hundreds of these studies and by current standards concludes nearly all of them, due to technical deficiencies, neither substantiate the safety of irradiated foods or show evidence of harm. This position, of course, is counter to that of the Joint Expert Committee (FAO/IAEA/WHO) which recommended general approval of food irradiation up to a dose of 1 megarads (10 kilograys).
Why has the FDA proposed to limit food irradiation to a dose of one tenth that considered safe by international science and health authorities? In its 1980 report "Recommendations For Evaluating The Safety of Irradiation Foods", FDA noted that the estimated yield of URP's in irradiated foods at a dose of 100 kilorads is 3 mg/kg (3ppm). Since production of URP's has a fairly linear relationship with dose level, irradiation at one megarad results in an estimated URP's level of 30 ppm. FDA's proposal to limit irradiation to 100 kilorads is based on the premise that up to 3 ppm of these identified URP's is safe when considering the role the foods covered in the proposal play in the average diet. The agency stated that in the medium dose range of 100 kilorads to one megarad "foods may contain enough URP's to warrant toxicological evaluation."

Since FDA implies 30 ppm of the URP's in irradiated food may not be safe, while the Joint Committee believes they would be, it is worth spending a few moments discussing what is known about these URP's since this may provide some insight into how, and when, FDA may propose a more extensive irradiated foods regulation.

The identity of individual radiolytic products has been examined in detail in several studies. The best known study by the U.S. Army Natick Labs, on irradiation-sterilized beef, was evaluated by the Federated Societies for Experimental Biology. The latter identified 65 volatile compounds, generally low molecular weight hydrocarbons, aldelydes, and ketones, breakdown products of normal food constituents. Similar studies have been conducted in a number of other irradiated foods, including fish, fruits and
vegetables, spices, carbohydrates, and so forth, and the results published in the usual technical journals.

Less is known about any nonvolatile URP's that may be produced, primarily because of the difficulty in finding and identifying nonvolatile radiolytic products, which presumably could include oligomers based on some of the identified volatile radiolytic products.

Returning to the FDA proposal of February 1984, I would like to bring you up to date on the status of FDA's review of the over 4,000 comments received. The large number reflects the intense interest and publicity surrounding the proposal which was the subject of numerous newspaper and magazine articles, and TV talk shows.

The vast majority of the responses were from private citizens and were overwhelmingly negative. Although they represented technically uninformed opinion, the attitudes expressed nevertheless must be considered by those responsible for preparing a final regulation, especially with respect to the issue of labeling. Regardless of whether the public's concern is informed or not, consideration must be given to its right to know if food is irradiated, and whether to not label it as such would be misleading.

FDA also received a number of negative comments from scientific and health experts obviously well informed about food irradiation. A number of these, while acknowledging absence of acute toxicological effects in tests performed so far, note the
possibility of more subtle long-term effects (carcinogenesis, mutagenesis, etc.). Obviously, such comments focus on the difficulty of establishing absolute safety, or proving a negative.

A significant number of comments approving FDA's proposal were received, some from companies likely to gain from food irradiation, others more objective, such as food processors (who may gain or lose), trade associations and so forth. The American Medical Association, which of course has considerable influence in the U.S. in safety and health issues, has come out in favor of food irradiation.

Everyone would like to know, of course, when FDA is likely to publish a final rule on its 100 kilorad proposal. Although several statements have reportedly been made by FDA spokesmen that a decision will be made "soon", my personal view is that a final rule will not be published until well into 1985 or later. My reasons are based on the following:

1. Evaluation of the over 4,000 comments with the very limited FDA staff available is proceeding very slowly.

2. There are no powerful forces pushing for a regulation. The most earnest advocates to date have been radiation equipment manufacturers and operators. The processed food industry has, with a few exceptions, been lukewarm towards this technology. There is of course the possibility of Government action stimulating its use.
For example, in the U.S. there has been renewed concern about salmonellae and campylobacter poisoning. It is estimated that in the U.S. there are 2.5 million cases, and well over 5,000 deaths, per year from these widespread contaminant in red meat, poultry, eggs, and so on. The Canadian government reportedly is more actively trying to reduce salmonellae and campylobacter levels than the U.S. government and may advocate irradiation as one of the promising solutions to this problem.

The recent banning of ethylene dibromide in the U.S. has also forced consideration of alternatives, one of which is irradiation.

3. Consumer fears and increasingly organized opposition by consumer and health advocate groups make regulatory officials, and their politically appointed supervisors, wary of approving this controversial technology.

Even if, and when, FDA does issue a final rule, the uses of food irradiation in the U.S. will be very limited. The present proposal provides only for the maturation of fruits and vegetables, insect disinfestation, and reduction of microbial contamination in spices. What is the likelihood of FDA allowing wider use, such as in extending the shelf life of fish and meats, in salmonellae control, ensuring trichinae-free pork, even in making sterilized meats and other foods?
Since many of you are interested in the potential for irradiation of meats, fish, and other foods, and when regulations allowing these are likely, I will spend a few moments outlining why it is taking so long to gain approval for more widespread use of irradiation.

FDA's comments on the quality of the data provided so far to demonstrate the safety of irradiation in these applications, confirm approval will be slow. A good example of the problems regulatory officials encounter is provided by recent evaluation of the many feeding studies conducted with high dose (5.9 Mrads) irradiated chicken. Although the majority of these studies appear to substantiate the safety of food irradiation, a number of them also appear to raise uncertainties.

Since many of you are interested in the potential for irradiation of meats, fish, and when regulations allowing it are likely, I will spend a few moments discussing this.

The numerous irradiated chicken feeding studies conducted over the years are currently being evaluated by FDA. At a recent meeting of Research and Development Associates in Boston, Dr. Donald Thayer of USDA noted the following areas where more information is needed about irradiated meat.

1. Effect of temperature and atmosphere (carbon dioxide versus oxygen, for example).

2. Evaluation of combination treatments of temperature and atmosphere.
3. The mechanism of meat structure damage and changes in flavor, taste, etc.

4. The effect of ionization on competition between normal microbial flora and pathogens.

Answers to these questions are unlikely to be clearcut. Toxicology, particularly that branch involving animal feeding studies is, of course, not as precise a discipline as we would like, and frequently involves judgement as to what is significant. These uncertainties conflict with the regulator's desire for evidence of absolute safety. A frequent result is inaction, delay, or further study. (What we call in Washington, paralysis by analysis.).

FDA's limited 100 kilorad proposal is obviously a cautious compromise and there are obvious merits to this stepwise approach to move widespread applications at higher doses. Any potential problems can be limited, and much practical information gathered, as food irradiation is expanded. Questions to be answered include those of nutritional quality, the possible development of radiation-resistant bacteria, and consumer reaction.

To end on a positive note, the approval of food irradiation as safe and wholesome by a majority of informed scientists and medical authorities (as witnessed by the AMA endorsement) especially in view of concern over chemical additives such as ethylene dibromide, ethylene oxide, nitrites, etc., or over microbial contamination, such as salmonellae and campylobacter,
all justify the belief that irradiation will eventually find selective applications in ensuring the availability of safe, wholesome, inexpensive and attractive foods.

Much remains to be done, especially in consumer education. It is obvious to all but the most fervent proponents, that the early forecasts for the uses of food irradiation were wildly over optimistic. Nevertheless, I believe food irradiation will continue to grow in important specialized applications in the future.
Annex 5

PROCESS CONTROL TO CERTIFY THE IRRADIATION TREATMENT OF FOOD

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1. INTRODUCTION

1.1. Responsibility

In the case of a radiation service facility it is the responsibility of the radiation plant operator to certify that the radiation treatment demanded by the food manufacturer has in fact been given to individual consignments. Furthermore, the operator must establish with the co-operation of the manufacturer that the average dose given and the maximum dose given fall within those limits prescribed by national legislation. Where radiation plants operate 'in-house' all these responsibilities lie entirely with the food manufacturer.

1.2. Dose Specification

The food manufacturer is responsible for specifying the dose required for the treatment of individual food consignments delivered to the radiation facility. The specification usually refers to a dose range. The minimum dose is the lowest dose needed to attain the required objective of the treatment as claimed by the manufacturer. The maximum dose is the highest dose which the food will tolerate with respect to quality. The radiation plant operator should be required to certify the range of dose given. This is often achieved by measuring and certifying a maximum dose measured at a position on the product which has been previously designated following process validation studies.

The specification of dose given by the manufacturer must be such as to conform with legal limitations. The plant operator should satisfy both himself and the manufacturer that legal requirements are met and present evidence of process control to meet this need and to conform with needs of the inspectorate of the national authority.
1.3. Process Control

The information given in this paper complements the Recommended International Code of Practice for Operation of Radiation Facilities as published in IAEA - TECDOC - 258 Vienna 1981. There are 4 main areas of process control which are relevant to the use of either a radionuclide source (\(^{60}\)Co or \(^{137}\)Cs) or machines generating either X-rays or electrons. These areas cover the radiation source itself, the conveyor systems, the product and the documentation.

2. RADIATION SOURCE

2.1. Type, Size and Location

Radionuclide sources consist of a number of tubes or rods in which the radioactive material is contained. The supplying organisation states the activity of each source tube in curies (Ci) or bequerels (Bq) at the time of purchase. Each source tube is numbered. The position of each tube in the source frame is determined by computing the best arrangement of tubes consistent with the required disposition of the emitted gamma radiation. Source tube numbers and frame positions must be recorded using appropriate charts together with details of acquisition and disposal.

Machine sources are described in terms of the energy of the emitted electron beam measured in millions of electron volts (MeV) and this relates to the product penetration which will be achieved. The power of the machine expressed in kilowatts (kw) indicates the product throughput that can be achieved. Machines are equipped with recording devices measuring various beam parameters including beam scan and pulse frequency where applicable.

2.2. Decay and Other Source Changes

The half-life of a radionuclide source will determine its rate of decay and hence the frequency of extent of modification of the conveyor speed necessary to ensure a consistent dose delivery to the product. For example, a cobalt 60 source decays at a rate of approximately 1% per month. A record chart should be maintained by the plant manager showing the appropriate modifications to conveyor speed occasioned through the acquisition and/or disposal of sources.
Similarly, records are maintained giving details of modifications made which alter the properties of the beam generated by machines and hence the mode and speed of product handling.

3. CONVEYOR SYSTEM

3.1. Speed

For a given product presented in an established loading pattern and a given source size or machine output, the speed of the conveyor will determine the dose absorbed. The speed which is set using a timing device, with a suitable back-up, must be continually recorded for inspection purposes. A suitable pen recorder will deliver a chart which should be examined at regular intervals. The chart for each 24 hour period is removed and dated and initialed by the plant manager and stored for inspection purposes.

3.2. Interlock with Source

An interlock system will ensure that conveyor movement occurs when the source is in the 'exposed' position or the machine is switched on. Conversely, no conveyor movement shall occur when the source is in the 'safe' position or a machine is 'off', this ensuring that product cannot pass through the cell without receiving treatment. The pen recorder chart referred to in 3.1 should also carry a continuous record of the source position alongside the record of conveyor movement.

4. PRODUCT

4.1. Loading Pattern

The distribution of dose throughout products being irradiated will vary with their density and with the geometry of the manner of presenting the product target to the source. A specification for the loading pattern is necessary. Generally, the product is processed in a manner which ensures that half the dose is given from one side and half from the other. However, more complicated movements aimed at reducing the overdose ratio (ratio of maximum to minimum dose) may be incorporated into the design. Records should be kept showing the size and weight of the cartons, sacks, drums etc., which are handled and manner of loading into the irradiation containers; these should refer to each different product which is handled. Such notes should include details of any special product conditions e.g. frozen or unfrozen state.
Similarly with electron machines, records of the manner of product handling are necessary although in practice the treatment will be applied to thin layers of pre-packaged product or to powders or other loose product carried on a suitable conveyor.

4.2. Establishment of Dose Distribution

4.2.1. Dose distribution in carrier - A number of different quantitative dosimeters are commercially available for routine use covering the range 0.1 - 5.0 Mrad (1 - 50 kGy). Others are being developed and measurements in the area less than 0.1 Mrad (1 kGy) can be made using current techniques. The source geometry and mode of irradiation container or carrier movement will determine the dose distribution throughout the carrier. This can be measured directly using a "dummy" or "phantom" target constructed from wood or other material. It is designed to fill a typical carrier and allow dosimeters to be distributed in a manner which will give the dose distribution at numerous points throughout the carrier, ensuring measurements at the points of minimum and maximum dose. Such data gives guidance with respect to the results to be expected with the product itself.

4.2.2. Validation dosimetry - The distribution of dose through each different product should be measured when the product is introduced for processing. Dosimeters are inserted into the product over a centre plane and similarly over a parallel outside plane. The resulting data will confirm the choice of conveyor speed i.e. tier setting, to achieve the required dose and to demonstrate that any maximum dose limitation is not exceeded, and allow calculation of the average dose. The position of dosimeters to be used in routine monitoring will become apparent from the data; this position is usually at a convenient point on the outside of the product container. Results of this validation dosimetry must be recorded and made available for inspection. Validation dosimetry is repeated following any major change in plant design or source size if the dose distribution in the carrier is changed.

Similarly, in the case of electron machines quantitative measurement of dose can be made using various dyed films placed under product targets both "phantom" and actual.

4.2.3. Routine dosimetry - Having established the convenient point at which to place dosimeters as referred to in 4.2.1, dosimeters
are used at regular intervals in the case of a 'continuous' plant. They should be placed on the product in the first carrier at the beginning of a run and then spaced out in carriers to achieve presence of at least 1 dosimeter within the radiation cell at any given time. Where a small number of carriers are involved with a consignment, dosimeters are placed at the beginning, in the centre and in the last carrier of the row. With a radiation plant operating on the "batch" principle, there must be at least 1 dosimeter within a batch carrier during the irradiation.

Records giving details of both the validation and routine dosimetry results should be made preferably with an appropriate government or university department which specialises in this area. Such intercomparison should take place when a new batch of dosimeters is introduced into routine use or when routine results raise any queries. Calibration curves used to 'read out' results should be traceable back to national standard sources.

The use of dosimetry techniques in a similar manner can be applied to electron machines.

4.3. Product Separation and Identification

The storage space adjacent to the radiation plant will be divided into 2 distinct areas. For example, the division may be achieved by the use of a barrier or fence substantial enough to prevent movement of product from the incoming to outgoing area without passing through the irradiation facility. The need for product separation should be taken into account at the design stage of any new facility. For pre-packaged, sealed products where microbiological control is to be achieved or where the application concerns sprout control of unpackaged vegetables, the methods of product separation just described could apply. However, in some instances separate buildings may be involved in order to avoid cross-contamination of unpackaged products after irradiation treatment.

To assist in distinguishing between irradiated and non-irradiated product, qualitative radiation indicator labels are used. These are already commercially available and they consist of coloured 'stick-on' labels which change colour decisively and specifically during irradiation. For example, in common use is a yellow label based on polyvinylchloride impregnated with an acid-sensitive dye. Irradiation causes the release of a minute quantity of HCl which turns the dye a bright red.
Further general identification of processed product should be made by allocating consignment or batch numbers to incoming product which itself should be accompanied by descriptive paper-work prepared by the consignor.

The irradiation batch number and date of irradiation is carried on labels attached to the food containers in the case of pre-packaged products. From this information full details of the time of irradiation and dosimetry results can be recalled. Identification, in this manner, of food handled in loose form is obviously not possible.

5. RECORDS AND DOCUMENTATION

5.1. Records

The need for various log and record books is referred to frequently in previous sections.

5.1.1. The source - In particular, detailed information concerning the radionuclide source must be maintained not only to satisfy enquiries regarding source geometry but also to meet requirements of the safety inspectorate. Inspectorates concerned with assessing the nature and quantity of food which has been irradiated will require information concerning the following:

5.1.2. The radiation plant - Its output capability can be assessed from information on source size and usage. It is expected that a plant log will be kept showing the source position at precise times and such information as the batch number of consignments being processed on particular dates. The conveyor speed will also be recorded.

5.1.3. Product records - Details will include customer order number, quantity in consignments, description of product, dose requirements, irradiation batch number, date of receipt, processing and dispatch and dosimetry results.

5.1.4. Calibration of instruments - Conveyor timers, dosimeters and instruments such as spectrophotometers and thickness gauges must be calibrated routinely and results recorded using standards traceable to recognised official national laboratories.

5.2. Documentation

A Certificate of Irradiation will be issued covering each individual consignment which is collected from the radiation facility which is clearly identified. The document certifies the dose which has
been given and identifies the consignment in terms of customers order number and date of collection. A copy of the certificate accompanies the consignment, a second is delivered to the customer at the time of invoice, and a third copy is retained at the radiation plant. The information on the certificate makes it possible to trace the full details of irradiation.

6. QUALITY CONTROL

A person who is independent of production responsibilities must be designated as quality controller. QC activities will include regular inspection of the procedures outlined in section 2 - 4 and of the records referred to in section 5. There will be particular emphasis on dosimetry and the calibration of dosimeters and instruments. Product must be inspected to ensure that environmental conditions are up to standard and that storage areas are properly designated. The flow of product through the facility should be such as to avoid re-irradiation of the same product. The quality controller will have the authority to require a halt in production or to forbid the dispatch of consignments when incorrect processing is suspected.

The following situations require special attention:

a) Any special product handling instructions prior or post irradiation must be clearly communicated to the warehouse staff.

b) Re-irradiation of products previously irradiated for the same or other purpose requires investigation with respect to both the total dose given and the reason.

c) If the process is interrupted and the product position altered within the radiation cell then care must be taken to re-position the product prior to start-up.

d) If the process of irradiation is interrupted for maintenance or other reasons the effect on the product must be assessed, particularly with respect to the possibility of microbial growth during the interval.
The director or manager responsible for quality assurance is required to hold written QA audit procedures, a procedure to investigate complaints and formal contracts with customers in the case of service irradiation. Such contracts give specifications of treatment required and special product handling instructions.
Annex 6

LICENSING OF FOOD IRRADIATION FACILITIES

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I. Introduction

In the Revised Draft Recommended International General Standard for Irradiated Foods\(^1\), it is said (2.3.1.):

"Radiation treatment of food shall be carried out in facilities licensed and registered for this purpose by the competent national authority."

In licensing a food-irradiation facility two sets of requirements should be dealt with. The facility uses a big radiation source for the purpose of treating food.

It follows that the first set of requirements for a facility are the requirements of radiation protection and the second set of requirements have to do with the way food will be processed.

This paper deals with the first set of requirements and the registration of a facility.

II. Basic rules of radiation protection

All rules on radiation protection are based on the Recommendations of the International Committee on Radiological Protection (ICRP).

These Recommendations have been incorporated in all international and national legislations.

The basic dose limits for men, recommended by ICRP are:
- a radiological worker (some one who, in the course of his

\(^1\) Food Irradiation Newsletter, Vol. 6, No. 2, September 1982, page 31-34.
professional duties may be exposed to ionizing radiation) should not receive over 50 mSv (5 rem) per year; 2) on individual members of the public (any other person not being a radiological worker) should not receive a dose over 5 mSv (0.5 rem) per year; provided that the total dose averaged over the whole population does not exceed 0.5 mSv (50 mrem) per year.

Doses received as a result of the national background radiation and doses received for medical reasons are excluded from those dose-limits.

Starting from these basic limits, ICRP has recommended other, derived limits. It would however go to far to enumerate them in this paper.

Quite apart from the dose limits, which should never be exceeded, ICRP has recommended two other principles, viz. justification and ALARA. Justification means that no ionizing radiation should be used for any purpose if it has not been established that the use of ionizing radiation for a particular purpose has advantages over other methods.

A simple example will make this clear. Smoke- and firedetectors containing a small amount of radioactivity are nearly everywhere permitted. The justification is that these detectors are much more sensitive than detectors working on other principles and so contribute to the prevention of loss of life or damage to property caused by fire. On the other hand - at least in the Netherlands - the use of lighting conductors containing a small amount of radioactivity, is not permitted on the grounds that it has never been demonstrated that these conductors function better than conductors that do not contain radioactivity; in other words the use is not justified.

ALARA means that all exposures should be kept As Low As Reasonable Achievable, economic and social factors being taken into account3).

2) In ICRP-26 it is stated that an annual dose of 5 rem during the working lifetime is rather high, but as yet no other value has been worked out.

3) ICRP 26 - 3.
In determining whether a certain use of ionizing radiation should be permitted the following steps have to be taken.

First of all the justification principle is applied. If it has been determined that that specific use of ionizing radiation is justified, the second step is the application of the ALARA-principle. Thirdly the doses which will be received by men as a result of that application of ionizing radiation are compared with the dose limits for the various categories of men. If it appears that doses will stay under the limits, that use of ionizing radiation will be acceptable, if not it will not be acceptable.

The application of these principles in regulations and licensing has had the result that the actual radiation doses received in many countries, are appreciably lower as the dose limits, formulated by ICRP.

These very short remarks on the principles of radiation protection will be necessary to introduce more specifically what factors are relevant in licensing on radiation facility for food.

Why the use of ionizing radiation for the preservation of food is justified does not need to be elaborated here. The justification has been made abundantly clear by the results of, among others, the IFFIP-project.

In application of the ALARA-principle two factors are the most important. Firstly the design and lay-out of the irradiation plant and secondly the way in which it will be operated, including the training of operators. (Even the best equipped plant will not function properly if handled by incompetent people.)

For these end an analysis should be made of the proposed lay-out of the facility to determine in what ways people in, or in the neighbourhood of the facility might be exposed to radiation. If the application of the ALARA-principle should have the result that even if ALARA is applied, the doses will be higher than the limits, the proposal will not be acceptable. If, to contrary, doses will be lower as the limits the proposal will be accepted.

Experience has shown that in most cases it is quite possible to reduce doses to a fraction of the limit values, without endangering the financial feasibility of a project.
The next step will be to see how the expertness of the operators will be assured, because even with the best lay-out and construction dose limits may be exceeded if the operators have insufficient knowledge in handling the installation. It is therefore essential that in any plant, where radiation is being used, a suitable degree of knowledge of radiation protection is available. This does not mean that every member of the personnel of the facility has to have special training. It will be sufficient if – in a food irradiation facility – one or two persons will be employed who knew what radiation is, how it can be harmful, in what ways protection from harm can be achieved, and how to keep unavoidable exposures to a minimum (ALARA).

It is usual – at least in the Netherlands – that one of the duties of a radiation protection expert is to draw up instructions for the rest of the personnel aimed at avoiding doses as much as possible.

From this follows that an applicant for a licence must provide the licensing authorities with sufficient data to enable them to judge whether the principles of radiation protection are complied with.

This general outline of the principles of radiation protection is necessary to introduce more specifically which data are relevant for licensing a food irradiation plant.

Essentially the application for a licence is a list of data, relevant from the point of view of radiation protection to enable the licensing authority to judge whether or not the requested licence should be given.

The licencing authority must have the power, not only to refuse the licence, but also to impose rules that are different from the proposals of the applicant.

The list of relevant data is:

a) **The irradiation source to be used and its characteristics**

If the irradiation source will be radioisotopes it should be indicated which radioisotope will be used, e.g. $^{60}$Co, or, in the case accelerators are to be used the details of this accelerator.

Also the maximum activity of the radiation source, before the radioactive decay has made a significant difference should be given. The word maximum is underlined, because a common mistake
is to give the average output. This is a mistake, because all radiation protection measures must be geared to the maximum output of the source. In the case of radioisotopes being used, the physical and chemical form of the isotope used should be given. Otherwise it will not be possible to determine e.g. what handling problems might be encountered, or what might be the possibilities of accidental release of radioactive materials into the rest of the facility or into the environment. This is of special importance in the case of irradiation facility for food, in which the food that is being irradiated might be contaminated by radiation material from the radiation source.

The material of which the irradiation source is constructed and its activity do not only determine the dose to which the food can be exposed, but also the dose which people will receive in the vicinity of the source. This leads to the next point.

b) Details of the construction of the irradiation cell

All walls of a radiation-room should, in principle, be constructed from such a material of such a thickness that, with the irradiation source in its operating position, the dose-rate on the outside of the radiation cell should not exceed at any point 0.1 mR/hour. Cell walls include also the floor and the roof of the cell. Radiation goes in all directions, so all directions should be equally well protected. E.g. if the thickness of the roof is insufficient, radiation going through the roof will reach quite unexpected places by "sky-shine" (scattering by the air).

The construction of an irradiation cell however has some complications because the cell must have some openings to pass through the conveyor belts, and to enter the cell for maintenance and inspection work. Moreover there must be facilities to reload the irradiation source, which means taking radioactive material out of the transport container, placing it in the source matrix and doing the reverse operation with used-up rods. A door cannot be as massive as the walls. This means that measures must be taken that the same reduction of dose rate on the outside is achieved. This can be accomplished by constructing a zig-zag.
c) Mechanical safety, meaning devices to ensure that doors cannot be opened and the cell cannot be entered if the irradiation source is in its operating position.

The most current and practicable measure is that the irradiation source, when not in use, is mechanically lowered into a basin filled with water, under the cell. The water provides a shield that absorbs the radiation to a level where the cell may be safely entered, and at the same time provides an easy method to work on the source, e.g. for changing the position of rods of radioactive material. As an extra safety precaution a permanent monitor should be installed within the radiation-cell, connected with a light-signal on the outside of the cell. In this way it is visible that the source is in its operating position. As a matter of course the entrance-door(s) to the cell should be closed with lock and key. The keys should be in the keeping of a special staff-member. Anybody who wishes to enter the radiation-cell must apply to him for the key, and return it to him after use. This key-keeper should only give the key after having made sure that the source is in its basin.

In case particle accelerators are being used, the same principles are applicable. Being in the "off"-position means in that case that the current has been switched off and cannot accidently be turned on as long as people are inside the radiation cell.

From an engineering point of view all this means a rigorous application of the "fail-safe" principle meaning that doing something wrong - even on purpose - will always result in a safe situation.

d) Loading and unloading facilities

The same principles must be applied to these facilities. As during handling of highly active materials a potential risk exists of an accident, e.g. dropping a rod out of the loading apparatus, a constant monitoring should be practised during these operations. An increase of radiation-level should signalled by a sound or visual signal.
Personnel requirements

The best built plant can be misused and accidents can happen, if the operators of the plant are not sufficiently instructed and trained. It is common practice in the application of radiation for any purpose that a condition for licensing is the presence of one or more people with a special training in radiation protection. Such an officer will be responsible for the maintenance of all apparatus for radiation protection; training of radiological workers and supervision of all questions in which a potential radiation risk is present.

People who in the line of duty have to handle radioactive materials or are coming near to it, are classified as radiological workers and subject to special rules, medical inspection, wearing of personal dosimeters ((film-badges) etc.4)

Only radiological workers are in principle, allowed to enter areas where it is possible to receive a higher than normal radiation dose.

As a consequence, these areas should be clearly indicated by appropriate signs (the trefoil) and a notice that only authorised people are allowed beyond that point.

A system like this cuts both ways. Other people outside the indicated areas can pursue their duties without special precautions and can be assured that no radiation-risks are incurred if they stay outside the marked areas.

Other requirements

In the preceding chapter some general rules of radiation protection have been explained. Basically these requirements are the same, when a large radiation source is being used for whatever purpose.

The fact that a radiation source is being used for treatment of food makes it important to consider some other requirements or advisable practices.

4) Basic Requirements for Personal Monitoring. IAEA, STI/PUB/559.
As JECFI 1980 advised a general clearance of food irradiated up to an overall average dose of 10 kGy 5), it should be made sure that this dose will not be exceeded in the course of the normal operation of the plant.

It follows that use of the requirements for licensing should be that the applicant gives sufficient information on the method of dosimetry he intends to use, and the way in which an overdose will be discovered.

As the techniques for dosimetry are still being developed and what is acceptable in a certain situation might not be acceptable in another situation, it is advisable not to be too specific in regulations. It is advisable to require a system of dosimetry and of recording of doses that ensures that no overdoses have been received by products leaving the plant. If at this point regulations are too specific the result will be that the situation at the time the regulation was issued will be fixed. If some time later better methods to achieve the desired results are discovered, they can't be put into practice until the regulations have been changed. In this way regulations could become an impedement rather than a way to help the process to use the best possible means to achieve the desired result.

At this point an international aspect appears. The requirements that the dosimetry employed should be up to adequate standards is, of course, in the interest of the company owning the plant. They can assure their customers that dose limits will not be exceeded. An adequate dosimetry is also of interest for the national authorities whose duty it is to watch over the quality of the food supply. As the irradiation facility is the only place where applied doses can be directly measured, national authorities also need the assurance of an adequate dosimetry method.

Trade in food, however, is an international trade. Therefore, food authorities have not only to watch food being produced or processed in their own country, but also food being imported from other countries. This means that they have to trust the authorities in another country to see to the correct and internationally accepted appliance of doses.

This trust would be greatly improved if irradiation facilities were encouraged to take part in the programme for calibration of dose control, set up by IAEA\textsuperscript{6}).

In some countries this service is already provided by a national laboratory, that will provide an independent check on the methods employed.

Part of the requirements for licensing a facility for food irradiation should be a good system of record-keeping. This system should be designed in such a way that inspectors from the authorities can see from the records what foods have been treated. Also the quantities and dates and the doses which were applied.

Again, it seems advisable not to regulate in too much detail as the system should be kept as flexible as possible and is not an end in itself, only a means to an end.

As a last requirement it may be mentioned that, just as training in radiation protection is necessary also a good training in operating a facility is needed. People responsible for using the irradiation process should have a general understanding of the underlying principles of food irradiation. For this purpose the Training Courses organized by IFFIT are very important.

\textbf{Registration}

The already cited clause in the Draft Standards of Codex Alimentarius mentions next to licensing registration.

This can only mean registration as a facility for treating food.

This is a bit of a special provision, for in many countries no special registration (or licensing) for erecting a food treating facility is necessary.

The requirement for licensing and registration for a facility to irradiate food must serve a good purpose.

The only logical reason is the following argument: Irradiation of food is a physical process that leaves no irradiation-specific traces in the food after treatment. If a normally Salmonella-contaminated food is present without any salmonellae at all, a strong suspicion may exist that it has been irradiated, but no laboratory test exists to prove that, let alone to ascertain with what dose it has been irradiated.

The only place where records about irradiation and the dose employed are available is at the irradiation facility. Therefore, the facility should be officially registered as such.

But there again this registration must serve a good purpose, otherwise it would be only another example of red-tape.

Food-irradiation facilities are few in number and the number will remain comparatively small during the years to come.

The competent national authorities in any country will know, without the help of a special register, what companies have facilities for the irradiation of food.

If a special register is of no particular use for the national authorities, it must be of use for others. And here again the international aspects of trade in food come in.

It has already been said that one of the duties of national authorities, responsible for the quality of food within a country must also be to watch the food that is imported into a country. National authorities have no power to inspect in other countries. Therefore, the register could be very useful as a means to find out if a food-irradiation facility in another country has been properly licensed and registered as such.

This means that the register should not so much be a national register, but an international one. This would mean that national authorities after licensing and registering a food irradiation facility would notify the appropriate international organization of these facts. The international organization would enter the notification in an international register, and notify all Member-States of the registration. This would be a big step forward to inform national authorities that are confronted with a batch of irradiated food, processed in another country, to satisfy themselves that the irradiation facility was duly licensed and registered.
No new international instrument would have to be set up for this purpose as the Joint FAO/IAEA Division, located at the IAEA in Vienna, already exists and plays an important role in distributing information on food-irradiation. If this is accepted, the system could be simple and practical.

The registration should include the licensing country, the licensed irradiation facility and, perhaps and only if necessary, an indication of the foods for which the facility is registered. A code indicating this code would give an indication of the country, the facility, and if necessary other information.\(^7\)

In the Netherlands two facilities for food irradiation have been licensed. So the appropriate code could be NL-01 and NL-02 respectively. If exporters of irradiated food would be required to indicate this code on invoices etc., used in international trade, the authorities of the importing countries would be immediately assured that the food was irradiated in a proper licensed and registered facility. All this, however, is a suggestion and open to discussion by experts in food-trade.\(^2\)

**Final Remarks**

1. The international harmonisation of rules for irradiated food and the exchange of information are very useful and important. It should, however, be kept in mind that as long as the irradiation of food is still in a stage of development, international as well as national regulations should be kept at a minimum, and confine themselves to the relevant points only, and that in a general rather than a detailed way. International regulation and registration is a means to the end to help the development of a very important technique in an orderly way, not to impose barriers on this development.

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\(^7\) Cornelis, J.C. Legal, administrative and phychological barriers to the industrial application of food irradiation and the trade in irradiated food, IAEA-SM-221/6.
2. The technical and scientific possibilities and also the practical experience in the field of food-irradiation vary widely from country to country. Therefore, it would be advisable to make it possible for authorities in countries, where no experience in food irradiation is available, to have access to the needed experience and knowledge in other countries by the intermediary of the appropriate international organization (IAEA). This could be achieved by another kind of registration, viz. setting up a list of experts in various fields, who could act as consultants. On technological questions IFFIT might be used.
Introduction

The first version of a proposed text of the "Model Regulations for the Control of and Trade in Irradiated Foods" was prepared in 1978 in the framework of the Joint FAO/IAEA/WHO Advisory Group on International Acceptance of Irradiated Food" (1). This version was based on a draft "General Standard for Irradiated Foods" and a draft "Code of Practice for the Operation of Radiation Facilities for the Treatment of Foods". These two documents were adopted by the Codex Alimentarius Commission in 1979 as the "Recommended International General Standard for Irradiated Foods" (2), and the "Recommended International Code of Practice for the Operation of Radiation Facilities for the Treatment of Foods" (3).

The Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food convened in 1980 (JEFCI) was able to formulate a general recommendation on the acceptability of food irradiated up to an overall average dose of 10 kGy. In view of the findings and recommendations of the latter JEFCI (4) the Recommended International General Standard for Irradiated Foods was amended, and adopted by the Codex Alimentarius Commission at its 15th session in 1983. The amended version entitled "Codex General Standard for Irradiated Foods" as well as the "Recommended International Code of Practice for the Operation of Irradiation Facilities used for the Treatment of Foods" have been published in the Codex Alimentarius Commission, Volume XV, in 1983 (5), and distributed to all Member Nations and Associate Members of FAO and/or WHO in 1984.

Since the proposed "Model Regulations" must comply with the present Codex General Standard for Irradiated Foods, it appears necessary to revise several provisions of the "Model Regulations". The revised text of the "Model Regulations for the Control of and Trade in Irradiated Foods" is presented on the following pages.

References

(1) International Acceptance of Irradiated Food. Legal Aspects. Legal Series No. 11, IAEA, Vienna, 1979 (STI/PUB/530).
(2) CAC/RS 106-1979
(3) CAC/RCP 19-1979
CHAPTER 1

SCOPE AND DEFINITIONS

Scope

Art. 1 -- The object of this law (1) is to control the intentional exposure of food to ionizing radiations, and to control the sale, offer for sale, importation, exportation, transport or storage, for commercial purposes, of irradiated food or food containing irradiated ingredients.

Definitions

Art. 2 -- For the purpose of this law (1), the following definitions shall be understood to apply:

(a) Irradiation: Any procedure, method or physical treatment involving the intentional exposure of food to ionizing radiations, whether this exposure takes the form of a single application or of several repeated applications, provided that the maximum authorized irradiation dose is not exceeded;

(b) Irradiation facility: any establishment, enterprise, undertaking or facility, whether stationary or mobile, which is used, even on only a limited scale or occasionally, for the treatment of food by irradiation, including all auxiliary equipment used for purposes of irradiation.

(c) Irradiation unit: any part of an irradiation facility which contains a source of radiation;

(d) Operator of an irradiation facility: any person, natural or juristic, whether or not the owner of an irradiation facility, who uses this facility, even occasionally, on his own account for food irradiation purposes;

(e) Person liable for an undertaking: the physical person exercising, at the highest level, the management or supervision of an undertaking operating an irradiation facility;
(f) Food: any substance, food product or raw material, in either the processed or the unprocessed state, intended for human consumption and subject to legislation related to food (2) or agricultural (3) products;

(g) Irradiated food: any food intentionally exposed, in its totality, to ionizing radiation or rays, whatever the source or duration of the irradiation or the nature of the energy used;

(h) Batch of irradiated food: a set of foods of the same nature, produced under identical conditions and subjected to the same irradiation treatment, the upper limit of the length or amount of irradiation for each batch being laid down if necessary by appropriate provisions.

CHAPTER II

CONTROL OF IRRADIATION FACILITIES

Special approval of facilities

Art. 3 -- Irradiation facilities cannot be used, even on an occasional basis, for the treatment of food unless:

(a) They comply with the general conditions for approval (authorization), operation and control established by the appropriate legislation .... (4);

(b) They have been specially approved by .... (5) after verification of the safety and efficiency criteria set out in the Recommended Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods, published by the Codex Alimentarius Commission.

Certificate of approval

Art. 4 -- The special approval referred to in Article 3(b) shall be established by a certificate of approval, the standard model for which shall be laid down by .... (5). This certificate shall specify the
national and international reference number (6) of the irradiation facility or unit, the name and address of the operator, the type of food likely to be irradiated, the radiation source used for the treatment, together with any special restrictions or operating conditions concerning the use of the facility for food irradiation.

Periodic inspection of facilities

Art. 5 -- A periodic inspection of each irradiation facility, of which the frequency may not be less than once a year, shall be carried out by the inspectors, experts or institutions designated or delegated for this purpose by .... (5) (7). The performance of the inspection shall be recorded by an entry on the certificate of approval and by an inspection report of which a copy shall be sent to the operator and must be kept by him.

Suspension or withdrawal of the certificate of approval

Art. 6 -- When it is established, from the inspection report referred to in the preceding Article, that the irradiation facility has ceased to conform to the safety and efficiency criteria set out in the Recommended Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods, published by the Codex Alimentarius Commission, the .... (5) may, on the basis of a reasoned decision, either suspend the validity of the certificate of approval until such time as the reported defects have been remedied, or fix a term within which the operator is required to take the necessary measures, on penalty of definite suspension or withdrawal of the certificate of approval. This decision shall be notified to the operator and will take effect after a period of .... days from the date of the notification, to enable the operator to present his explanations. Any decision about suspension or withdrawal of the certificate of approval must be recorded by an entry on the said certificate and must be attached to this certificate.
CHAPTER III

CONTROL OF FOOD IRRADIATION

General and particular restrictions governing the irradiation of food

Art. 7 -- The irradiation of food for the purpose, in particular, of its preservation, protection against parasites or improvement of its hygienic or technological quality, is authorized subject to the following restrictions and conditions:

(a) The food to be irradiated must be wholesome and of good quality, both from the toxicological and from the nutritional and microbiological points of view and must conform to the legal provisions governing its composition. Its storage and handling must likewise comply with the legal regulations for food hygiene. In the case of packaged products, the packing material must be appropriate for irradiation treatment and maintained in good condition, and must conform to the provisions relating to materials entering into contact with food products.

(b) The irradiation must be carried out in accordance with the general conditions laid down in the Recommended Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods, published by the Codex Alimentarius Commission.

(c) In addition, the irradiation should conform, particularly as regards the dose limit and the radiation source, to the specific conditions established for each type or category of food approved for treatment by irradiation. Examples of such technological conditions are set out in Annex B of the Recommended International Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods.

(d) Food which has been treated by irradiation, under the general and particular conditions referred to in sub-paragraphs (b) and (c) above, must be identified in such a way as to prevent its being subjected to subsequent irradiation;
(e) The irradiation must be carried out by personnel meeting the requirements as to training and qualifications laid down by (5);

(f) Any treatment of food by irradiation must be recorded in accordance with the provisions of Article 9;

(g) The operation of irradiation facilities and the maintenance of the general and particular conditions concerning the treatment of food by irradiation must be regularly checked by the (5), in accordance with the provisions of Articles 10-14.

**Updating of technical conditions for irradiation**

Art. 8 -- The general irradiation conditions and the specific conditions provided for in Article 7(b) and (c) shall be modified or supplemented by the (5) in line with progress in scientific and technological knowledge, and with due allowance for the recommendations of the Codex Alimentarius Commission of the Joint FAO/WHO Food Standards Programme.

**Record of food irradiation**

Art. 9 -- The operator of any irradiation facility approved in accordance with Article 3 must maintain, for each source of radiation used, a record indicating, for each batch of food subjected to irradiation treatment:

(a) The serial number of the batch;

(b) The date of irradiation;

(c) The nature and the quantity of the batch of irradiated food;

(d) Where appropriate, the type of packaging used during the irradiation treatment;

(e) The controls and measurements performed during the treatment, particularly as regards the minimum and maximum limits of the absorbed dose (10);
Where appropriate, all supplementary information required by the specific irradiation conditions provided for in Article 7(c);

Any incidents or anomalies observed during the irradiation treatment.

The records referred to in the previous paragraph should contain the national and international reference number of the irradiation facility together with the name and address of the operator. The records must be kept by the operator for a period of at least five years. The (5) shall establish the standard model for the food irradiation record referred to in this Article.

Irradiation voucher

Art. 10 -- For each batch of food subjected to irradiation treatment, the operator is required to issue to the person or undertaking which has ordered the treatment, at the same time as the batch of irradiated food, an irradiation voucher, which is dated and signed and contains the following information:

(a) The national and international reference number of the irradiation facility (6) together with the name and address of the operator;

(b) The nature and quantity of the batch of irradiated food, and also the purpose of the irradiation;

(c) The date of the irradiation treatment;

(d) The radiation source used;

(e) The serial number of the batch which has been subjected to the treatment, which number must correspond to the information in the irradiation record.

Food irradiation treatment inspectors

Art. 11 -- Inspectors, experts or institutions (7) designated or delegated for the purpose by the ..... (5) and meeting the conditions as to training and technical qualifications established by the said ..... (5)
shall verify that the operation of the facility and the use of the irradiation treatment procedures conform with the general or specific conditions provided for in Article 7(b) and (c) and, where appropriate, in the certificate of approval.

Powers of inspectors or inspection services

Art. 12 — The inspectors, or the experts or representatives of the approved institutions referred to in the preceding Article shall have permanent right of access to any place which is used, even occasionally, for the irradiation of food or for the storage of food which has been, or is to be treated by irradiation.

They shall ensure that the treatment of food by irradiation is carried out in accordance with the general and specific provisions provided for in Article 7(b) and (c) and, where appropriate, in the certificate of approval, and in particular:

(a) They shall check the radiation sources which are used and measure the dose limits to which the irradiated foods are subjected;

(b) They shall require to see all documents relating to the irradiation facility and to the batches of food which have been, or are to be, irradiated, and in particular the certificate of approval referred to in Article 4, the copies of the inspection reports referred to in Article 5, the text of any decisions about suspension or withdrawal of approval referred to in Article 6, the food irradiation records referred to in Article 9, together with the commercial documents accompanying the batches of food which have been, or are to be, subjected to irradiation treatment;

(c) They shall have the power to take samples of food subjected to irradiation treatment in order to have its wholesomeness checked in accordance with the provisions of Article 7(a). In such a case, the general provisions governing the taking of samples of food products for inspection purposes (11) shall apply;
(d) When batches of food which have been, or are to be, irradiated do not satisfy the requirements of Article 7(a), or when their treat-
ment by irradiation contravenes the general or specific provisions provided for in Article 7(b) and (c), or the restrictions laid down in the certificate of approval, in such a way as to constitute a serious health risk for the consumers, the inspectors or inspection services can carry out seizure in accordance with the provisions relating to the detection and repression of fraud in connection with food products (12).

**Inspection reports**

Art. 13 -- The inspection procedures carried out in accordance with Article 12, and the findings, observations and eventual measures to which these give rise, shall be recorded in an inspection report, a copy of which shall be sent to the operator or his representatives.

This report shall be sent as soon as possible to the .... (5) and, if appropriate, to the judicial authority (13).

The provisions concerning the procedure for establishing the fact of in-
fringements relating to foodstuffs (14) shall be applicable.

**Inspection procedures**

Art. 14 -- .... (5) shall determine the frequency of and the procedures for inspection and organize the inspection services.

**Appeal by the operator**

Art. 15 -- Any operator of an irradiation facility shall be required to allow the inspection and measurement procedures to be carried out in accordance with the above provisions.

An operator who challenges the conclusions or findings recorded in the inspection report, or the measures to which they give rise, may submit a reasoned appeal to the .... (5) within the time limit entailed by legal provisions.
CHAPTER IV

CONTROL OF TRADE IN IRRADIATED FOOD

Principles

Art. 16 --

(a) It is prohibited to sell, offer for sale, transport or store with a view to sale, import or export irradiated food, or food containing irradiated ingredients, which does not satisfy the provisions concerning labelling, presentation and packaging laid down in Article 17;

(b) It is prohibited to import or export irradiated foods unless they are accompanied by the certificate provided for in Article 20.

Shipping documents

Art. 17 -- The invoices, waybills, consignment notes or any other shipping documents accompanying food which has been irradiated, or which contains at least 5% of irradiated ingredients, must mention the nature of the food or the ingredient that has been irradiated, the date of the treatment and a code reference identifying the country in which the irradiation treatment took place as well as the registered facility or unit responsible.

Labelling, presentation and packaging

Art. 18 --

(a) Without prejudice to the application of legal provisions relating to the labelling and packaging of foodstuffs and to the requirements of the Codex Alimentarius General Standard for the Labelling of Food Products, the ... (5) may prescribe that irradiated food, or food containing at least 5% of irradiated ingredients, shall carry on the package, in readable and indelible letters, the words: "Product treated by irradiation", accompanied by informa-
ition showing the date of treatment and a code reference identifying the country in which the irradiation treatment took place and also the irradiation facility or unit responsible. The date of treatment is indicated by the month and year, except as otherwise laid down by the .... (5);

(b) When food which is irradiated is not packaged, the .... (5) may prescribe that it shall be marketed in bags, boxes or containers, or in separate places, which preclude any possibility of confusion or mix-up with similar non-irradiated products and which carry the wording and references referred to in sub-paragraph (a) above.

(c) Whenever the .... (5) has enacted labelling and packaging requirements in accordance with the provisions of sub-paragraphs (a) and (b) of this Article, the operator of an irradiation facility is required to have each batch of irradiated food labelled and packaged, before it leaves the facility, in accordance with the said requirements.

Optional information

Art. 19 -- When a mandatory declaration is prescribed by the ... (5) on the label of a prepacked irradiated food or food containing at least 5% of irradiated ingredients, in accordance with Article 17(a), the labelling of that food may also contain additional information mentioning the advantages sought from the irradiation, a reference to the present law as a guarantee of irradiation control and, where appropriate, the expected shelf-life of the product in its initial state (15). The optional information referred to in this provision may not, however, include any indication which is inexact or which is liable to mislead the consumer, or any reference to medical preventive or healing properties.

Certificate of irradiation for products involved in international trade

Art. 20 -- Food which has been irradiated and which is either imported or intended for export must be accompanied, for each batch of food under-
going the same commercial operation, by a certificate prescribed by the competent authority in the exporting country. This certificate shall mention the fact that the food has been subjected to irradiation treatment, the reasons for the treatment, the coded reference number (6) of the irradiation facility or unit, the date of the treatment, the source of radiation used, and also the nature, the quantity and the serial number of the batch of irradiated food. The .... (5) shall draw up the standard model for the certificate of irradiation referred to above (16).

Request for certificate of irradiation

Art. 21 -- Any person or enterprise wishing to export food which has been irradiated must request for each batch of food undergoing the same commercial operation the certificate of irradiation provided for in Article 19. The request for a certificate of irradiation shall be addressed to .... (5). The request must mention, in addition to the country of destination, the nature and the quantity of the batch of irradiated food being exported. The request must be accompanied by the irradiation voucher referred to in Article 10, or a copy of this voucher, duly certified by the operator of the facility which has carried out the treatment.

Issue of certificate of irradiation

Art. 22 -- The issue of the certificate of irradiation may be made dependent on the verification of the irradiation conditions on the basis of the data contained in the record of irradiated food referred to in Article 9. A copy of the certificate of irradiation shall be kept by the .... (5), who may, upon request, issue duplicates.

International cooperation in the control of irradiated foods

Art. 23 -- The .... (5) shall take all appropriate measures to develop international cooperation in the control of irradiated food, and in particular:

(a) He shall provide, at the request of the health authorities in the importing country or of any international health authority, all or
part of the information described in sub-paragraphs (d) to (g) of Article 9, after verification of the irradiation records kept by the operator of the irradiation facility which has carried out the treatment;

(b) He shall supply to the same authorities, at their request, all appropriate information concerning the existence and validity of the approval of the facility, the frequency of inspections carried out, or the radiation sources and dose limits provided for each type of food which may be treated by irradiation;

(c) He shall collaborate with the health authorities of other countries and international organizations concerned with establishing and developing any international system for keeping a record of irradiation facilities and setting up reference codes for such records (6), or any system which, on the basis of equivalent conditions to be laid down in an appropriate international convention, would have the purpose of establishing between two or more countries a reciprocal recognition of measures for the control of radiation facilities or irradiated food.

CHAPTER V

GENERAL AND FINAL PROVISIONS

Civil liability of the operator

Art. 24 -- Without prejudice to the application of other provisions of law, the operator of an irradiation facility is liable for any damage resulting from irradiation operations carried out in the said facility, even if this damage is due to accidental causes (16). When the size of the facility, or the danger resulting from its use justifies such a step, the .... (5) may impose the requirement that the operator takes out insurance cover for the risk, to a minimum amount which he shall determine. This obligation shall, in that case, be mentioned on the certificate of approval referred to in Article 4.
Penal provisions

Art. 25 --

(a) The operator of an irradiation facility, or the person liable for an undertaking (17), who contravenes the provisions of Article 7 of the present law (1), or who obstructs the execution of the inspection measures provided by Articles 5 and 12, will be liable to .... (18). In the case of repeated offences, the special approval granted by the .... (5) in fulfilment of Article 3(b) may be suspended or withdrawn (19);

(b) The operator of an irradiation facility, or the person responsible for an undertaking, who uses all or part of the facility in contravention of an administrative measure of suspension or prohibition taken in virtue of Article 6 will be liable to .... (18);

(c) The operator of an irradiation facility or the person responsible for an undertaking who contravenes the provisions concerning labelling and packaging laid down in Article 17, will be liable to .... (18);

(d) The operator of an irradiation facility, or the person responsible for an undertaking, who fails to keep up-to-date irradiation records in accordance with the provisions of Article 9, or who fails to issue the irradiation voucher required by Article 10, will be liable to .... (18);

(e) Any person who contravenes the provisions of Article 16 of the present law (1) will be liable to ....(18). However, any such person may be exonerated if he can prove that he could not reasonably have known that the food in question was irradiated food (20).

Annulment provisions

Art. 26 -- The present law (1) annuls the provisions of .... (21).

Entry into force

Art. 27 -- The present law (1) will enter into force on .... .
(1) Or (as appropriate): "The present decree", ".... order", "regulation", etc.

(2) Where applicable, make reference to the general law on food products. Reference can likewise be made to the "Model food law" proposed at a FAO/WHO Regional Conference on Food Standards in Asia, Bangkok, 1975 (Ref.: CX/Asia 75/7).

(3) Where applicable, make reference to the law governing the trade in and control of agricultural raw materials.

(4) Where applicable, make reference to the law governing the approval (authorization) and inspection of nuclear facilities or undertakings.

(5) Indicate here the Minister concerned with controlling the production of and trade in food products, or any other Minister specifically concerned with the matter in question.

(6) A recording system with coded references must be established at the national level and should likewise be organized at the international level in order to facilitate identification of the irradiation facilities used for the treatment of food or agricultural products. Suggestions to this effect were made within the working groups of IAEA, FAO and WHO. (See, for example, CORNELIS, J.Ch., "Legal, administrative and psychological barriers against industrial application of food irradiation and the trade of irradiated food", Food Preservation by Irradiation (Proc. Symp. Wageningen 1977), IAEA, Vienna (1978).)

(7) The aim of this wording is to allow the competent authority to designate for inspection purposes technically qualified persons or institutions not belonging to the administration or experts from overseas or international institutions (technical assistance).

(8) Where applicable, make reference to the national regulations governing food hygiene. Reference may likewise be made to the Code of
Practice on Food Hygiene drawn up by the Codex Alimentarius Commission of the Joint FAO/WHO Food Standards Programme.

(9) Where applicable, make reference to the national regulations concerning materials destined to come into contact with food products.

(10) The reference here is to the absorbed dose, rather than to the distributed dose, in accordance with the agreement reached on this point within the relevant working group on irradiated food.

(11) Where applicable, make reference to the general law on food products or the national regulations governing the inspection procedures for such products. Reference may be made to the draft "Model food law" mentioned in Note (2) above.

(12) The seizure that is referred to here is a preventative measure taken by the inspectors and not a penalty imposed by a judge ("seizure" in United States law). The same reference may be made as in Note (11) above.

(13) Indicate the judicial authority concerned with preventing the evasion of food laws.

(14) Same comment as in Note (11) above.

(15) As an example, the optional information referred to here could be presented in the following way:

"The treatment of this product by irradiation ensures it a shelf-life of about .... (years, months or days, as the case may be) in its initial state. The treatment was carried out under controlled conditions laid down in the law of .... (reference to present law)."

(16) This provision establishes the principle of "absolute" civil liability (or "irrespective of negligence") which is recognized in numerous countries in connection with damage resulting from the use of nuclear facilities, in accordance with various international agreements which are applicable.
(17) In many countries where the law does not admit the principle of penal liability of juridical persons (companies, undertakings) as such, it must be stated, when the operator is a juridical person, that the person who bears penal liability is the one who assumes responsibility for the control or management of the facility.

(18) Indicate the minimum and maximum penalties applicable, for example: "imprisonment from .... days to .... months and a fine of .... to ...., or one of these penalties alone".

(19) This is an additional penalty to be pronounced by a judge and not the administrative measure provided for in Article 6.

(20) When the good faith of the trader who has unknowingly sold the irradiated food has been established, it will be necessary to determine who was the operator of the facility where the irradiation took place, because this operator is required to label and package the irradiated products in virtue of Article 17(c).

(21) Mention must be made here either of the former legislation governing the irradiation of food and trade in irradiated food or to all regulations which are incompatible with the provisions of the present law or which have become redundant by reason of its entry into force.
IMPLEMENTATION OF FOOD IRRADIATION IN FRANCE

Involvement of public institutions

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In France irradiation has become one of the main issues of the food industry for about two years. Though the development and use of this process will lie in the hands of private companies, public institutions have a paramount role, especially in the early stages, at four different levels:

1. BASIC RESEARCH

In the fifties and early sixties, most of what was said or written about food irradiation came from a businessman, Pierre VIDAL, who created the first commercial Cobalt 60 facility, named CONSERVATOME in 1959-1960. Those years were very difficult for the process, considered as an additive, since the Food Additives Amendment had just been issued in the United States. It appeared unmanageable and too expensive to manufacturers to do the necessary research to determine whether food irradiation was safe or not. Of all the existing public research institutions, the French Atomic Energy Commission was the most relevant to undertake such studies. For twenty years now, basic research has been continuously going on in the CEA laboratories at Cadarache. Our studies dealt with radiation chemistry of carbohydrates and we participated in the fruitful International Project in the Field of Food Irradiation. We identified and measured the radiolysis products of starch. We demonstrated that none of them were in such an amount that it could be toxic and that all of them could be either obtained with conventional processes or were natural food components. Later we showed that the results for maize starch were also true for other types of starch, thus bringing more basis to the "Chemiclearance" principle.

Applied research was carried out in several departments of the National Institute of Research in Agriculture (INRA), mostly for vegetable products. This institution was actively involved in the "Seibersdorf Project" which undertakes an exhaustive program on the effects of irradiation on the model: fruit juice. When this project was terminated, INRA stopped its program on food irradiation and has not yet resumed it.

With the renewed interest for food irradiation, other public laboratories will probably start new programs, especially for meat products, in cooperation with food companies.
2. CLEARANCES

The key to any progress was the legislation. The first petition was submitted in 1967 for potatoes. At this time, food irradiation was simply forbidden or, more exactly there was no real existing rule; hence what not permitted was forbidden. It is only in 1970 that the basic decree on food irradiation was published. It permits use of the three types of ionising radiations but it must be demonstrated that no radioactivity is induced within the food. Three commissions examine the petition:

- The Higher Council for Public Health, responsible for food regulations in general,
- The National Academy of Medecine,
- The Commission of Artificial Radiochemicals for the aspects of the process dealing with the sources and irradiation facilities.

If there is no objection from any of these three commissions, irradiation of the product is permitted after publication of a ministerial order signed by five ministries. It is compulsory to mention the process on the labels and trade documents. Other very severe requirements for the control of the process are indicated.

A clearance was issued in 1973 for potatoes, in 1975 for laboratory animal feedstuff and in 1977 for onion, garlic and shallots.

The conclusions of the JECFI in 1980 were the signal for a new start. The toxicological studies required for the petitions were a major obstacle because of their cost. However we thought that is was a too important step for the french authorities to follow the opinion of the JECFI and grant a general clearance up to 10 kGy. We decided to propose an intermediate policy. We wrote a general toxicological report about the possible applications of the process, a synthesis of the numerous studies published and we explained how the experts were lead to the conclusion that irradiated food is safe.

After a presentation to the three commissions a guideline for petitioners was written and agreed upon by the five ministries. This guideline asks for three types of information:

- what is the purpose of the process why to use irradiation ?
- has irradiation any detrimental effect on the chemical, physical, nutritional and sensory qualities of the product ?
- what are the guarantees given for a good application of the process ?

Up to 10 kGy, toxicological data are no longer required.

This very significant progress was obtained in late 1982. Two years later, nine petitions have been submitted for the following products: gum arabic, muesli-like cereal products, dehydrated vegetables, mechanically deboned poultry meat, food packaging, dehydrated blood products, egg-whites, dried fruit and legumes, herbal teas. The five first have been approved while the four last are under examination.

The health authorities are becoming increasingly familiar with the process and the approval procedure now seems easier and faster.
In March 1983, the Higher Council for Public published a notice encouraging use of irradiation to replace controversial food additives. A similar statement was published in June 1984 by the National Academy of Medicine. These facts will encourage the submission of more petitions in the near future.

We think it is now time to reconsider the basic regulations and with the help of various ministries and food companies we are discussing possible changes in the 1970 decree. At the same time, a general clearance of up to 1 kGy is under consideration.

3 - INDUSTRIAL DEVELOPMENT

In the early sixties, two irradiation facilities were built for radio-sterilisation of medical supplies. The first one is run by a subsidiary of the Thomson Company and use electron beams. It is located near Paris. The second one is a cobalt irradiator with three irradiation chambers and a total activity of approximately 1.7 million curies.

The number of clearances that will soon be issued now make it possible to built a facility that would predominantly irradiate food products. Since no food company seemed ready to undertake the financial and commercial risk to build such a facility, it appeared natural to turn toward the public authorities. The Regional Council of Provence (elected body in charge, among other things, of the economic development) was very interested by the project and believed in its relevance for various reasons:

- the improved quality brought by irradiation will help companies to sell their products better on markets where there is a fierce competition, especially abroad.
- the increased shelf life of some products should contribute to a market regulation and a decrease of losses.
- an irradiation facility will reinforce the leading role of the Provence region for spices, herbs, dried fruit, etc... and will eventually attract companies interested in being close to a service irradiator.
- Many small food companies would like to use irradiation but the investments are too high.

Consequently an in-depth study of the project was undertaken.

Discussions started between the Regional Council and the Atomic Energy Commission, along with several other institutions like the Chambers of Commerce, Chambers of Agriculture, professional associations (consumers associations attend the meetings). As the region of Provence is the leading producer of fresh fruit and vegetables in France, something had to be done in this respect in relation with irradiation. We realized that a great deal of know-how is necessary to irradiate successfully such products. It was understood that it would take a few more years but the best chances of success were to gather people knowing the process and people knowing the food products and put at their disposal an irradiation source. However it is difficult to do research and development without disturbing a commercial activity. Hence our project comprises two parts:

- a multipurpose gamma pallet irradiator:

As the first of its kind in France, it will be a demonstration facility. It has to be able to irradiate in a wide dose range all types of food products.
The companies will then be able to test in actual conditions the technical and economical aspects of the technique. If it is multipurpose it has to be a gamma irradiator. Also, minimizing the costs means that the products must be handled as little as possible; therefore they must be irradiated in pallets. The location of this facility will be Marseille. Our first market studies indicate that the initial source activity should be of 500 000 Curies of Cobalt 60.

- a development facility of 100 000 Curies maximum where irradiation technology will be studied. The staff will also be in charge of training food technologists and informing various groups of people: consumers, journalists, doctors, etc... It will work for public institutions and private companies as well and will be independent from the commercial team.

The necessity for such a development irradiator was acknowledged by the Ministry of Agriculture (Food Industries Department) who is aware that many companies would like to use it to experiment their products. Therefore a major participation to the investment will be obtained from this Department. The problem is different for the commercial facility. It will be owned in majority by public institutions though part of the capital will come from private business. Indeed, we think that it is very important that the first large food irradiation company be mostly public. There are two main reasons:

1. It is the best guarantee for the public that nothing in contradiction with consumers' interests will be done,

2. all companies will have access to the process and not only large groups having the financial capacity to invest in this equipment.

The public funds will come from the Ministry of Agriculture, the National Agency for Development, the Regional Council, the Departmental Council and the City of Marseille. A final of market study is under process before starting the construction of the facilities which are expected to operate in 1986.

We think that the experience gained with this irradiator will be used to build more specialised ones where only one or several types of food will be processed at better costs.

Another large French company, THOMSON, recently designed an electron beam accelerator that seems well-suited to some food irradiation applications (10 kW-10 MeV maximum). The first machine should be sold to a French company in Britanny for radurisation of mechanically deboned poultry meat. The return on investment is expected after 3,3 years of operation.

4. INFORMATION

We consider that information is a top priority and we put a lot of time and energy into it. We naturally began with the food companies and created a "Food Ionizing Club" which started with 5 members in 1978. There are now almost 30, including all the major food companies. It constituted a kind of lobby, important enough to lead the Ministries to admit that food irradiation should be given serious consideration, and that not only the French AEC was interested in the process. Though this club, important progresses could be obtained, especially in the field of regulations.
In a second stage, we put most of our efforts in informing scientists and doctors who can in turn become sources of information. They appear more trustworthy to the consumers than business people. The very positive standpoints recently published by the Higher Council for Public Health and the National Academy of Medicine will be most helpful to gain the acceptance of the public.

Though very few if any products directly consumed will be irradiated in the coming years, discussions with consumers associations have started. Detailed articles were published in their two leading magazines. On the whole they were generally judged favorable, even if labeling of the process was demanded. One of the two main associations, "Institut National de la Consommation" is controlled by the government and has an important impact on the public through daily programs on the three national TV channels.

In the past months, many representatives submitted written questions and bills at the Parliament and the Senate. All of them were in favor of making the development of food irradiation easier by all possible means. Sometimes too many hesitations were reproached. Ministries often responded positively, ensuring that all that could be done would be.

In comparison with some other countries, a lot has yet to be done for a true development of food irradiation in France but the current situation is very encouraging. There is a general agreement and a fruitful cooperation between the food industry and public institutions to acknowledge the importance of food irradiation as an innovation, and a common will to use it.
LEGISLATION ON FOOD IRRADIATION IN CHILE

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Introduction

Chile, like the majority of developing countries has big losses of foods, which are calculated about 25% of the production. These losses are produced by a lot of factors, one of them is the lack of adequate technologies in food preservation.

Lately, the use of ionizing radiation has been studied with a very great interest because this technology can reduce drastically the magnitude of the problem and it could improve the quality of the exported products.

The studies about food irradiation started with the Food Irradiation Project, in the Chilean Nuclear Energy Commission (C.N.E.C.), during the seventies. To make researches in this field, two experimental irradiators were acquired: a Co-60 Cammacell 3500 (A_i = 8015 Ci) and a Cs-137 (A_i = 108,000 Ci, 1970).

So far a series of studies have been carried out with these facilities. Among them it is possible to mention the researches on potatoes, onions and garlic in order to inhibit sprouting; in fruits like strawberries and raspberries to diminish the load of microorganisms, as well as, in other products such as species, dehydrated vegetables, sea products like fish meal, hake and smoked salmon. Studies have also been done in avocados to retard ripening; and in bread to inhibit the growth of fungi during the storage (more than 6 months).

Due to the very positive results obtained during the first studies on food irradiation, a multipurpose irradiation plant was built to treat some products at pilot scale. This plant is located in the Nuclear Center Lo Aguirre, about 27 kms, from Santiago. The initial activity of the source (Co-60) was 101,306 Ci, 1977.
At the beginning of this decade, pilot scale irradiations were done using this facility and today the same Plant is carrying out the first commercial irradiations with onions, potatoes and dehydrated vegetables, once the Ministry of Health authorized the use of this technology, in 1982.

**General information related with the legislation in Chile**

- In Chile, the processing and sanitary control of food is regulated by the Ministry of Health, however, no one of the regulations in force mentioned, till 1982, food irradiation and the requirements to use it.

For this reason the CH.N.E.C. to carry out a first pilot scale study, with 164 tons of irradiated potatoes, had to submit to Ministry a special petition in October, 1974. The approval for this study was obtained by an official document of the Direction of the National Service of Health and signed by the Director of this Service. The experience comprised a study about the acceptance of the irradiated product and the results were very positive.

- In relation with the legal aspects, another important point to take into account is the acceptance by Chile, in 1981 of the Codex Alimentarius Commission Standards titled: "Recommended International General Standards for irradiated foods" and "Recommended International Code of Practice for the operation of Radiation Facilities for the treatment of food". The inquiry arrived in Chile through the National Normalization Institute and then it was remitted to the CH.N.E.C. to elaborate the answer.

- As soon as the recommendations of the Joint Expert Committee FAO/WHO/IAEA were known in Chile, it was agreed to start thinking of giving an impulse for the use of this technology in the country at semi-commercial scale.

To achieve this aim, the first matter necessary to clarify was in relation with the authorization by the Ministry of Health to apply this method on food for human consumption. For this reason a "Commission" was formed in 1982, sponsored by the CH.N.E.C. with the
participation of the Ministry of Health and the National Normalization Institute. The final proposal of this "Commission" was then sent to the Health Ministry with the application for authorization of the irradiation technology in the country.

The answer from the Ministry stated that: "The Ministry of Health approves your request to use the ionizing radiation as another method to preserve food in the country, for that purpose it will be able to apply this energy on all foods on which the Joint Expert Committee of FAO/WHO/IAEA fixed limits of irradiation doses. On this base, Chile has approved since 29 December, 1982 the following products:

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>OBJECTIVE (S)</th>
<th>DOSES LIMIT (kGy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potatoes</td>
<td>- To inhibit sprouting</td>
<td>0.15</td>
</tr>
<tr>
<td>Papayas</td>
<td>- To control insect infestation</td>
<td>1</td>
</tr>
<tr>
<td>Wheat and ground wheat products</td>
<td>- To control insect infestation</td>
<td>1</td>
</tr>
<tr>
<td>Strawberries</td>
<td>- To prolong the storage life</td>
<td>3</td>
</tr>
<tr>
<td>Chicken</td>
<td>- To prolong storage life and/or</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>- To reduce the number of certain pathogenic microorganisms</td>
<td></td>
</tr>
<tr>
<td>Onions</td>
<td>- To inhibit sprouting</td>
<td>0.15</td>
</tr>
<tr>
<td>Rice</td>
<td>- To control insect infestation</td>
<td>1</td>
</tr>
<tr>
<td>Teleost, fish and fish products</td>
<td>- To control insect infestation</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>- To reduce microbial spoilage of the packaged or unpackaged fish and fresh products.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- To reduce the number of certain pathogenic microorganisms in packaged or unpackaged fish and fish products</td>
<td></td>
</tr>
<tr>
<td>Cocoa beans</td>
<td>- To control insect infestation</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>- To reduce the microbial load of fermented beans with or without heat treatment.</td>
<td>5</td>
</tr>
<tr>
<td>Dates</td>
<td>- To control insect infestation</td>
<td>1</td>
</tr>
<tr>
<td>Mangoes</td>
<td>- To control insect infestation</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>To improve the keeping quality by delaying ripening</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- To reduce the microbial load by combining irradiation</td>
<td>1</td>
</tr>
<tr>
<td>PRODUCT OBJECTIVE (S)</td>
<td>DOSES LIMIT (kGy)</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------------------</td>
<td></td>
</tr>
<tr>
<td>Pulses</td>
<td>- To control insect infestation 1</td>
<td></td>
</tr>
<tr>
<td>Spices and condiments</td>
<td>- To control insect infestation 1 - To reduce the microbial load 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- To reduce the number of pathogenic microorganisms</td>
<td></td>
</tr>
</tbody>
</table>

Under these conditions, the authorization was not a surprise, because traditionally Chile has acknowledged the recommendations about the international food standards. On the other hand, the Chilean position is agreed with one of the main objectives of the creation of the Joint Expert Committee FAO/WHO/IAEA, which, is in relation with their recommendations could have influence in the legislation of some countries related with the control of the production and consumption of the irradiated foods, so, through a common point of view it could be possible to facilitate the international acceptance of this process.

In relation with the construction of any industrial Plant of food irradiation must be in accordance with the Chilean Nuclear Law (Law No 18302, published in the Official Bulletin of the Government of Chile, 2 May 1984) and for the Regulation of the authorizations for radioactive facilities or sources of ionizing radiation, personnel who worked in them or operate equipment or related activities (Decree No 155 of Ministry of Health, published in Official Bulletin, 23 August 1984) (Annex: Official Documents, in Spanish).

Both legal documents give to the Ministry of Health the responsibility of the authorizations of construction and operation of this type of facilities. Any further specific legislation in relation with facilities used for irradiating food will be a complement of the documents that have already been mentioned above and it must be in accordance with the international recommendations established for that purpose.

To sum up:

a) Chile accepts into its legislation the food irradiation if it is carried out in foods which the doses were established by the Joint Expert Committee FAO/WHO/IAEA, Geneva, 1980.
b) To carry out semi-commercial irradiations in foods there is a Multipurpose Pilot Plant which belongs to the CI.N.E.C.

c) The Chilean legislation accepts the construction and the operations of food irradiation facilities which can be done after the authorization of the Ministry of Health.

IDEAS ABOUT A POSSIBLE FUTURE REGULATION ON FOOD IRRADIATION IN CHILE

I. SCOPE AND DEFINITIONS

The object of the present regulation is to control the exposure to ionizing radiations for the preservation of foodstuffs for human consumption. That control will be applicable to all facilities in the country in which such a process is carried out.

Ionizing radiations for food preservation will be used for technical-economic reasons, food hygiene or any other justified reason. The main object for the application of this process, among others, is the inhibition of sprouting in bulbs and tubers, disinfestation, to retard ripening and to reduce the quantity of microorganisms.

All foodstuffs treated with ionizing radiations must comply with all the legal provisions with respect to wholesomeness from the nutritional and microbiological point of view. The irradiation facility can require before applying the process a quality control clearance, if it is found necessary.

For the purposes of the present regulation the following definitions are included:

a) Ionizing radiations
   - X rays and gamma rays with energies lower or equal to 5 MeV.
   - The electrones generated in accelerators that operate with energies lower or equal to 10 MeV.

b) Foodstuffs
   As defined and accepted by present regulations.

II. FOOD PRESERVED BY IONIZING RADIATION WITH UNCONDITIONAL ACCEPTANCE

Will be considered as such, all the foods authorized by the Ministry of Health. The treatment with ionizing radiation for food preservation cannot be repeated, exceptionally in cases of disinfestation in wheat and other cereals.
III. CONTROL OF IRRADIATION FACILITIES FOR FOOD PRESERVATION

The facilities used for food preservation by ionizing radiations will not be able to operate without the corresponding clearance from the Ministry of Health, according to the Decree No. 133 of May 22, 1984 published in the Official Bulletin of August 23, 1984.

Among the specific requirements for the issue of the above mentioned authorization, the following should be considered:

a) A full description of the facility and the technology used. Any modification made to the facility or technology applied should be informed previously for approval.

b) Detailed description of the construction of the facility, security systems to avoid repetition of the irradiation process which could lead to surpass the maximum approved doses established by the Ministry of Health.

c) Physical separation for the different types of processes to be applied in the facility.

d) The products not yet irradiated must be labelled and separated.

The storage place must have adequate conditions in order to avoid contamination.

e) The responsibility for the operation of the facility will be undertaken by a professional trained in radiological protection and food irradiation.

This training will be evaluated and certified by the Ministry of Health.

The food irradiation process cannot be carried out without the supervision of the above mentioned person.

The rest of the staff in charge of the operation of the facility must comply with the requirements specified in decree No. 133 mentioned in this draft.

The doses applicable to foodstuffs will be certified by a laboratory authorized by the Ministry of Health.

Every facility that applies ionizing radiations to food must have a record of the products irradiated or processes used that must contain the following information:

1. Name of the foodstuff preserved by ionizing radiations and information if necessary on whether the product has been treated by physical or chemical methods.

2. Reference number of consignment

3. Type of packing material

4. Dose applied, fractioning of dose if necessary
5. Dosemetric results (maximum and minimum dose obtained)
6. Date of irradiation
7. Location of the storage place after treatment
8. Comments if necessary

The facilities used for the treatment of food by ionizing radiations will be inspected periodically, not less than once a year, by experts designated for this purpose.

The results and recommendations, dates and name of the inspector will be indicated in the records of the facility and a copy should be sent to the corresponding office in the Ministry of Health that issued the licence.

The owners or managers of the facility used for food preservation cannot prohibit the entrance of the experts to perform inspection nor to the records of the facility as established in this document, and under no circumstance and on the other hand must give all the assistance in order to comply the inspection.

IV. IMPORT, EXPORT OF FOOD PRESERVED BY IONIZING RADIATIONS

Certificates for exportation will be required with respect to the technology used in the country of origin, if the authorities of health find it necessary, according with the rulings of this regulations.

Health authorities with the purpose of control for exports, will issue through its specialized section, the certificate of approval that establishes the compliance with the present regulations and/or the ones required by the buyer.

V. SANCTIONS

The sanctions to be applied in case of failure to fulfill the rulings of the present regulation, not taking into account the guides applied by the health authorities according to the Sanitary Code for foods, will be those established by the Law of Nuclear Safety and the regulations derived from it.
SCOPE OF THE CODEX GENERAL STANDARD

The Codex General Standard for Irradiated Foods covers only those aspects which relate to the process of treating food with ionizing radiation. Although the standard is intended to cover only those aspects which are thought to require regulatory control in connection with foods moving in trade, certain aspects relating to the irradiation facility have also been included which cannot, as yet, be checked on the food offered for sale.

As treatment with ionizing radiation does not alter the nature, freshness or actual state of the food, but endows it with certain additional desirable properties, e.g. improved hygiene or prolonged storage life, the applicability of Codex or national standards relating to food quality, food hygiene, weights and measures, labelling, etc., to irradiated foods is not affected. In fact, such standards exist for practically all foods suitable for treatment by irradiation. Some of these standards are international standards (e.g., Codex, OECD, UN/ECE, ISO, etc.), others are national standards of quality or safety. International as well as national standards exist for hygiene quality, safety, labelling, purity, packaging, and other aspects covered in food regulations. In fact,
the Codex General Standard for Irradiated Foods assumes that foods prior to and following irradiation are in conformity with such existing standards and have been produced under good manufacturing practices.

**ASPECTS DEALT WITH IN THE CODEX GENERAL STANDARD**

The aspects of irradiation dealt with in the Codex General Standard include definition of radiation sources, energy levels of the radiation employed, recommended maximum overall average absorbed dose, dosimetry, control of the irradiation facility, repeated irradiation, labelling of bulk shipments of irradiated foods, and inventory control for the identification of the registered facility, date of treatment and lot identification. The labelling of prepackaged irradiated foods, on the other hand, is covered in the Codex General Standard for the Labelling of Prepackaged Foods, adopted at step 8 by the Codex Alimentarius Commission at its 16th session, 1-12 July 1985, Geneva, Switzerland.

**PERMITTED RADIATION SOURCES**

Food irradiation uses the energy of electromagnetic radiation for the various technological purposes and, in principle, differs little from those other methods of food processing which employ energy, e.g., thermal processing or deep freezing. The basic physical process in food irradiation is the application to food of quanta of electromagnetic radiation energy at a given rate, causing ionizations. The dose of radiation energy absorbed is measured in Grays. In thermal processing, on the other hand, quanta of heat energy, measured in Joules, are either applied to or abstracted from food.

The Codex General Standard describes the various radiation sources which are suitable for use in food irradiation and prescribes the maximum energy levels below which these sources should operate. In this manner assurance is obtained that no radioactivity whatsoever is induced in the
food when exposed to radiation generated by such sources. The energy
levels of the radionuclide sources $^{60}$Co and $^{137}$Cs are well below those
which are capable of inducing radioactivity in the exposed food material.
For these and practical reasons only and are recommended as isotopic
sources, while X-ray and electron generating machine sources are limited in
their operating power.

LIMITATION OF THE ABSORBED DOSE

The Codex General Standard recommends that the "overall average dose"
absorbed by a food processed by irradiation should not exceed 10 K Gy. A
definition of "overall average absorbed dose" is given in Annex A to the
Codex Recommended International Code of Practice for the Operation of
Irradiation Facilities used for the Treatment of Foods. It should be
noted, however, that the value of 10 K Gy need not necessarily be regarded
as a recommended legal maximum limit or as a toxicological upper limit
above which irradiated foods become unsafe for human consumption; it is
simply the level for which the existing data base is adequate for judging
the wholesomeness of irradiated foods (Ref. 3). The level of 10 K Gy, incidentally,
is an adequate umbrella limit for almost all technological purposes for
which food might be irradiated. In establishing the recommended "maximum
overall average absorbed dose" in relation to health protection,
consideration was given to the existence of a considerable data base
including that derived from the use of higher levels of absorbed dose,
which had not given cause for concern. However, the total information on
nutritional microbiological and toxicological aspects of higher irradiation
doses was not sufficiently complete, at that time, to establish a maximum
level above 10 K Gy.

The definition of the "overall average absorbed dose" in the Codex
Standard recognizes the fact that the dose distribution in the irradiated
food implies some mass fraction of the product receiving a dose in excess
of the 'overall average' and some receive a dose below it. The establishment of the wholesomeness of food receiving 10 Kgy "overall average absorbed dose" also takes account of the dose distribution and the variation in dose found in practice.

The recommendation for a "maximum overall average absorbed dose", of 10 KGY which is of an advisory nature, should not be interpreted that it is appropriate to irradiate all foods up to that level from a technological point of view, even though from a point of view of any induced radiolytic products and other toxicological considerations, processing by irradiation up to 10 KGY would be safe, leaving the food non-injurious to the health of the consumer and causing no nutritional or microbiological hazards. Such a practice would in most cases be technologically unacceptable, because foods would suffer adverse organoleptic and quality changes, making them unacceptable to the consumer from a point of view of quality. Similar technological restrictions apply to the thermal processing of food which cannot be applied to every kind of food without affecting its quality.

The objectives of food irradiation are mainly threefold. The first is the protection of food during storage against spoilage by the natural microbial flora or destruction by contaminating insect pests. The second is the prevention of the spread of pests harmful to agriculture, or of human pathogens or animal parasites, carried by foods despite proper handling. The third is to delay maturation or germination of certain seasonally harvested foods to prolong their storage. It is clearly the responsibility of the irradiator to ensure that the processing is carried out correctly for the desired technological purpose and that appropriate radiation doses are applied to the food. It is clear that the technological purposes of irradiation must be achieved without adversely affecting the quality of the finished treated foodstuff.
It is not considered feasible to specify *a priori* in a standard generally valid technological ranges of absorbed dose for each proposed use of the process. It is equally difficult to try to establish maximum limits for absorbed doses for individual food commodities, because of the variability of the parameters determining the appropriate procedure to be followed under commercial scale practices. Examples of these parameters relate to the quality of the food, its physical characteristics, its compositional variability with location and season of harvesting, its nutritional role in the dietary of the national population, the manner of packaging and the nature of the irradiation source at the time of proposed treatment. The choice of the average absorbed dose or range of absorbed doses for each foodstuff to be irradiated will, therefore, depend on the expertise of the food irradiator and the results obtained during the initial trials. While the role of the irradiator in establishing the parameters of good irradiation practice is clear, it is not suggested that governments should not cooperate with industry and the irradiation facilities in establishing guidelines for the parameters for proper processing, where plant quarantine or other public health concerns are involved or in any other circumstances deemed necessary or desirable. Government action would depend also on the existence of other national plans and regulations related to the foodstuffs concerned.

As in the case of technological maxima of absorbed dose, it is not considered to be feasible to specify in a standard minimum absorbed doses, since these are dictated by scientific and technological considerations which vary with a number of parameters that become evident during the proper application of the process. It is preferable to check for correct irradiation treatment by carrying out the usual microbiological or other quality examinations.
It is for reasons such as stated above that the Codex General Standard does not deal specifically and in any detail with the technological aspects or needs for processing by irradiation, except for requiring that good radiation processing practice be followed.

It should be noted also that the inclusion in Annex B to the Recommended International Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods of a list of foods with specified "average doses" is purely for illustration of the utility of the irradiation process. It is not the intention of the Codex General Standard either to imply a need for clearance of the process on a food by food basis or to restrict the authorization of the process only to the foods listed in Annex B. The "average doses" specified are only intended as approximate descriptions of the conditions for achieving the desired purpose and should not be taken to be suggested legal limits or exact technological parameters. The Codex General Standard leaves Governments free to regulate the process in any desired manner in the light of the requirements of the Codex General Standard.

ENSURING GOOD RADIATION PROCESSING PRACTICE

In order to provide means of enforcing that good radiation processing practice is being followed, the Standard recommends the licensing, registering and the supervision of irradiation facilities and keeping records of the conditions of irradiation. Moreover, inspection of the quality of the irradiated food and of its hygienic condition as part of normal food control will assist in the governmental control of the process. For example, food irradiated for disinfestation purposes can be examined for the presence of fertile insects. If the purpose of treatment is the reduction of microbial load, compliance with the relevant microbiological criteria can be checked. The irradiation technique is self-regulating, since excess treatment may alter the quality of the processed food in an
adverse manner or since under-treatment will not achieve the desired technological purpose. Furthermore, as total absorbed dose is time dependant, there will be the unavoidable tendency for economic limitation on the amount of radiation a food will receive. Another safeguard is that all current technological applications operate below 10 KĠv.

Just as thermal processing is not applied indiscriminately to every food possible, but is used for specific technological needs, so food irradiation is applied where it offers technological advantages over other methods of processing. Examples of such application are the removal of human pathogens from pre-packed chicken, the prevention of spoilage of tropical fruits by the natural flora, the desinfestation of cereals, the inactivation of deepseated parasites in fruits and animal products not accessible without serious damage to the food, or the inhibition of sprouting of potatoes, onions and other vegetables to prolong their storage life. As mentioned above in relation to the use of appropriate doses of radiation, processing by irradiation requires the existence of well controlled licensed and registered installations and represents an added cost which is added to the total cost of production and processing. There is thus no incentive to apply this process to food unless there is a valid technological need. The Codex General Standard, therefore, does not deal with the clearance of individual foods to be irradiated but emphasises the need for the food to comply with the provisions of existing quality standards and of the International Code of Practice on the General Principles of Food Hygiene relative to the particular food, in the same way as untreated food. However, it may be that if irradiation is used for solving a particular public health or plant quarantine problem, the efficacy of the process for these specific purposes might require evaluation by national authorities in cooperation with the industry and specific authorization in relation to regulations not covered in the Codex Standard.
NUTRITIONAL ASPECTS

The Codex General Standard recommends that nutritional adequacy of the irradiated food be preserved. In fact, experiments have revealed that the effects of irradiation up to an overall average absorbed dose of 100 KGY on proteins, amino acids, vitamins and other nutrients are not significant and do not cause a health problem. Therefore, regulatory control of the nutritional content of irradiated food is as little indicated for irradiation as it is for thermal processing. There may be a need, however, for national control in certain isolated cases where the irradiated food is the major source of supply of a nutrient for the population, as part of a national nutrition policy.

REPEATED IRRADIATION

Re-irradiation is defined and permitted in the Codex General Standard under certain circumstances. International as well as national control of re-irradiation can be achieved through notification of the fact of radiation treatment having been given, in the document accompanying the food. For example, under the Codex General Standard low moisture content foods may be re-irradiated if they have become reinfested with insects, provided the quality of the food remains unaffected and the total dose absorbed does not exceed the maximum overall average dose of 10 KGY.

DOSIMETRY

The Codex General Standard provides an 'overall average absorbed dose' of radiation as an advisory limit to cover nutritional and other safety considerations and all radiation chemical effects, which are assumed to be proportional to doses up to 10 KGY. Specifying an "overall average" also assumes that, following mixing of the irradiated food or processing it to a homogeneous product, ingestion by consumers of the trace amounts of radiolytic products which may be present will also be an average amount.
Specifying average doses for technological purposes, on the other hand, would not be fully informative, since an average dose does not give an indication of the range of the absorbed doses involved.

The 'overall average absorbed dose' is defined and methods of monitoring it are described in Annex A to the Recommended International Code of Practice for the Operation of Irradiation Facilities used for the Treatment of Foods. The Code also provides guidance on routine dosimetry, process control and other aspects.

Although, as pointed out above, the quality - both hygienic and technological - of irradiated foods can be tested using conventional food control methods, it may be desirable to reach international agreement on more detailed dosimetry procedures, ways of establishing the acceptability of irradiation facilities and monitoring their performance.

LABELLING

On the subject of labelling, the Codex General Standard deals only with irradiation aspects relating to inventory control (i.e. information to be included on shipping documents) and the labelling of foods in bulk containers. The Standard recommends that appropriate information be recorded in the documents accompanying the food in transport. The labelling of prepackaged foods intended for direct sale to the consumers are covered in the Codex General Standard for the Labelling of Prepackaged Foods and other standards being developed for these situations.

There is still a considerable divergence of opinion regarding the extent of the information to be included on the label for the information of the consumer. Furthermore, the form in which this is to be done is subject to international harmonization. The question of the need for the
labelling of "second generation" foods, where irradiated foods are further processed or represent a component of a new processed food is also still under discussion. This latter question applies to such products as flour milled from irradiated wheat, to fishpaste made from irradiated fish, to irradiated chicken in canned chicken soup and to irradiated potatoes in canned meat with vegetables.

The Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Foods has concluded that it is not necessary on scientific grounds to envisage special requirements for the quality, wholesomeness and labelling of irradiated foods. This can also be taken to mean that there is not need to distinguish between irradiated as against un-irradiated foods from a safety (e.g. presence of radiolytic products) point of view. This does not mean that the declaration of the fact of irradiation, as a claim for certain desirable properties acquired by the food following irradiation, should not be envisaged. There can also be "technical grounds" for specific applications of food irradiation and the declaration of this fact on the label. For instance, in the case of foods irradiated for the purpose of eliminating pathogens (which should not be stored together with potentially contaminated foods), a statement on the label and/or on the shipping documents of such decontamination treatment would be considered appropriate and informative to manufacturers, traders and others.

ACCEPTANCE OF THE CODEX GENERAL STANDARD FOR IRRADIATED FOODS

Members of the Codex Alimentarius Commission are requested to notify the Secretariat of the Codex Alimentarius Commission - Joint FAO/WHO Food Standards Programme, of their acceptance of the Codex General Standard for Irradiated Foods, according to paragraph 4 of the General Principles of the Codex Alimentarius (see Fifth Edition of the Commission's Procedural Manual). (Ref. 1).
Member Nations and Associate Members of FAO and/or WHO which are not Members of the Commission are also invited to notify the Secretariat if they wish to accept the Codex General Standard for Irradiated Foods.

Countries which cannot give a formal acceptance to the Codex General Standard in accordance with paragraph 4A of the General Principles, are, none-the-less urged, to indicate whether irradiated foods may be permitted to be distributed freely within the territories of jurisdiction in accordance with para 4.B of the General Principles of the Codex Alimentarius.

Even where food irradiation may not be applied in a given country for a variety of practical reasons, it would be in the interest of facilitating international trade in irradiated foods if that country could make administrative or legal provisions to permit the entry of foods irradiated in accordance with good processing practices and in conformity with the Codex General Standard, and so notify the Secretariat of the Codex Alimentarius Commission.

The Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods is intended for the guidance of Governments and is not governed by the acceptance procedure for Codex Standards.

REFERENCES

(1) Codex Alimentarius, Volume XV (CAC/VOL.XV - Ed.1)
1. **SCOPE**

This standard applies to foods processed by irradiation. It does not apply to foods exposed to doses imparted by measuring instruments used for inspection purposes.

2. **GENERAL REQUIREMENTS FOR THE PROCESS**

2.1. **Radiation Sources**

The following types of ionizing radiation may be used:

(a) Gamma rays from the radionuclides $^{60}$Co or $^{137}$Cs;

(b) X-rays generated from machine sources operated at or below an energy level of 5 MeV.

(c) Electrons generated from machine sources operated at or below an energy level of 10 MeV.

2.2. **Absorbed Dose**

The overall average dose absorbed by a food subjected to radiation processing should not exceed 10 kGy (1) (2).

2.3. **Facilities and Control of the Process**

2.3.1. Radiation treatment of foods shall be carried out in facilities licensed and registered for this purpose by the competent national authority.

2.3.2. The facilities shall be designed to meet the requirements of safety, efficacy and good hygienic practices of food processing.

2.3.3. The facilities shall be staffed by adequate, trained and competent personnel.

2.3.4. Control of the process within the facility shall include the keeping of adequate records including quantitative dosimetry.

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(1) and (2) See notes on page 4.
2.3.5. Premises and records shall be open to inspection by appropriate national authorities.

2.3.6. Control should be carried out in accordance with the Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods (CAC/RCP 19-1979, Rev. 1).

3. HYGIENE OF IRRADIATED FOODS

3.1. The food should comply with the provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (Ref. No. CAC/RCP 1-1969, Rev. 1, 1979) and, where appropriate, with the Recommended International Code of Hygienic Practice of the Codex Alimentarius relative to a particular food.

3.2. Any relevant national public health requirement affecting microbiological safety and nutritional adequacy applicable in the country in which the food is sold should be observed.

4. TECHNOLOGICAL REQUIREMENTS

4.1. Conditions for Irradiation
The irradiation of food is justified only when it fulfils a technological need or where it serves a food hygiene purpose (3) and should not be used as a substitute for good manufacturing practices.

4.2. Food Quality and Packaging Requirements
The doses applied shall be commensurate with the technological and public health purposes to be achieved and shall be in accordance with good radiation processing practice. Foods to be irradiated and their packaging materials shall be of suitable quality, acceptable hygienic condition and appropriate for this purpose and shall be handled, before and after irradiation, according to good manufacturing practices taking into account the particular requirements of the technology of the process.

(3) See note on page 4.
5.1 RE-IRRADIATION

5.1. Except for foods with low moisture content (cereals, pulses, dehydrated foods and other such commodities) irradiated for the purpose of controlling insect reinestation, foods irradiated in accordance with sections 2 and 4 of this standard shall not be re-irradiated.

5.2. For the purpose of this standard food is not considered as having been re-irradiated when: (a) the food prepared from materials which have been irradiated at low dose levels e.g. about 1 kGy, is irradiated for another technological purpose; (b) the food, containing less than 5% of irradiated ingredient, is irradiated, or when (c) the full dose of ionizing radiation required to achieve the desired effect is applied to the food in more than one instalment as part of processing for a specific technological purpose.

5.3. The cumulative overall average dose absorbed should not exceed 10 kGy as a result of re-irradiation.

6. LABELLING

6.1. Inventory Control

For irradiated foods, whether prepackaged or not, the relevant shipping documents shall give appropriate information to identify the registered facility which has irradiated the food, the date(s) of treatment and lot identification.

6.2. Prepackaged foods intended for direct consumption

The labelling of prepackaged irradiated foods shall be in accordance with the relevant provisions of the Codex General Standard for the Labelling of Prepackaged Foods (4).

6.3. Foods in bulk containers

The declaration of the fact of irradiation shall be made clear on the relevant shipping documents.

(4) See note on page 4.
(1) For measurement and calculation of overall average dose absorbed see Annex A of the Recommended International Code of Practice for the Operation of Radiation Facilities used for Treatment of Foods (CAC/RCP 19-1979, Rev. 1).

(2) The wholesomeness of foods, irradiated so as to have absorbed an overall average dose of up to 10 kGy, is not impaired. In this context the term "wholesomeness" refers to safety for consumption of irradiated foods from the toxicological point of view. The irradiation of foods up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems (Wholesomeness of Irradiated Foods, Report of a Joint FAO/IAEA/WHO Expert Committee, Technical Report Series 659, WHO, Geneva, 1981).

(3) The utility of the irradiation process has been demonstrated for a number of food items listed in Annex B to the Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods.

(4) Under revision by the Codex Committee on Food Labelling.
1. **INTRODUCTION**

This code refers to the operation of irradiation facilities based on the use of either a radionuclide source ($^{60}\text{Co}$ or $^{137}\text{Cs}$) or X-rays and electrons generated from machine sources. The irradiation facility may be of two designs, either "continuous" or "batch" type. Control of the food irradiation process in all types of facility involves the use of accepted methods of measuring the absorbed radiation dose and of the monitoring of the physical parameters of the process. The operation of these facilities for the irradiation of food must comply with the Codex recommendations on food hygiene.

2. **IRRADIATION PLANTS**

2.1. **Parameters**

For all types of facility the doses absorbed by the product depend on the radiation parameter, the dwell time or the transportation speed of the product, and the bulk density of the material to be irradiated. Source-product geometry, especially distance of the product from the source and measures to increase the efficiency of radiation utilization, will influence the absorbed dose and the homogeneity of dose distribution.

2.1.1. **Radionuclide sources**

Radionuclides used for food irradiation emit photons of characteristic energies. The statement of the source material completely determines the penetration of the emitted radiation. The source activity is measured in Becquerel (Bq) and should be stated by the supplying organisation. The actual activity of the source (as well as any return or replenishment of radionuclide material) shall be recorded. The recorded activity should take into account the natural decay rate of the source and should be

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accompanied by a record of the date of measurement or recalculation. Radionuclide irradiators will usually have a well separated and shielded depository for the source elements and a treatment area which can be entered when the source is in the safe position. There should be a positive indication of the correct operational and of the correct safe position of the source which should be interlocked with the product movement system.

2.1.2. **Machine sources**
A beam of electrons generated by a suitable accelerator, or after being converted to X-rays, can be used. The penetration of the radiation is governed by the energy of the electrons. Average beam power shall be adequately recorded. There should be a positive indication of the correct setting of all machine parameters which should be interlocked with the product movement system. Usually a beam scanner or a scattering device (e.g. the converting target) is incorporated in a machine source to obtain an even distribution of the radiation over the surface of the product. The product movement, the width and speed of the scan and the beam pulse frequency (if applicable) should be adjusted to ensure a uniform surface dose.

2.2. **Dosimetry and Process Control**
Prior to the irradiation of any foodstuff certain dosimetry measurements (1) should be made, which demonstrate that the process will satisfy the regulatory requirements. Various techniques for dosimetry pertinent to radionuclide and machine sources are available for measuring absorbed dose in a quantitative manner (2).

Dosimetry commissioning measurements should be made for each new food, irradiation process and whenever modifications are made to source strength or type and to the source product geometry.

Routine dosimetry should be made during operation and records kept of such measurement. In addition, regular measurements of facility parameters governing the process,

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(1) See Annex A to this Code.
such as transportation speed, dwell time, source exposure time, machine beam parameters, can be made during the facility operation. The records of these measurements can be used as supporting evidence that the process satisfies the regulatory requirements.

3. GOOD RADIATION PROCESSING PRACTICE
Facility design should attempt to optimize the dose uniformity ratio, to ensure appropriate dose rates and, where necessary, to permit temperature control during irradiation (e.g. for the treatment of frozen food) and also control of the atmosphere. It is also often necessary to minimize mechanical damage to the product during transportation irradiation and storage, and desirable to ensure the maximum efficiency in the use of the irradiator. Where the food to be irradiated is subject to special standards for hygiene or temperature control, the facility must permit compliance with these standards.

4. PRODUCT AND INVENTORY CONTROL

4.1. The incoming product should be physically separated from the outgoing irradiated products.

4.2. Where appropriate, a visual colour change radiation indicator should be affixed to each product pack for ready identification of irradiated and non-irradiated products.

4.3. Records should be kept in the facility record book which show the nature and kind of the product being treated, its identifying marks if packed or, if not, the shipping details, its bulk density, the type of source or electron machine, the dosimetry, the dosimeters used and details of their calibration, and the date of treatment.

4.4. All products shall be handled, before and after irradiation, according to accepted good manufacturing practices taking into account the particular requirements of the technology of the process (3). Suitable facilities for refrigerated storage may be required.

(3) See Annex B to this Code.
DOSIMETRY

1. The overall average absorbed dose

It can be assumed for the purpose of the determination of the wholesomeness of food treated with an overall average dose of 10 kGy or less, that all radiation chemical effects in that particular dose range are proportional to dose.

The overall average dose, $\bar{D}$, is defined by the following integral over the total volume of the goods

$$\bar{D} = \frac{1}{M} \int \rho (x, y, z) \cdot d \cdot (x, y, z) \cdot dV$$

where

- $M$ = the total mass of the treated sample
- $\rho$ = the local density at the point $(x, y, z)$
- $d$ = the local absorbed dose at the point $(x, y, z)$
- $dV = dx \cdot dy \cdot dz$ the infinitesimal volume element

which in real cases is represented by the volume fractions.

The overall average absorbed dose can be determined directly for homogeneous products or for bulk goods of homogeneous bulk density by distributing an adequate number of dose meters strategically and at random throughout the volume of the goods. From the dose distribution determined in this manner an average can be calculated which is the overall average absorbed dose.

If the shape of the dose distribution curve through the product is well determined the positions of minimum and maximum dose are known. Measurements of the distribution of dose in these two positions in a series of samples of the product can be used to give an estimate of the overall average dose. In some cases the mean value of the average values of the minimum ($D_{\text{min}}$) and maximum ($D_{\text{max}}$) dose will be a good estimate of the overall average dose.

i.e. in these cases

$$\text{overall average dose} \approx \frac{D_{\text{max}} + D_{\text{min}}}{2}$$
2. **Effective and limiting dose values**

Some effective treatment e.g. the elimination of harmful microorganisms, or a particular shelflife extension, or a disinfestation requires a minimum absorbed dose. For other applications too high an absorbed dose may cause undesirable effects or an impairment of the quality of the product.

The design of the facility and the operational parameters have to take into account minimum and maximum dose values required by the process. In some low dose applications it will be possible within the terms of section 3 on Good Radiation Processing Practice to allow a ratio of maximum to minimum dose of greater than 3.

With regards to the maximum dose value under acceptable wholesomeness considerations and because of the statistical distribution of the dose a mass fraction of product of at least 97.5% should receive an absorbed dose of less than 15 kGy when the overall average dose is 10 kGy.

3. **Routine Dosimetry**

Measurements of the dose in a reference position can be made occasionally throughout the process. The association between the dose in the reference position and the overall average dose must be known. These measurements should be used to ensure the correct operation of the process. A recognized and calibrated system of dosimetry should be used.

A complete record of all dosimetry measurements including calibration must be kept.

4. **Process Control**

In the case of a continuous radionuclide facility it will be possible to make automatically a record of transportation speed or dwell time together with indications of source and product positioning. These measurements can be used to provide a continuous control of the process in support of routine dosimetry measurements.
In a batch operated radionuclide facility automatic recording of source exposure time can be made and a record of product movement and placement can be kept to provide a control of the process in support of routine dosimetry measurements.

In a machine facility a continuous record of beam parameters, e.g. voltage, current, scan speed, scan width, pulse repetition and a record of transportation speed through the beam can be used to provide a continuous control of the process in support of routine dosimetry measurements.
ANNEX B

EXAMPLES OF TECHNOLOGICAL CONDITIONS FOR THE IRRADIATION OF SOME INDIVIDUAL FOOD ITEMS SPECIFICALLY EXAMINED BY THE JOINT FAO/IAEA/WHO EXPERT COMMITTEE

This information is taken from the Reports of the Joint FAO/IAEA/WHO Expert Committees on Food Irradiation (WHO Technical Report Series, 604, 1977 and 659, 1981) and illustrates the utility of the irradiation process. It also describes the technological conditions for achieving the purpose of the irradiation process safely and economically.

1. **CHICKEN** *(Gallus domesticus)*

   1.1. **Purposes of the Process**
   The purposes of irradiating chicken are:
   (a) to prolong storage life
   and/or
   (b) to reduce the number of certain pathogenic microorganisms, such as *Salmonella* from eviscerated chicken.

   1.2. **Specific Requirements**
   Average dose: for (a) and (b), up to 7 kGy

2. **COCOA BEANS** *(Theobroma cacao)*

   2.1. **Purposes of the Process**
   The purposes of irradiating cocoa beans are:
   (a) to control insect infestation in storage
   (b) to reduce microbial load of fermented beans with or without heat treatment.

   2.2. **Specific Requirements**

   2.2.1. Average dose: for (a) up to 1 kGy
   for (b) up to 5 kGy

   2.2.2. **Prevention of Reinfestation**: Cocoa beans whether prepackaged or handled in bulk, should be stored as far as possible, under such conditions as will prevent reinfestation and microbial recontamination and spoilage.
3. **DATES (Phoenix dactylifera)**

3.1. **Purpose of the Process**
The purpose of irradiating prepackaged dried dates is to control insect infestation during storage.

3.2. **Specific Requirements**

3.2.1. **Average dose:** up to 1 kGy

3.2.2. **Prevention of Reinfestation:** Prepackaged dried dates should be stored under such conditions as will prevent reinestation.

4. **MANGOES (Mangifera indica)**

4.1. **Purposes of the Process**
The purposes of irradiating mangoes are:
(a) to control insect infestation
(b) to improve keeping quality by delaying ripening
(c) to reduce microbial load by combining irradiation and heat treatment.

4.2. **Specific Requirements**

Average dose: up to 1 kGy

5. **ONIONS (Allium cepa)**

5.1. **Purpose of the Process**
The purpose of irradiating onions is to inhibit sprouting during storage.

5.2. **Specific Requirement**

Average dose: up to 0.15 kGy

6. **PAPAYA (Carica papaya L.)**

6.1. **Purpose of the Process**
The purpose of irradiating papaya is to control insect infestation and to improve its keeping quality by delaying ripening.
6.2. Specific Requirements

6.2.1. Average dose: up to 1 kGy

6.2.2. Source of Radiation: The source of radiation should be such as will provide adequate penetration.

7. POTATOES (Solanum tuberosum L.)

7.1. Purpose of the Process
The purpose of irradiating potatoes is to inhibit sprouting during storage.

7.2. Specific Requirement
Average dose: up to 0.15 kGy

8. PULSES

8.1. Purpose of the Process
The purpose of irradiating pulses is to control insect infestation in storage.

8.2. Specific Requirement
Average dose: up to 1 kGy

9. RICE (Oryza species)

9.1. Purpose of the Process
The purpose of irradiating rice is to control insect infestation in storage.

9.2. Specific Requirements

9.2.1. Average dose: up to 1 kGy

9.2.2. Prevention of Reinfestation: Rice, whether pre-packaged or handled in bulk, should be stored as far as possible, under such conditions as will prevent reinfestation.
10. **SPICES AND CONDIMENTS, DEHYDRATED ONIONS, ONION POWDER**

10.1. **Purposes of the Process**
The purposes of irradiating spices, condiments, dehydrated onions and onion powder are:
(a) to control insect infestation
(b) to reduce microbial load
(c) to reduce the number of pathogenic microorganisms.

10.2. **Specific Requirement**
*Average dose:* for (a) up to 1 kGy
for (b) and (c) up to 10 kGy.

11. **STRAWBERRY** (*Fragaria* species)

11.1. **Purpose of the Process**
The purpose of irradiating fresh strawberries is to prolong the storage life by partial elimination of spoilage organisms.

11.2. **Specific Requirement**
*Average dose:* up to 3 kGy

12. **TELEOST FISH AND FISH PRODUCTS**

12.1. **Purposes of the Process**
The purposes of irradiating teleost fish and fish products are:
(a) to control insect infestation of dried fish during storage and marketing
(b) to reduce microbial load of the packaged or unpackaged fish and fish products
(c) to reduce the number of certain pathogenic microorganisms in packaged or unpackaged fish and fish products.

12.2. **Specific Requirements**

12.2.1. *Average dose:* for (a) up to 1 kGy
for (b) and (c) up to 2.2 kGy
12.2.2. **Temperature Requirement:** During irradiation and storage the fish and fish products referred to in (b) and (c) should be kept at the temperature of melting ice.

13. **WHEAT AND GROUND WHEAT PRODUCTS (Triticum species)**

13.1. **Purpose of the Process**
The purpose of irradiating wheat and ground wheat products is to control insect infestation in the stored product.

13.2. **Specific Requirements**

13.2.1. **Average dose:** up to 1 kGy

13.2.2. **Prevention of Reinfestation:** These products, whether prepackaged or handled in bulk, should be stored as far as possible under such conditions as will prevent reinfestation.
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