

International Acceptance of Irradiated Food

Legal Aspects

LEGAL SERIES No.11



INTERNATIONAL ATOMIC ENERGY AGENCY, VIENNA, 1979

INTERNATIONAL ACCEPTANCE OF IRRADIATED FOOD

Legal Aspects

LEGAL SERIES No. 11

INTERNATIONAL ACCEPTANCE OF IRRADIATED FOOD

Legal Aspects

REPORT OF A JOINT FAO/IAEA/WHO
ADVISORY GROUP ON
INTERNATIONAL ACCEPTANCE OF IRRADIATED FOOD
WAGENINGEN, 28 NOVEMBER – 1 DECEMBER 1977

INTERNATIONAL ATOMIC ENERGY AGENCY
VIENNA, 1979

INTERNATIONAL ACCEPTANCE OF IRRADIATED FOOD: LEGAL ASPECTS
IAEA, VIENNA, 1979
STI/PUB/530
ISBN 92-0-176079-5

© IAEA, 1979

Permission to reproduce or translate the information contained in this publication may be obtained by writing to the International Atomic Energy Agency, Kärntner Ring 11, P.O. Box 590, A-1011 Vienna, Austria.

Printed by the IAEA in Austria
March 1979

FOREWORD

The three international organizations competent in the field of irradiation processing for the preservation of food (FAO, WHO, IAEA) convened, at the end of 1977, an Advisory Group to revise and up-date the recommendations of a similar group which met in early 1972. The Advisory Group considered how national regulations could be harmonized so as to facilitate the international movement of irradiated food.

More and more food items are being granted clearance after extensive wholesomeness and technological studies. This demonstrates the advantages of the irradiation process and the interest being shown in an increasing number of countries. It is obviously important for the relevant national regulations governing food irradiation to be harmonized, and the Codex Alimentarius Commission actively pursues the establishment of standards for this process.

The present publication contains the Report of the Advisory Group, which summarizes the considerations of the Group on regulatory control over the irradiation plant and the irradiation of foods, and on assurance for comparability of control (international labelling and documentation). Annexes 1 to 6 are included in order to complete the relevant information on the legal aspects of this subject. Upon the recommendation of the Group, model regulations were prepared after the 1977 meeting by Prof. A. Gérard, one of the members of the multi-disciplinary expert group. These appear in the present publication as Annex 7.

CONTENTS

I. INTRODUCTION	1
II. CONSIDERATION OF ISSUES	3
A. Regulatory control of irradiation plant	3
B. Regulatory control of irradiated foods	4
1. Issuance of regulations	4
2. Licensing and approval	4
3. Enforcement of regulations	4
C. Food irradiation control practices	5
D. Assurance for comparability of control	5
1. Labelling provisions	6
2. Food lot documentation	6
3. Intergovernmental co-operation in comparability assurance ...	6
III. RECOMMENDATIONS TO FAO/IAEA/WHO	7

ANNEXES

Annex 1. List of participants	9
Annex 2. List of documents placed before the Advisory Group	13
Annex 3. Draft General Standard for Irradiated Foods. Report of the Eleventh Session of the Codex Committee on Food Additives, Appendix VII, Alinorm 78/12, 1977	15
Annex 4. Draft Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods. Report of the Eleventh Session of the Codex Committee on Food Additives, Appendix VIII, Alinorm 78/12, 1977	23
Annex 5. Recommendations of a Consultation Group on the Legal Aspects of Food Irradiation. Section III reprinted from the Report of a Consultation Group on the Legal Aspects of Food Irradiation, Vienna, 20–24 March 1972, organized by FAO, IAEA, WHO (IAEA, Vienna (1973, out of print))	29
Annex 6. Legislation on Food Irradiation Adopted in Member States (1971 – 1976)	33
Annex 7. Model regulations for the control of and trade in irradiated food. .	55

I. INTRODUCTION

An Advisory Group on International Acceptance of Irradiated Food was convened jointly by FAO/IAEA/WHO, with participation of NEA (OECD) representatives. The group met in Wageningen, The Netherlands, from 28 November to 1 December 1977.

The membership of the group consisted of the following experts: Messrs. R. Angelotti, D.J. Clegg, J.Ch. Cornelis, J.F. Diehl, P. Elias, J. Farkas, A. Gérard, H.M. Roushdy, R. Souverain, P.N. Swanepoel, P. Vanasatit, G.F. Wilmink. Mr. J.Ch. Cornelis served as chairman of the group and Mr. Angelotti as rapporteur.

A complete listing of participants including special advisors, observers and secretariat members is provided in Annex 1 to this Report.

The Consultation Group on the Legal Aspects of Food Irradiation which was convened by the same sponsoring organizations in 1972 stated in para. I.6 of its Report "that it is premature to develop detailed legal guidance for member countries who are concerned with the irradiation of food, because there were still unanswered questions regarding the safety evaluation of irradiated food".¹ Further, in para. I.12 of the Report, it was noted that "With regard to wholesomeness testing to demonstrate the safety or otherwise of the process of treating food with ionizing radiation, the Group agreed that the development of appropriate methodology for this purpose should be done at an international level. Development of methods in this field is one task of the International Project in the Field of Food Irradiation (a collaborative research project supported by 24 countries). The results of this methodology research and other appropriate information should be reviewed by a Joint FAO/IAEA/WHO Expert Committee convened especially for this purpose. The Group also agreed that it was desirable that an internationally recognized expert body such as a joint FAO/IAEA/WHO Expert Committee on food irradiation should continue to evaluate all the available data on the various aspects of food irradiation and make appropriate recommendations. The Group noted that the Codex Alimentarius Commission, which presently has a membership of 93 countries and which has responsibility for all aspects of food standards, could provide the appropriate facilities and means of securing international agreement in the field of food irradiation legislation and control through one or several of its subsidiary bodies which have competence in subjects such as food hygiene, food labelling, food additives and various groups of food commodities".

After the recommendation in 1969 of the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food to accept temporarily the irradiation of three foodstuffs for human consumption, wholesomeness tests on several other foodstuffs continued at the International Project in the Field of Food

¹ Report of a Consultation Group on the Legal Aspects of Food Irradiation, IAEA, Vienna (1973, out of print).

Irradiation (IFIP). On the basis of data produced by IFIP, the Joint FAO/IAEA/WHO Expert Committee at its meeting in 1976 recommended that the irradiation of five food items be given unconditional clearance (wheat, potato, chicken, papaya and strawberries), and of three others provisional clearance (onion, cod fish and red fish intended for evisceration, and rice).²

After this recommendation the Food Additives Committee of the Codex Alimentarius Commission, which included already in 1969 the irradiation process within its terms of reference, adopted at its last meeting in 1977 a Draft General Standard on Irradiated Food and a Draft Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods and submitted them to the Codex Commission at Step 5 of the Codex Procedures (see Annexes 3 and 4).

These developments have stimulated increased interest among nations for international trade in irradiated foodstuffs. As a result of these recent developments it is necessary that a legal framework be developed which could serve as the basis for harmonization of national legislation and regulatory procedures that will enhance confidence among trading nations that foods irradiated in one country and offered for sale in another country have been subjected to commonly acceptable standards of wholesomeness, hygienic practice and irradiation treatment control.

Over 40 countries are involved in some aspect of food irradiation. Numerous countries desire that irradiated foods be made available to their people because of the obvious advantages of such foods relative to public health and safety, to energy savings, increased shelf-life, enhanced hygienic qualities, reduced losses in storage and because the process of food irradiation is environmentally clean. Moreover, in that it is not possible analytically to determine that a food has been irradiated in accordance with an approved treatment process or, for that matter, whether the food has or has not been irradiated, it is necessary that systems be developed and implemented by countries that assure that irradiated foods moving in international trade meet internationally acceptable standards of wholesomeness, good manufacturing practice, hygienic quality, and irradiation treatment control. Such standards contribute to international trust and provide assurance that, independent of source country, irradiated foods are of comparable acceptability.

The present Advisory Group was convened to consider these recent developments in the acceptance of irradiated foods. The sponsoring organizations were of the opinion that standardization in irradiated food and harmonization in the regulatory control of irradiation processes will ensure international trade of such food which is safe for public health.

Toward this end the Advisory Group directed its attention to the issues of irradiation installation approval, regulatory control of irradiated foods, safety and

² FAO/IAEA/WHO, Wholesomeness of Irradiated Food, Report of the Joint FAO/IAEA/WHO Expert Committee, FAO, Rome (1977) pp. 24–40.

efficacy of food irradiation, assurances for comparability of control, labelling provisions, food lot documentation and recommendations to FAO/IAEA/WHO for future considerations.

II. CONSIDERATION OF ISSUES

A. Regulatory control of irradiation plant

As a general approach to its work the Advisory Group recognized that it was not necessary to elaborate recommendations concerning the approval of the installation and operation of irradiation plants. This aspect which involves radiological protection of the public and plant personnel will already be covered by existing national legislation and regulations or will be adequately covered by existing international recommendations.

For food irradiation it will be necessary to develop legislation relating to approval of irradiation plants by the appropriate national food control authority with regard to the suitability of plants and technical personnel for the specific purpose of food irradiation. The Advisory Group was of the opinion that food irradiation facilities should be approved by national food control authorities on the basis of technological considerations, for the carrying out of the process of food irradiation.

Hygienic requirements would also determine the types of food suitable for processing within any particular plant. However, such requirements will be governed by the already existing national food hygiene regulations in general, as well as by the "Recommended International Code of Practice. General Principles of Food Hygiene" (CAC/RCP 1-1969, Codex Alimentarius Commission, Rome).

With reference to para. 1 of the Draft General Standard for Irradiated Foods of the Codex Alimentarius (see Annex 3) and to para. I.9 of the Report of a Consultation Group on the Legal Aspects of Food Irradiation³, the Advisory Group confirmed that a low dose of radiation used in food technology for purposes other than irradiation processing of food was not to be considered as such, and that such an internationally acceptable dose limit should be established in order to facilitate further international comparability.

³ Para. I.9 of the Report of a Consultation Group on the Legal Aspects of Food Irradiation, IAEA, Vienna (1973, out of print) reads as follows: "The Group has decided that the use of radiation for process control, such as quality and quantity control with gauges containing radioisotopes, was not within the meaning of food irradiation as considered by the Group."

B. Regulatory control of irradiated foods

During its deliberations, the Advisory Group determined that control of food irradiation involves the following areas of concern: issuance of regulations; licensing and approval; and enforcement of regulations.

1. Issuance of regulations

The Advisory Group was of the opinion that, since considerable variation will occur at the national level with respect to food varieties to be irradiated, the technical effect desired or achieved by irradiation, and food needs, each individual country will have to develop its own regulations for food processing/regulation combinations, bearing in mind the considerations of appropriate relevant international recommendations so as to achieve international trust and comparability.

2. Licensing and approval

The Advisory Group discussed various existing legislative approaches to controlling irradiated foods. At the present time the Draft General Standard for Irradiated Foods of the Codex Alimentarius and national legislation (see Annexes 3 and 6) exercise control over individual irradiated foodstuffs rather than over food irradiation as a process. The recommendation in 1972 of the Consultation Group on the Legal Aspects of Food Irradiation was also in the same direction (Section III, para. 7 of the Report – see Annex 5). The Advisory Group was of the view that the legal control of food irradiation should not be based upon a prohibition of the process of food irradiation with permitted exceptions but rather upon acceptance of the principle that the process of food irradiation is permitted provided that limitations or conditions which are particular to each type of food may be defined by regulation.

3. Enforcement of regulations

National enforcement measures should be taken to ensure that all facets of the regulations (e.g. wholesomeness, hygienic controls, treatment controls, economic fraud, labelling etc.) are in compliance. The Advisory Group recognized the importance of record keeping by plant managers and operators. Such records should report on such relevant information as product, product density, energy source and type, absorbed dose, dosimetry methodology, date and location of irradiation treatment. These records should be available to inspectors and enforcement officials upon request for their use in determining that treatments have been conducted in compliance with all appropriate laws and regulations. The Advisory Group, in further discussions, also emphasized the importance of the need for

inspectors to be able to evaluate food hygiene and health physics aspects of the process of food irradiation. In discussing the frequency of inspection the Advisory Group determined that this is a national matter. However, the national governments are advised to consider compliance with internationally agreed standards relating to inspection of food processing plants.

The Advisory Group recommended particularly:

- a) that the inspectors should receive specialized training;
- b) that the powers of inspectors, the rights of individuals and the procedures and methods of control should be defined by appropriate regulations;
- c) that national regulations should be made compatible with internationally accepted guidelines at the earliest opportunity to enhance international trade in irradiated foods.

C. Food irradiation control practices

In order to meet the requirements of safety and efficacy of food processing by irradiation the Advisory Group recommended that each country promulgate a code of practice based on the Draft Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods of the FAO/WHO Codex Alimentarius Commission (see Annex 4).

As a minimum the code should include provisions governing: 1) the source of ionizing radiation; 2) time/radiation exposure relationship; 3) dosimetry; 4) separation of incoming (untreated) and outgoing (irradiated) products to avoid re-irradiation or lack of irradiation; 5) utilization of technical personnel appropriately trained and duly qualified to apply irradiation to foodstuffs.

The Advisory Group endorsed the principle set forth in Section III, para. 6 of the Report of a Consultation Group on the Legal Aspects of Food Irradiation, relating to acceptable types and levels of ionizing radiations (see Annex 5).

D. Assurance for comparability of control

The Advisory Group, having in mind the recommendations set forth in Section III, paras 12, 14 and 15 of the Report of a Consultation Group on the Legal Aspects of Food Irradiation (see Annex 5), considered the implications of international acceptance of irradiated food with regard to compliance with regulatory controls. In this area two aspects required close examination: the labelling of irradiated foods and the information essential to assure free movement of irradiated foods in international trade.

1. Labelling provisions

The Advisory Group was of the opinion that labelling of irradiated foods fulfilled, inter alia, two major functions: provision of information to the retailer and consumer on the one hand, and to the wholesale trade and national authorities on the other. In the view of the Advisory Group the form of labelling to be adopted for irradiated foods for the information of the retail trade and the consumer was a matter for consideration by the Codex Committee on Food Labelling. It recommended that the attention of the Codex Committee on Food Labelling be drawn to this point with particular emphasis on developing internationally acceptable expressions and presentations of information in any future labelling proposals.

2. Food lot documentation

The Advisory Group considered the problem of additionally labelling irradiated foods for the purposes of drawing the attention of the wholesale trade and national controlling authorities to the fact that an irradiation had been applied to the food. This additional labelling would offer a means of preventing further irradiation processing of the irradiated food. It was suggested that labelling for this purpose take the form of an internationally agreed coding system providing, as a minimum, information on the batch identification, country of processing, date of processing and identification of the irradiation facility. This information should also appear on the appropriate documents e.g. bills of lading, invoices etc. accompanying the bulk packaging, and on the bulk packaging itself, particularly for the benefit of the importer or wholesaler. By this means the possibility of re-irradiation of already irradiated bulk food may be avoided. This was particularly important for foods intended for incorporation into other foods which are subsequently to be processed by irradiation.

3. Intergovernmental co-operation in comparability assurance

In the opinion of the Advisory Group it was advisable to encourage the negotiation of separate agreements among governments, the purpose of which will be to promote co-operation between two or more countries for achieving, on the basis of commonly accepted standards, the control of installations that have been approved for irradiation of food.

III. RECOMMENDATIONS TO FAO/IAEA/WHO

A. The Advisory Group recommended that the attention of the Codex Committee on Food Additives be drawn to the wording of paragraph 2.2 of the Draft General Standard for Irradiated Foods. In the view of the Advisory Group, reconsideration may be warranted to make it clear that the list of approved applications of the food irradiation process included in Annex I of the Draft General Standard for Irradiated Foods of the Codex Alimentarius is not exhaustive and to allow for the possibility that a national authority may wish to permit the irradiation of any food considered appropriate but not as yet listed in Annex I of the Draft General Standard for Irradiated Foods (see Annex 3).

B. The Advisory Group further recommended that the attention of the Codex Committee on Food Labelling be drawn to the view that labelling of irradiated food for the purpose of information of the retail trade and the consumer is a matter for that Codex Committee, and that while considering this matter the Committee could develop an internationally acceptable expression and presentation of appropriate information.

C. The Advisory Group recommended that the next Joint FAO/IAEA/WHO Expert Committee address the following issues:

1. Reconsideration of the system of dose limit specifications and in particular reconsideration of the need for prescribing the lower limits of those ranges specified for foods where the purpose of irradiation is not related to microbiological or parasitological safety. It has been the practice generally to lay down a range of dosages for irradiation of foods and this practice has been followed also by the Joint FAO/IAEA/WHO Expert Committee and the Codex Alimentarius when drawing up the Draft General Standard for Irradiated Foods. It is, however, generally considered advantageous from a broad range of aspects to use the smallest dose of irradiation effective for its intended purpose and thus it would be only necessary to prescribe a maximum dose of irradiation for those processes not directed to control of microorganisms and parasites.

2. The need for revising paragraph 2.1 of the Draft General Standard for Irradiated Foods. The Advisory Group suggested that the radiation permitted for food irradiation have a maximum energy level of a) 10 MeV for electrons, b) 5 MeV for gamma rays and X-rays.

D. The Advisory Group, taking account of the recommendations of the Codex Alimentarius and those contained in the present report, was of the opinion that a legal framework for the approval and control of food irradiation should be drawn up, in relation to the general provisions governing the treatment and trading of foodstuffs.

It recommended, therefore, that FAO/IAEA/WHO prepare model regulations which could ultimately be submitted to the Member States for their consideration as they might deem appropriate.

The model regulations should be based on the recommendations contained in the Report of the Codex Alimentarius Committee on Food Additives and in the present report, and should be accompanied by concrete suggestions concerning legal methods for improving intergovernmental co-operation, possibly bilateral or regional, in controlling food irradiation plants and treatment of food by irradiation.

It was proposed that Mr. A. Gérard, as a consultant, could assist in the preparation of these model regulations.⁴

⁴ The model regulations were prepared by Mr. A. Gérard after the meeting of the Advisory Group and appear now as Annex 7 of this Report.

Annex 1

LIST OF PARTICIPANTS

(Wageningen, 28 November – 1 December 1977)

MEMBERS

Angelotti, R.	Administrator, U.S. Department of Agriculture, Food Safety and Quality Service, Washington, DC 20250, USA
Clegg, D.J.	Head, Pesticide Section, Toxicological Evaluation Division, Department of National Health and Welfare, Ottawa, Ont. K1A 0L2, Canada
Cornelis, J.Ch.	Ministry of Health and Environmental Protection, Leidschendam – Dokter Reijersstraat 12, The Hague, Netherlands
Diehl, J.F.	Bundesforschungsanstalt für Ernährung, Engesserstrasse 20, D-7500 Karlsruhe 1, Germany, Fed. Rep. of
Farkas, J.	Deputy Director, Central Food Research Institute, Ministry of Agriculture and Food Industry, Herman Ottó-út 15, H-1022 Budapest, Hungary
Roushdy, H.M.	National Centre for Radiation Research and Technology, 101 Kasr-el Eini Street, Cairo, Egypt
Souverain, R.	Inspecteur Général, Service de la répression des fraudes et du contrôle de la qualité, Ministère de l'Agriculture, 42 bis, rue de Bourgogne, F-75007 Paris, France
Swanepoel, P.N.	Department of Health, P.O. Box 386, Pretoria 0001, South Africa
Vanasatit, P.	Ministry of Public Health, Devaves Palace, Bangkok, Thailand

SPECIAL ADVISERS

- Elias, P. Director, IFIP, Institut für Strahlentechnologie,
Postfach 3640,
D-7500 Karlsruhe, Germany, Fed. Rep. of
- Gérard, A. Secretary General, European Food Law Association,
3, boulevard de la Cambre,
B-1050 Brussels, Belgium
- Wilmink, G.F. Cabinet Advisor, Ministry of Agriculture and Fisheries,
The Hague, Netherlands

OBSERVERS

- Brodrick, H.T. South African Atomic Energy Board, Private Bag X256,
Pretoria 0001, South Africa
- Brynjolfsson, A. Chief, Radiation Preservation of Food Division,
Natick Laboratory,
Natick, MA 01760, USA
- Chadwick, K.H. Association Euratom-ITAL, Wageningen,
Netherlands
- Donahue, M. U.S. General Accounting Office, Boston Regional
Office, Room 1903, John F. Kennedy Federal Bldg,
Boston, MA 02203, USA
- Kauffman, F.L. Assistant Director for Manufacturing Practices,
Department of Health, Education and Welfare,
Food and Drug Administration,
Washington, DC 20204, USA
- Kitson, A. Head, Food Processing Section, Agriculture Canada
Research Station, Summerland, B.C. V0H 1Z0,
Canada
- Lucas, L. U.S. General Accounting Office, Boston Regional Office,
Room 1903, John F. Kennedy Federal Bldg,
Boston, Mass. 02203, USA
- Oosterheert, W.F. Institute for Atomic Sciences in Agriculture,
6 Keyenbergseweg,
Wageningen, Netherlands

Owen, E. (Mrs.)	Food Contaminants Branch (Admin.), Ministry of Agriculture, Fisheries and Food, Great Westminster House, Horseferry Road, London SW1, UK
Potter, W.T.	(Secretary, IFIP) Nuclear Development Division, OECD/NEA, 38 boulevard Suchet, F-75016 Paris, France
Prades Canet, F.M.	Investigador, Comité Estatal de Ciencia y Técnica, Comisión Nacional para el Uso Pacífico de la Energía Atómica de Cuba, Havana, Cuba
Reyners, P.	Legal Affairs Section OECD/NEA, 38, boulevard Suchet, F-75016 Paris, France
Tolan, A.	Ministry of Agriculture, Fisheries and Food, Great Westminster House, Horseferry Road, London SW1P 2AE, UK

SECRETARIAT

Camcigil, M.	Legal Division, International Atomic Energy Agency, Vienna
Loaharanu, P. Vas, K.	Joint FAO/IAEA Division of Atomic Energy in Food and Agriculture, Vienna
Ladomery, L.G.	Food and Agriculture Organization of the United Nations, Rome
Blomberg, B. (Mrs.)	Environmental Legislation and Food Control Unit, World Health Organization, Geneva

Annex 2

LIST OF DOCUMENTS

placed before the Advisory Group
(Wageningen, 28 November – 1 December 1977)

AG-143/1	Topics proposed for discussion
AG-143/2	Legislation on food irradiation adopted in Member States
AG-143/3	The proposed directive of the Council of European Communities regarding harmonization of legislation on irradiated food
AG-143/3	Proposition d'une directive de la Commission des Communautés européennes relative au rapprochement des législations concernant les aliments irradiés
AG-143/4	Legal and administrative status of food irradiation in The Netherlands
AG-143/5	La législation française sur l'irradiation des aliments – procédure d'autorisation
AG-143/INF/2	General survey of irradiated food products cleared for human consumption in different countries
AG-143/6	Work to be done at the international level towards the acceptance of irradiated food
AG-143/7	Legal, administrative and psychological barriers against industrial application of food irradiation and the trade in irradiated food
AG-143/8	Excerpts from the departmental order no. 25/1976 VII/MEM of the Minister of Agriculture and Food about the enforcement of the food law of the Hungarian People's Republic – published July 11, 1976
AG-143/9	Aspects juridiques et implications internationales de l'irradiation des denrées alimentaires
AG-143/10	Outline of irradiated food control in Thailand
AG-143/11	Draft report

Annex 3

DRAFT GENERAL STANDARD FOR IRRADIATED FOODS

(Advanced to Step 5)

Appendix VII of the Report of the Eleventh Session of the Codex Committee on Food Additives, The Hague, 31 May – 6 June 1977, published in ALINORM 78/12, Codex Alimentarius Commission.

1. SCOPE

This standard applies to foods which have been treated by means of ionizing radiation. It does not apply to foods exposed to doses of 50 rad (0.5 Gy) (*) or less. This standard refers only to the irradiation aspects of the processing and handling of foods.

2. GENERAL REQUIREMENTS FOR THE PROCESS

2.1. Gamma rays from the isotope ^{60}Co or ^{137}Cs or electrons generated from machine sources operated at or below an energy level of 10 MeV shall be used.

2.2. No food shall be irradiated except as provided for in *Annex 1* of this standard.

2.3. In order to meet the requirements of safety and efficacy of food processing, the dose absorbed (**) by the food shall be within the range (***) specified for each individual food irradiation treatment in *Annex 1* of this standard.

2.4. Radiation treatment of foods shall be carried out in facilities licensed and registered for this purpose by the competent national authority. In this respect, the following is relevant:

2.4.1. Such facilities shall be designed to meet the requirements of safety and efficacy of food processing.

(*) Doses are expressed in rad and in Gy (gray), the newly introduced SI unit (1 Gy = 10^2 rad).

(**) General definition in the Manual of Food Irradiation Dosimetry, IAEA, Vienna (1977) Chapter III.

(***) In this context, "dose range" figures indicate that no part of the foods to be irradiated shall receive less than the minimum absorbed dose or more than the maximum absorbed dose stated (see: Wholesomeness of Irradiated Food, Report of a Joint FAO/IAEA/WHO Expert Committee, Techn. Rep. Ser. 604, WHO, Geneva (1977) 11).

- 2.4.2. The facilities shall be staffed by adequately trained and competent personnel.
- 2.4.3. Control of the process within the facility shall include the keeping of adequate records including quantitative dosimetry.
- 2.4.4. Premises and records shall be open to inspection by appropriate authorities.
- 2.4.5. Control shall be carried out in accordance with the Draft Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods.

3. SAFETY OF IRRADIATED FOODS

In order to protect the health of the consumer, irradiated foods shall have been thoroughly evaluated and found to be safe and wholesome by competent and appropriate authorities, not only from the toxicological but also from the nutritional and microbiological points of view.

In this respect, at the international level, only those irradiated foods which have been evaluated and found to be safe and wholesome by a Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food are acceptable. Two categories of acceptance have been used, unconditional and provisional, and are defined in *Annex 2* of this Standard.

4. FOODS TO BE IRRADIATED AND THEIR PRE- AND POST-IRRADIATION HANDLING

4.1. Foods to be irradiated and their packaging materials shall be of suitable quality, acceptable hygienic condition and appropriate for this process, 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.

4.2. Food irradiated in accordance with Section 2 (General Requirements for the Process) shall not be re-irradiated.

5. LABELLING

5.1. For the information of the consumers, labelling shall be in conformity with the provisions of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1–1969).

5.2. For the information of the trade and for the purposes of control, foods which have been treated with ionizing radiation shall be designated in an appropriate way in the accompanying documents and/or on the label. The accompanying documents and/or the label shall also identify the registered facility which has irradiated the food.

Annex 1

PROVISIONS FOR THE IRRADIATION OF SOME INDIVIDUAL FOOD ITEMS

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

1.1. Purpose of the process

The purpose of irradiating chicken is:

- (a) to prolong storage life of
and/or
- (b) to eliminate pathogenic microorganisms from eviscerated chicken stored below 10°C.

1.2. Specific requirements

In addition to meeting the general requirements of the standard, the following specific requirements shall be met:

1.2.1. Dose range

- (a) 200 – 700 krad (2 – 7 kGy)
- (b) 500 – 700 krad (5 – 7 kGy)

1.2.2. Temperature requirement

During irradiation and storage the product shall be kept at or below 10°C.

(*) Granted “Unconditional Acceptance” by the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food, Geneva, 31 August – 7 September 1976.

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

2.1. Purpose of the process

The purpose of irradiating papaya is to control insect infestation and to improve its keeping quality by delaying ripening.

2.2. Specific requirements

In addition to meeting the general requirements of the standard, the following specific requirements shall be met:

2.2.1. Dose range

50 – 100 krad (0.5 – 1.0 kGy)

2.2.2. Source of radiation

The source of radiation is limited to ^{60}Co or ^{137}Cs in order to provide adequate penetration.

3. POTATOES (*) (*Solanum tuberosum* L.)

3.1. Purpose of the process

The purpose of irradiating potatoes is to inhibit sprouting during storage and marketing.

3.2. Specific requirements

In addition to meeting the general requirements of the standard, the following specific requirement shall be met:

3.2.1. Dose range

3 – 15 krad (0.03 – 0.15 kGy)

(*) Granted “Unconditional Acceptance” by the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food, Geneva, 31 August – 7 September 1976.

4. STRAWBERRY (*) (*Fragaria* species)

4.1. Purpose of the process

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

4.2. Specific requirements

In addition to meeting the general requirements of the standard, the following specific requirement shall be met:

4.2.1. Dose range

100 – 300 krad (1 – 3 kGy)

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

5.1. Purpose of the process

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

5.2. Specific requirements

In addition to meeting the general requirements of the standard, the following specific requirements shall be met:

5.2.1. Dose range

15 – 100 krad (0.15 – 1.00 kGy)

5.2.2. Prevention of reinfestation

These products, whether prepackaged or handled in bulk, shall be stored under such conditions as will prevent reinfestation.

(*) Granted “Unconditional Acceptance” by the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food, Geneva, 31 August – 7 September 1976.

6. COD AND RED FISH (**) (*Gadus morhua* and *Sebastes marinus*)

6.1. Purpose of the process

The purpose of irradiating cod and red fish is to:

- (a) reduce microbial spoilage of the packaged or unpackaged fish refrigerated at or below 3°C, and
- (b) reduce the number of pathogenic microorganisms in packaged or unpackaged fish refrigerated at or below 3°C.

6.2. Specific requirements

In addition to meeting the general requirements of the standard, the following specific requirements shall be met:

6.2.1. Dose range

100 – 220 krad (1.0 – 2.2 kGy)

6.2.2. Temperature requirement

During irradiation and storage the product shall be kept at or below 3°C.

7. ONION (**) (*Allium cepa*)

7.1. Purpose of the process

The purpose of irradiating onions is to inhibit sprouting during storage and marketing.

7.2. Specific requirements

In addition to meeting the general requirements of the standard, the following specific requirement shall be met:

7.2.1. Dose range

2 – 15 krad (0.02 – 0.15 kGy)

(**) Granted "Provisional Acceptance" by the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food, Geneva, 31 August – 7 September 1976.

8. RICE (**) (*Oryza* species)

8.1. Purpose of the process

The purpose of irradiating rice is to control insect infestation in storage.

8.2. Specific requirements

In addition to meeting the general requirements of the standard, the following requirements shall be met:

8.2.1. Dose range

10 – 100 krad (0.1 – 1.0 kGy)

8.2.2. Prevention of reinfestation

This product, whether prepackaged or handled in bulk, shall be stored under such conditions as will prevent reinfestation.

Annex 2

DEFINITIONS OF CATEGORIES OF ACCEPTANCE OF IRRADIATED FOODS (*)

“Unconditional Acceptance – Acceptance granted when adequate data are available for the unequivocal establishment of the wholesomeness of the irradiated product.”

“Provisional Acceptance – Acceptance granted when additional testing is required to establish the wholesomeness of the irradiated product for life time use by humans but when there are sufficient existing data to indicate that no hazards to health would arise from consumption of the irradiated product in the diet over the period that would elapse before the additional testing was carried out and the findings were evaluated. It is recommended, therefore, that a provisional acceptance should remain in force until the new data are evaluated by a future FAO/IAEA/WHO Joint Expert Committee.”

(*) Report of the meeting of a Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food, Geneva, 31 August – 7 September 1976.

Annex 4

DRAFT CODE OF PRACTICE FOR THE OPERATION OF RADIATION FACILITIES USED FOR THE TREATMENT OF FOODS

(Advanced to Step 5)

Appendix VIII of the Report of the Eleventh Session of the Codex Committee on Food Additives, The Hague, 31 May – 6 June 1977, published in ALINORM 78/12, Codex Alimentarius Commission.

1. INTRODUCTION

This code refers to the operation of radiation facilities based on the use of either a radioisotope source (^{60}Co or ^{137}Cs) or an electron accelerator. The radioisotope source plant may be of two designs, either “continuous” or “batch”. Control of all types of plants involves the monitoring of the physical parameters of the process and the use of accepted methods of dosimetry.

2. RADIOISOTOPE SOURCE PLANTS

2.1. Parameters

The doses absorbed by a product depend on the source strength and its photon energy, the dwell time or the conveyor speed and the bulk density of the material to be irradiated. In practice the conveyor system is at a fixed distance from the source when in its exposed position.

2.1.1. Source

The source strength as measured in curies (Ci) (*) is stated by the supplying organizations and records should be kept by the operator giving details of each consignment as well as of any isotope which is returned. The actual total source strength will be known at any time. This strength will take into account the natural decay rate of the source which is constant for each isotope.

(*) The SI unit now introduced is Bq (becquerel); 1 MCi = 37 PBq (:peta Bq = 10^{15} Bq).

2.1.2. Source movement and conveyor speed

There should be a positive indication of the correct operational position of the source which should be interlocked with the conveyor drive. The speed of the conveyor intended to give the required dose is determined by dosimetry procedures referred to herebelow. The actual speed should be monitored continuously using a pen-recording chart situated outside the cell. Such chart should be kept for inspection. This chart should also show the position of the source, i.e. whether in the "exposed" or in the "safe" position.

In the case of a "batch" plant a timing device should be linked to the source movement mechanism which causes the source to descend automatically to the "safe" position when the pre-set time has expired.

Changes in the conveyor speed in the case of a "continuous" plant, or dwell times in the case of a "batch" plant, should be made in accord with the natural decay of the source. Such changes should be recorded in the plant record book.

2.2. Dosimetry

Various techniques for dosimetry pertinent to sources are available for measuring absorbed dose in a quantitative manner (**).

Special studies should be carried out at the commissioning of a plant and, similarly, if modifications are made to the source strength or type. Routine dosimetry measurement should be made during operation and recorded.

2.2.1. Dosimetry on commissioning and after source changes

In order to establish the dose distribution throughout the product to be treated and also to derive the correct setting of the conveyor speed, dose meters should be distributed in suitable numbers throughout the product. These dose meters should be placed at such positions as will give the best indication of dose variability. When the dose distribution is known, the conveyor speed should be determined which ensures that at least the specified minimum dose is given and that the maximum dose allowed is not exceeded.

If the source size or its geometry is changed or the type of product to be processed is changed, the procedure described above should be repeated.

2.2.2. Routine dosimetry

Dose meters should be included with the product itself so that at least two dose meters are used at least every 24 hours of operation of a "continuous" plant.

(**) Detailed in the Manual of Food Irradiation Dosimetry, IAEA, Vienna (1977).

In case of a “batch” operation, 2 dose meters should be used in every batch. Their locations and the results obtained should be recorded in the plant record book.

2.3. Product

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

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

2.3.3. Records should be kept in the plant record book which show the nature of the product being treated, its bulk density, the type of source, the dose given, and the date of treatment.

3. ELECTRON MACHINE PLANTS

3.1. Parameters

A conveyor carries the product through a beam of electrons generated by a suitable accelerator. Various machine parameters (energy, average current and width of scan) are adjusted to ensure a consistent beam, thus giving the correct irradiation to the product for a given conveyor speed. A scanner is incorporated into the machine to oscillate the beam to give an even distribution over the surface of the product packages.

3.2. Dosimetry

Various techniques for dose measurements pertinent to machines are available. A considerable programme of measurements is made when the machine is first installed. Following this, routine dosimetry should be performed and recorded.

3.2.1. Dosimetry after installation and following modification of operating parameters

The parameters of the beam should be measured when the installation is brought into use and following any interruption of the accelerator which might entail a modification of these parameters. The techniques for measuring the beam parameters should be those appropriate to the type of machines used.

To determine the speed of the conveyor for a given set of parameters of the beam, the distribution of the dose in a plant package should be established. Because of the highly variable absorption characteristics of high-energy electrons, the plant packages to be treated successively should be of the same density and the contents should be evenly distributed within the packages. The dose meters should be placed at such locations as will give the best indication of dose variability. A recognized system (*) of dosimetry should be used.

When the distribution of the dose has been determined for a given set of parameters of the beam, the conveyor speed should be adjusted to ensure that the specified dose is received at the point of minimum dose within the plant and that the maximum dose is not exceeded.

This investigation should be repeated each time there is a modification in any of the operating parameters of the installation or in the characteristics of the product to be irradiated.

3.2.2. Routine dosimetry

When the characteristics of the installation have been determined and the conveyor speed adjusted to ensure that the plant package receives the correct dose throughout, routine controls can be limited to the following:

- (i) measurements of the stability of the operating parameters by continuously recording the characteristics of the beam and the conveyor speed;
- (ii) there should be an immediate and simultaneous automatic stop device for the accelerator and conveyor in the case of any operating irregularities either of the beam or of the conveyor;
- (iii) there should be a procedure for the regular measurement of the correct dose absorbed by the product. Where large numbers of similar packs have to be treated, it is acceptable to place dose meters on only a small fraction of the packs and at least during each 8 hours of operation. The dose meters should be placed in pre-determined positions which give the best indication of the acceptable absorbed dose within the product pack. Their locations and the results obtained should be recorded in the plant record book.

3.3. Product

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

(*) Detailed in the Manual of Food Irradiation Dosimetry, IAEA, Vienna (1977).

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

3.3.3. Records should be kept in the plant record book which show the nature of the product being treated, its bulk density, the type of electron machine, the dose given, and the date of treatment.

Annex 5

RECOMMENDATIONS OF A CONSULTATION GROUP ON THE LEGAL ASPECTS OF FOOD IRRADIATION

Section III reprinted from the Report of a Consultation Group on the Legal Aspects of Food Irradiation, Vienna, 20–24 March 1972, organized by FAO, IAEA, WHO (IAEA, Vienna (1973, out of print)).

III. RECOMMENDATIONS

There are certain conclusions that can be reached at this time that may provide some general legal guidance. The three organizations should give consideration to the possibility of convening another consultation group to develop more detailed legal guidance when the results of the various current wholesomeness studies have become known.

1. The ultimate purpose of all food regulations is the protection of health and safety of the consumer, and prevention of deception. Treatment of food by irradiation for the purpose of general human consumption should be regulated at national and eventually at international level. The fundamental lines for such regulations are recommended herebelow.
2. There should be, until international regulations would materialize, an internationally common approach to the problems for the sake of harmonization of relevant legislation. The Group felt that it was the responsibility of Governments, particularly for the purposes of international trade in irradiated food, to adopt as far as possible uniform lines for regulations.
3. The protection of health and safety of the consumer would be best achieved by subjecting irradiated food to authorization by an enforcement body, before it is allowed on the market.
4. Processing techniques should be evaluated for the safety of the consumer. Even though no standard method of evaluation has so far been established, all authorizations should be based upon sound scientific principles for establishing safety of ingested substances and in accordance with the findings and recommendations of the duly constituted national or international bodies. Recommended technical procedures and tests required to permit an evaluation on the safety for consumption of irradiated food have been outlined in the 1964 Rome report.

5. Food irradiation generally falls into three categories that should be considered separately in developing regulations, as follows:

- (a) Low-dose treatment of food for various purposes, including sprout inhibition, insect disinfection, etc. in the dose range of up to 100 krad (1 kGy).
- (b) Medium-dose treatment of food to attain radicidation and radurization, i.e. reduction of the number, respectively, of viable specific pathogenic or spoilage microorganisms, in the dose range of 100 krad to 1 Mrad (1 kGy to 10 kGy).
- (c) High-dose treatment of food to attain radappertization, i.e. radiation sterilization, in doses of above 1 Mrad (10 kGy).

6. For the purpose of food irradiation, ionizing radiation should be of a type and energy level which does not result in induced radioactivity. Acceptable types of radiation sources, of radiation, and energy levels should be declared and revised by the competent authorities referred to in para. 3 above upon the advice of the advisory scientific bodies referred to in para.4. Types of radiation and energy levels which may be exempted from the application of the regulations should also be determined by the same bodies.

7. Specific authorizations should be issued for irradiation of individual food items or group of foods.

8. The purpose to be achieved by irradiation process should be stated in the authorization.

9. The type of radiation, the range of absorbed dose and other conditions of irradiation process should be specified in the authorization.

10. The authorization should specify the form and nature of records to be kept by the authorized person, including methods of dosimetry and dosimetry records.

11. The packaging material to be used in the irradiation of prepackaged food should be clearly defined in the authorization for the specific food item. Packaging materials which may be used in food irradiation could also be permitted through a separate authorization. The safety evaluation of such materials should be made by the appropriate scientific bodies at national or international level.

12. Any legislation should provide for informative labelling. The form or content of an appropriate label should preferably be established internationally. Labels should at least contain information with respect to the fact of irradiation, the country and the name of the food irradiation plant where treatment was undertaken, doses, etc. Labels for irradiated food, whether in bulk or not, should include a warning that the food must not be irradiated again.

13. Whenever necessary the competent authorities should regulate the conditions of storage and transport of irradiated food.

14. The competent authorities should allow exportation of irradiated food only if the importing country has authorized that irradiated food for general human consumption, and only if it is accompanied by a certificate of consignment containing the information required in labelling such as the absorbed dose, etc.

15. Importation of irradiated food should be allowed by the competent authorities of the importing country only if such a certificate of consignment as mentioned above accompanies the merchandise.

16. Definitions in a regulation on food irradiation should include the meanings attached to all words and phrases having a unique meaning for the purpose of the regulation. These definitions should include, among others:

- Ionizing radiation
- Irradiated food
- Low-dose treatment of food
- Medium-dose treatment of food
- High-dose treatment of food
- Total dose
- Dose units
- Irradiation plant
- Competent authority
- Food contact surface
- Intentional irradiation
- Unintentional irradiation.

Annex 6

LEGISLATION ON FOOD IRRADIATION ADOPTED IN MEMBER STATES

in the period of 31 December 1971 – 31 December 1976

Information for Argentina, Australia, Belgium, Canada, Denmark, Federal Republic of Germany, Israel, Italy, Luxembourg, Spain, Sweden, Switzerland, USSR and USA is taken from the Report of a Consultation Group on the Legal Aspects of Food Irradiation, Vienna, 20-24 March 1972, organized by FAO, IAEA, WHO (IAEA, Vienna (1973, out of print)).

ARGENTINA

I. Form of legislation

Article 174 of the Argentine Food Code promulgated with the Decree No. 2. 126 of 30 June 1971 (Boletín Oficial, 20 September 1971, page 12).

II. Object of legislation

Treatment by radiation

May be authorized.

III. Organization of control

1. Authorization is given by the National Health Organization,
2. “provided that it is proved experimentally by internationally recognized methods that the food preserved in this manner presents no hazard to the consumer”.

AUSTRALIA

The Federal Government is responsible for the control of consumption of irradiated food in Federal Territories; however, there does not exist a federal legislation in the field. State Governments have jurisdiction in respective States and among them only New South Wales has a regulation in the subject matter.

AUSTRALIA/NEW SOUTH WALES

I. Form of legislation

Insertion of para.5.A in the Regulation of the Pure Food Act of 1908 as amended – 26 June 1964. Official Gazette No. 79.

II. Object of legislation

1. *Treatment by radiation*

- (a) The manufacture and production of food which has been accidentally exposed to ionizing radiation:
Prohibition without exemption (Regulation 5 A (2) of the Pure Food Act).
- (b) The manufacture and production of food which has been intentionally exposed to ionizing radiation:
Prohibition with exemptions by special authorization (Regulation 5 A (1) of the Pure Food Act).

2. *Sale of irradiated food*

- (a) Sale of food which has been accidentally exposed to ionizing radiation:
Prohibition without exemption (Regulation 5 A (2) of the Pure Food Act).
- (b) Sale of food which has been intentionally exposed to ionizing radiation:
Prohibition with exemptions by special authorization (Regulation 5 A (1) of the Pure Food Act).

III. Organization of control

Authorization is given by the Director General of Public Health (Regulation 5 A (1) of the Pure Food Act).

AUSTRALIA/QUEENSLAND

Although there is no special legislation on food irradiation, the Health Department took a decision that the Radiological Advisory Council could grant a licence for irradiation of food, provided that there is no danger of contamination of the food.

AUSTRIA

I. Form of legislation

Food Law of 1975, para. 14, BGBl. 86, 18 February 1975 (Lebensmittelgesetz 1975).

II. Object of legislation

It shall be prohibited to market foodstuffs, consumption products, or additives, which have been treated with ionizing radiations without authorization or contrary to the requirements for authorization or without indication of the irradiation procedure on the label.

III. Organization of control

1. The Federal Minister for Health and Environmental Protection shall, if this is compatible with securing faultless food and with protection of the consumer from a health hazard or from deceit, taking into consideration the standard of science and technology, after consulting the Codex Commission, by way of ordinance authorize treatment with ionizing radiations generally or for groups of foodstuffs, consumption products, or additives. The procedure to be applied as well as the precautionary measures necessary for protection of the consumer and the form of designation of the irradiation shall be established.

2. The Federal Minister for Health and Environmental Protection shall, if this is compatible with securing faultless food and with protection of the consumer from a health hazard or from deceit, taking into consideration the standard of science and technology, upon application, authorize by decree the treatment of specified foodstuffs, consumption products, or additives with ionizing radiations or any other marketing of foodstuffs, consumption products, or additives treated in such a manner. In the decree the procedure of irradiation to be applied as well as the safety precautions necessary for the protection of the consumer and the form of designation of the irradiation shall be established. The period of validity of the decree shall not exceed three years; but the decree shall be revoked before the expiration of this period if the conditions for authorization are no longer met. With the application for authorization the applicant shall submit all material which allows an evaluation of the procedure of irradiation and of the irradiated goods.

BELGIUM

I. Form of legislation

Royal decree on the protection of the population and the workers against the hazards of ionizing radiation, dated 28 February 1963 (Moniteur Belge, 16 May 1963, p. 5206) and its amendment of 23 December 1970 (Moniteur Belge, 17 February 1971).

II. Object of legislation

1. Treatment by radiation

Prohibition (Art. 64.1(c) of the Royal Decree) with exemption through special authorization for the purposes of research, disinfection, or elimination of certain microorganisms (Art. 65.1(b) of the Royal Decree as amended).

2. Importation of irradiated food

Prohibition with exemption through special authorization (Art. 65.1(d) of the Royal Decree as amended).

III. Organization of control

1. Authorization is given by the Minister of Public Health and Family upon the favourable opinion of the Supreme Council of Public Health (Art. 65.1 of the Royal Decree as amended).

2. Authorization relates particularly to the approval of the equipment to be used and the conditions of treatment and to the means of identifying the irradiated food and the radiation dose (Art. 65.1(b) of the Royal Decree as amended). Authorization, wherever appropriate, may take into account the criteria appropriate for food in bulk.

BRAZIL

I. Form of legislation

Decree No. 72718 of 29 August 1973 establishing general standards for the irradiation of foodstuffs, made pursuant to Section 59 of Decree-Law No. 986 of 21 October 1969. (Diário Oficial, Section I, Part I, 30 August 1973, No. 167, p. 8665.)

II. Object of legislation

1. *Treatment by radiation*

This Decree regulates the processing, storage, transport, distribution, import, export, display for sale, and supply for consumption of irradiated foodstuffs throughout the country.

For the purposes of this Decree, “irradiated foodstuff” means any foodstuff which has been intentionally exposed to the action of ionizing radiations with a view to its preservation or for other lawful purposes, in compliance with the standards to be laid down by the competent agency of the Ministry of Health.

Ionizing radiations may, in general, be applied to foodstuff, if their energy is below the threshold level of nuclear reactions which might induce radioactivity in the irradiated foodstuffs. Only establishments duly licensed by the competent authority and granted an authorization by the National Nuclear Energy Commission may carry out irradiation of foodstuffs intended for display for sale, supply for consumption, or industrial processing.

2. *Labelling*

At the time of their display for sale or supply for consumption, irradiated foodstuffs must bear the legend “Foodstuff treated by an irradiation process” and the statement “This product has been processed in an establishment under the control of the National Nuclear Energy Commission”.

3. *Importation*

The provisions of this Decree and of other complementary standards are applicable, *mutatis mutandis*, to imported irradiated foodstuffs.

4. *Exportation*

Irradiated foodstuffs intended for export may be produced in accordance with the standards in force in the country of destination.

III. Organization of control

1. Authorization may be granted only for the irradiation of foodstuffs or groups of foodstuffs concerning which technical and scientific studies, carried out by national or international research institutions duly approved by the National Nuclear Energy Commission, are available. These studies must have established: (a) the safety of the irradiated foodstuff for consumption; (b) the extent of the

effects of irradiation on the principal nutritive ingredients of the foodstuff, in comparison with losses caused by treatment of the foodstuff by conventional processes; (c) the wholesomeness of the irradiated foodstuff and the efficacy of irradiation in achieving the results sought.

2. It is to be the responsibility of the National Food Standards Commission of the Ministry of Health, acting on the recommendation of the National Nuclear Energy Commission made on the basis of the above-mentioned technical and scientific data, to draw up a schedule of foodstuffs or groups of foodstuffs for which irradiation is authorized, stating in each case: the type and energy level of the radiation that may be used; the nominal radiation dose to be applied; the purpose of the radiation treatment; and any preliminary, concomitant, or subsequent treatments to be applied for the purpose of achieving the desired objective.

3. Irradiated foodstuffs supplied for consumption must meet the identity and quality standards specific to the particular foodstuffs, without prejudice to the approval by the National Food Standards Commission of the Ministry of Health of a specific identity and quality standard for an irradiated foodstuff. Prior authorization from the Commission is required for the use of intentional additives in foodstuffs which are to be, or have already been, irradiated. Plant protection products and other impurities in foodstuffs which are to be, or have already been, irradiated must not be present in amounts exceeding the residue tolerances laid down by the Commission.

CANADA

I. Form of legislation

Amendment E 13/24/1/66 of 14 July 1966 to Food and Drug Regulations defines irradiation as a food additive and thus brings it under the control of general food legislation (Section B.01.001(d)). Permissions for food irradiation appear in the list of permitted additives (Table VIII of Section B.16.100, item G.1).

II. Object of legislation

1. *Treatment by radiation*

Prohibition with exemptions through special authorization.

“Gamma radiation from cobalt-60 source” is an authorized food additive under the following circumstances:

Permitted in or upon	Purpose of use	Maximum level of use
a. Potatoes, onions	a. Antisprouting agent	a. 15 000 rad (150 Gy)
b. Wheat, flour, whole wheat flour	b. For disinfestation	b. 75 000 rad (750 Gy)

(Table VIII to Section B.16.000, item G.1 of the Regulations)

Wheat, flour and whole wheat flour are standardized foods, and the appropriate standards permit that they “may be treated with gamma radiation from cobalt-60 source” (Sections B.13.001 and B.13.005 of the Regulations).

2. *Labelling*

All food additives must be declared on the label (B.16.001). There are no specific requirements with respect to the type of statement which must appear on packages of irradiated onions or potatoes; the following have been accepted: “Sprout inhibited by gamma energy”; “Sprout inhibited by ionizing radiation”. Mandatory labelling for wheat and flour is prescribed by the appropriate food standards: “Where it is so treated, the flour shall be labelled and the label shall carry a statement to the effect that the flour has been “processed” or “treated” with ionizing radiation” (Sections B.13.001 and B.13.005 of the Regulations. Amendment P.C. 1699-384 of 25 February 1969. Canada Gazette, Part II, Volume 103, p. 88).

III. Organization of control

1. Authorization is given in the form of amendments to the Food and Drug Regulations, approved by the Governor-in-Council upon the recommendation of the Department of National Health and Welfare, and published in the Canada Gazette.

2. A request to amend the regulations must be accompanied by a submission of data detailing the proposed process, its efficiency, data to establish the safety of the food, and specimens of the proposed label (Section B.16.002 of the Food and Drug Regulations).

3. The inspection and control of premises where food is irradiated (after authorization has been granted) are the joint responsibility of the Food and Drug Directorate and the Radiation Protection Division of the Department of National Health and Welfare.

DENMARK

I. Form of legislation

Notice No. 413 of 31 October 1967 of the Ministry of Interior regarding the treatment of foodstuffs with ionizing radiation, issued under the terms of the Foodstuffs Act No. 174 of 28 April 1950.

II. Object of legislation

1. *Quality and/or quantity control by radiation*

Prohibition with exemption through special permission. The radiation dose absorbed by the foodstuffs in this process may not exceed 10 rad (0.1 Gy) and the energy 5 MeV (para. 2 of the said Regulation).

2. *Treatment by radiation*

Prohibition with exemption through special permission for individual food commodity (paras 3 and 4 of the said Regulation).

The Ministry of Interior, on the basis of a recommendation by the Board of Public Health, issued a permit, on 27.1.1970, to irradiate potatoes by 10 MeV electrons to a maximum absorbed dose of 15 000 rad (150 Gy).

3. *Importation of irradiated food*

Prohibition with exemption through special permission (para. 8 of the said Regulation).

4. *Labelling of irradiated food*

Compulsory declaration of "Treated with ionizing radiation".

III. Organization of control

Authorization is given by the Ministry of Interior upon an examination and recommendation by the Board of Public Health (para. 3 of the Regulation).

The application for authorization must include data on:

Type of radiation source

Maximum absorbed dose

Maximum radiation energy

Other treatment of the food besides radiation

Packaging

Results of any research on safety for consumption

(Para. 5 of the Regulation.)

The rules for inspection are established and inspections are carried out by the Ministry of Interior at the expense of the establishment doing the irradiation (para. 6 of the Regulation).

FRANCE

I. Form of legislation

Order of 8 November 1972 of the Minister of Agriculture and Rural Development and the Minister of Public Health for the implementation of the Decree of 8 May 1970 on trade in irradiated merchandise. (Journal officiel de la République française, 12 December 1972, No. 289, p. 12794.)

II. Object of legislation

The maximum absorbed dose referred to in Section 3 of Decree No. 70-392 of 8 May 1970 (i.e. the absorbed dose below which most of the provisions of this Decree do not apply) is fixed at 25 rad (0.25 Gy).

GERMANY, FEDERAL REPUBLIC OF

I. Form of legislation

1. Act concerning the commerce in food and commodities of 17 January 1936 as amended (Food Act) (Reichsgesetzblatt I 1936, P. 17/Bundesgesetzblatt I 1958, p. 950).

2. Regulation on the irradiation of food of 19 December 1959 (Bundesgesetzblatt I 1959, p. 761).

II. Object of legislation

1. *Quality and/or quantity control by radiation*

General authorization up to 10 rad (0.1 Gy) absorbed dose (§ 1, Sec. 1 of the Regulation of 19 December 1959).

2. *Treatment by radiation*

Prohibition with exemption through special authorization (Chapter 1, Sec. 4(c), Subsec. 1 of the Food Act).

3. *Labelling*

Compulsory declaration of a label indicating the irradiation in accordance with regulations issued by the Ministry of Interior (Chapter 4(c), Subsec. 2 of the Food Act; § 3 of the Regulation of 19 December 1959).

Exemption from labelling may be authorized by the same Ministry (Chapter 1, Sec. 5(a)(1), Subsec. 6 of the Food Act).

4. *Storage*

Prohibition without exemption (Chapter 1, Sec. 4(e), Subsec. 1 of the Food Act).

5. *Sale of irradiated food*

Prohibition without exemption (Chapter 1, Sec. 4(e), Subsec. 1 of the Food Act).

6. *Importation*

The importation of irradiated food the irradiation of which is not in conformity with German laws is prohibited (Chapter 1, Sec. 21 of the Food Act).

7. *Exportation*

The exportation of irradiated food is explicitly not restricted (Chapter 1, Sec. 5(b), Subsec. 1 of the Food Act).

III. Organization of control

Authorization is given – in the form of a regulation – by the Federal Minister for Youth, Family and Health in collaboration with the Federal Ministers of Food, Agriculture and Forestry, of Economics and of Scientific Research upon approval by the Bundesrat.

The authorization may be in general or for a certain foodstuff (Chapter 1, Sec. 4(c), Subsec. 1 of the Food Act).

In the extraordinary circumstance exemption may be authorized by the Ministry of Food, Agriculture and Forestry with the agreement of the Ministry of Nuclear Energy and Water Supply and without the approval of the Bundesrat (Chapter 1, Sec. 5(e) of the Food Act).

ISRAEL

I. Form of legislation

Regulations on People's Health (Conservation of food by irradiation), dated 5 July 1967 and 14 July 1968 issued by the Minister of Health under the authority of Section 3 of the Public Health (Rules as to Food) Ordinance of 1935 (Regulations Bulletin July 13, 1967, p. 2782 and July 25, 1968, respectively).

II. Object of legislation

1. *Treatment by radiation*

Prohibition with the exemption of commodities, radiation sources and doses specified in the Appendix to the Regulation and upon a permit showing the instructions on the method of irradiation (Sec. 2 of the Regulation).

Appendix reads: 1. Onions – Gamma rays of ^{60}Co – Up to 10 000 rad (100 Gy)
2. Potatoes – Gamma rays of ^{60}Co – Up to 15 000 rad (150 Gy)

2. *Labelling*

Irradiated food must be labelled: "Food conserved by irradiation" (Sec. 4 of the Regulation).

3. *Sale of irradiated food*

Prohibition with the same exemption as prescribed in para. 1 above (Sec. 2 of the Regulation).

4. *Import*

Prohibition unless a declaration from the relevant authority of the exporting country satisfies the requirements prescribed in para. 1 above (Sec. 3 of the Regulation).

III. Organization of control

The Director General of the Ministry of Health gives a written permit setting forth detailed instructions on the method of irradiation (Sec. 2, Subsec. 3 and Sec. 3, Subsec. 2 of the Regulation).

ITALY

I. Form of legislation

Law No. 283 of 30 April 1962 amending the Public Health Act 1265 of 27 July 1934 (Gazzetta Ufficiale 1962, p. 2194).

II. Object of legislation

1. *Treatment by radiation*

May be authorized with a ministerial decree (Art. 7 of the Amendment).

2. *Sale of irradiated food*

May be authorized with a ministerial decree (Art. 7 of the Amendment).

3. *Labelling*

Label and its content may also be prescribed in the Ministerial Decree (Art. 7 of the Amendment).

III. Organization of control

Authorization is given by the Minister of Public Health after consultation with the Higher Council of Health (Art. 7 of the Amendment).

JAPAN

I. Form of legislation

Food Sanitation Law, amendment of August 8, 1972.

II. Object of legislation

1. *Treatment by radiation*

When foods are manufactured or processed, they should not be irradiated by ionizing radiation, except when isotopes are used for control of machinery at food plants and foods are irradiated as a result thereof and when absorbed dose is less than 10 rad (0.1 Gy), or when specific processing standard of irradiation is established for each food.

2. *Labelling*

Labelling is required by the revision of Enforcement Regulation of Food Sanitation Law of August 29, 1972 as follows: Irradiated foods should bear the statement to the effect that they are processed by ionizing radiation.

III. Organization of control

Permission for an irradiation establishment is prescribed by the Cabinet Order of Food Sanitation Law of August 28, 1972 as follows: (1) Establishment of a food irradiation facility should be permitted by the Government of Prefecture. (2) A food irradiation establishment should assign a food sanitation supervisor to its establishment.

LUXEMBOURG

I. Form of legislation

Regulation on the execution of the Act of 25 March 1963 relating to the protection of the population against the hazards resulting from ionizing radiation, dated 8 February 1967 (Memorial No. 15, 8 March 1967, p. 142).

II. Object of legislation

1. *Treatment by radiation*

Prohibition with exemptions through special authorization (Art. 5.1, Sec. 4 of the Regulation).

2. *Importation of irradiated food*

Prohibition with exemptions through special authorization (Art. 5.1, Sec. 4 of the Regulation).

III. Organization of control

Authorization is given by the Minister of Public Health (Art. 5.1, Sec. 4 of the Regulation).

SOUTH AFRICA

I. Form of legislation

Government Notice No. R.172 of 8 February 1974. Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972). Regulation. — Irradiated foodstuffs. (Government Gazette, 8 February 1974, No. 4159, p.11.)

This Regulation has been made in pursuance of Section 15(1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972.

II. Object of legislation

Sale of irradiated food

Prohibition with exemption through special authorization.

III. Organization of control

Authorization for sale is given by the Ministry of Health.

SPAIN

I. Form of legislation

Decree by the Minister of the Interior No. 2725 of 6 October 1966 regulating the procedure for approval of preservation by irradiation of foodstuff intended for human consumption (Boletín Oficial del Estado, No. 260 of 31 October 1966, p. 13715 ff).

II. Objet of legislation

1. *Treatment by radiation*

May be undertaken upon approval (Art. 1 of the Decree). Packaging or any other component to be irradiated together with the foodstuff is subject to the same procedure (Art. 3 of the Decree). An authorization has been given for the use of gamma radiation from ^{60}Co source for the prevention of sprouting in potatoes intended for human consumption, with a maximum absorbed dose of 15 krad (150 Gy) and a minimum dose of 5 krad (50 Gy) (Order of the Ministry of Interior, Boletín Oficial del Estado No. 280, page 18220, 22 November 1969).

2. *Labelling*

The licence may specify type of packaging and labelling (Art. 6(c) of the Decree).

3. *Sale, importation, exportation*

May be undertaken upon approval (Art. 12 of the Decree No. 2725/66).

III. Organization of control

1. (a) Petitions for authorization must be filed with the Ministry of the Interior (Department of Health) (Art. 4 Sec. 1 and Art. 5 Sec. 1 of the Decree).
- (b) Such petition shall contain statements concerning (Art. 4 of the Decree):
 - (i) the promoting enterprise, the safety equipment and devices available, and the systems of inspection, control, storage, distribution, etc., in use
 - (ii) the type of food commodity, packaging or component, together with a description of the treatment or treatments to which it will be subjected and a statement of the specifications, conditions and requirements of all kinds applicable throughout the process up to the time of consumption
 - (iii) economic aspects of the treatment
 - (iv) the radiation source, energy and dose, and the monitoring system
 - (v) type of packaging and market presentation
 - (vi) evidence of fitness for consumption from the toxicological, microbiological and nutritional points of view
 - (vii) samples of labels of means of identification.

- (c) The petition is referred to the Consultative Group on Food Irradiation, at the Ministry of Interior (Department of Health) for an examination based on results of national and international experience (Art. 5, Sec. 1 of the Decree).
- (d) The petitioner may be invited to attend the meeting of the Group during which his petition is considered (Art. 11, Sec. 4 of the Decree).
- (e) The authorization is given by the Minister of Interior (Department of Health) and published in the "Boletín Oficial del Estado" (Art. 7 of the Decree). In cases of importation, exportation and trade, the authorization of the Ministry of Commerce is also required (Art. 12 of the Decree).
- (f) The licence contains (Art. 6 of the Decree):
 - (i) Type of food, packaging or component licensed, and description of the treatment
 - (ii) Radiation source, energy and maximum-minimum doses
 - (iii) Type of packaging and labelling
 - (iv) Any other provision relating to system of control, inspection, distribution, etc.
 - (v) Any limitation to which the licence will be subject in matters not yet governed by the Regulation.
- (g) In case of refusal or limitation the petitioner has recourse to the appropriate administrative or juridical appeals (Art. 8 of the Decree).

2. The Ministry of Interior (Dept. of Health) carries out inspections or any other measures it may deem necessary for compliance with the provisions of the licence. The Nuclear Energy Board is responsible to inspect radiation source, energy and maximum-minimum doses (Art. 9 of the Decree).

3. Failure in compliance is sanctioned by suspension or revocation of the licence, and penalties (Art. 10 of the Decree).

SWEDEN

1. Form of legislation

Article 10 of the Food Decree of 5 November 1971 (SFS 1971:807, 3 December 1971).

II. Object of legislation

Treatment by radiation

Prohibition with exemption by special authorization (Article 10 of the Decree).

III. Organization of control

Authorization is issued by the National Swedish Food Administration (Article 10 of the Decree).

SWITZERLAND

I. Form of legislation

Amendment of 11 March 1960 to the Regulation of the Marketing of Foods and Commodities of 26 May 1936, executing the Federal Law concerning the Marketing of Foods and Commodities of 8 December 1905 (Recueil Officiel des Lois et Ordonnances 1960, p. 330).

II. Object of legislation

1. Treatment by radiation

Prohibition with exemptions through special authorization (Art. 11.1 in connection with Art. 4 of the Regulation).

2. Sale of irradiated food

Prohibition with exemptions through special authorization (Art. 11.1 in connection with Art. 4 of the Regulation).

III. Organization of control

1. Authorization is given by the Federal Service of Public Hygiene if proof is provided by biological tests that the irradiation has no negative effects on the wholesomeness of the food, and has not resulted in altering other factors such as the nutritive value, taste, incidence of toxic substances, etc. The proof must be certified by an independent research laboratory approved by the Federal Service of Public Hygiene or by a university laboratory (Art. 11.1 of the Regulation).

2. Periodic biological investigations are carried out by the Federal Service of Public Health (Art. 11.1 of the Regulation).

THAILAND

I. Form of legislation

Notification No. 26 of the Ministry of Public Health. Dated 22 January 1971, made in pursuance of the Food Quality Control Act 1964 (Royal Thai Government Gazette, Vol. 88, No. 11, 20 April 1971, p. 170).¹

II. Object of legislation

This Notification prescribes that irradiated foodstuffs are henceforth to be subject to control.

UNION OF SOVIET SOCIALIST REPUBLICS

I. Form of legislation

Ministerial Orders on clearance for consumption of individual commodities.

II. Object of legislation

Clearance for human consumption in unlimited quantities has been issued on the following commodities:

Potatoes	For prevention of sprouting	10 000 rad (100 Gy)
Grain	For disinfestation	30 000 rad (300 Gy)
Dried fruits	For disinfestation	100 000 rad (1000 Gy)
Dry food concentrates	For disinfestation	70 000 rad (700 Gy)

¹ Although this Ministerial Notification was promulgated early in 1971 it was not available to the Secretariat for incorporation in the Report of a Consultation Group on the Legal Aspects of Food Irradiation, Vienna, 20–24 March 1972, organized by FAO, IAEA, WHO (IAEA, Vienna (1973, out of print)).

Clearance has also been given for human consumption of experimental batches of the following commodities:

Fresh fruits and vegetables	For extension of market life	200 000 – 400 000 rad (2000 – 4000 Gy)
Semi-prepared raw beef	For extension of market life	600 000 rad (6000 Gy)
Pork and rabbit products	For extension of market life	800 000 rad (8000 Gy)
Eviscerated poultry	For extension of market life	600 000 rad (6000 Gy)
Culinary prepared meat products	For extension of market life	800 000 rad (8000 Gy)
Onions	For sprout inhibition	6 000 rad (60 Gy)

III. Organization of control

Clearances are given by the Ministry of Public Health.

UNITED KINGDOM

I. Form of legislation

The Food (Control of Irradiation) (Amendment) Regulations 1972. S.I. 1972/205. Dated 16 February 1972. Similar Regulations, dated 24 February 1972, have been made for Scotland (Statutory Instruments, 1972, Part I, Section 1, pp. 961–962). (Statutory Instruments, 1972, Part I, Section 1, pp. 685–686.)

II. Object of legislation

The principal substantive provisions (Regulation 4) of the Food (Control of Irradiation) Regulations 1967 are amended to read as follows:

No person shall in the preparation of any food subject it to ionizing radiation:

Provided that this regulation shall not prohibit the subsection of food to not more than 50 rad (0.5 Gy) of ionizing radiation, where the energy of the radiation delivered does not exceed 5 000 000 electron volts, or the subsection to ionizing radiation of any food –

(a) which is certified by a registered medical practitioner to be intended for consumption by patients who require a sterile diet as an essential factor in their treatment; and

(b) in respect of which the person who subjects it to ionizing radiation so notifies the Department of Health and Social Security and keeps records which contain particulars of –

- (i) the certification mentioned in paragraph (a),
- (ii) the food so subjected,
- (iii) the quantity of radiation to which it has been subjected, and
- (iv) the despatch of the food.

The Food (Control of Irradiation) (Amendment) Regulations 1969.

UNITED STATES OF AMERICA

I. Form of legislation

1. Public law 85-929, Food Additives Amendment of 6 September 1958 to the Federal Food, Drug and Cosmetic Act (United States Code, Title 21).
2. Several regulations issued under Section 409 (348c) of the Federal Food, Drug and Cosmetic Act (21 USC para. 371) (Code of Federal Regulations, Title 21, Part 121, Chapter I, Sub-chapter B, Sub-parts F and G).

II. Object of legislation

1. *Treatment by radiation*

Prohibitions with exemptions

(Section 301 (b) of the Federal Food, Drug and Cosmetic Act (21 USC para. 331 (b)) in connection with Sections 402 (a) (2) (C) (21 USC para. 342 (a) (2) (C)) and 201 (s) (21 USC para. 321 (s)) of this Act.)

(a) General authorization for inspection of food and packaged food and control of food processing with X-radiation, up to 300 kV and with caesium-137, cobalt-60, krypton-85, radium-226 or strontium-90, up to 2.2 MeV (21 CFR 121.3001).

(b) Special authorization for control of insect infestation of wheat and ground wheat products by cobalt-60, caesium-137 or electron beam radiation not exceeding 5 million of electron volts – limitation of absorbed dose 20 000 to 50 000 rad (200 – 500 Gy) (21 CFR 121.3003, 121.3007).

For inhibiting sprout development of white potatoes by cobalt-60 or caesium-137 – limitation of absorbed dose: 5 000 to 15 000 rad (50 – 150 Gy) (21 CFR 121.3003).

2. *Labelling (21 CFR 121.3002 – 3007)*

(a) Food irradiated by high-dose gamma radiation must bear a label “Processed by ionizing radiation” or “Processed by gamma radiation”.

(b) Food irradiated by low-dose gamma radiation must bear a label “Treated with ionizing radiation” or “Treated with gamma radiation” on retail packages. It must further bear a label “Do not irradiate again” on wholesale packages and on invoices or bills of lading of bulk shipments.

(c) Food irradiated by high-dose electron beam must bear a label “Processed by ionizing radiation” or “Processed by electron radiation”.

(d) Food irradiated by high-dose X-radiation must bear a label “Processed by ionizing radiation” or “Processed by X-radiation”.

(e) Food irradiated by low-dose electron beam must bear a label “Treated with ionizing radiation” or “Treated with electron radiation” on retail packages. It must further bear a label “Do not irradiate again” on wholesale packages and on invoices or bills of lading of bulk shipments.

3. *Irradiation of packaging materials*

Prohibition with exemptions.

(Section 301 (b) of the Federal Food, Drug and Cosmetic Act (21 USC para. 331 (b)) in connection with Section 402 (a) (2) (C) (21 USC para. 342 (a) (2) (C)) and Section 201 (§) (21 USC para. 331 (a)) of this Act.)

(a) For fourteen different types of packaging materials which may be treated with irradiation not exceeding 1 Mrad (10 kGy) incidental to the use of gamma radiation in the radiation preservation of the prepackaged foods.

(b) For one type of packaging material which may be treated with radiation not exceeding 6 Mrad (60 kGy) incidental to the use of gamma or X-radiation in the radiation processing of prepackaged foods (21 CFR 121.2543).

4. *Trade*

Prohibition with exemptions as stated in II.1 above.

5. *Importation*

Prohibition with exemptions as stated in II.1 above.

III. Organization of control

Regulations authorizing the irradiation of food or packaging materials are issued by the Commissioner of Food and Drugs under authorization delegated to him by the Secretary of Health, Education and Welfare (Federal Register Vol. 29 (1964) page 471).

1. If the irradiation is intended solely for investigation use, the authorization is given pursuant to Section 409(a) (1) and (i) of the Federal Food, Drug and Cosmetic Act (21 USC para. 348(a) (1) and (i)).

2. In all other cases pursuant to a specifically regulated procedure (Section 409(a) 42 and (b) – (h) 21 USC para. 348 (a) (1), (b) – (h)).

(a) Petition for issuing a regulation authorizing the irradiation of food must be filed with the Commissioner of the Food and Drug Administration. Such petition shall contain statements concerning the characterization of the irradiation, its conditions of use, the effect and amount of irradiation, method of determining the quantity used, safety investigations carried out;

(b) A notice of the petition is published in the Federal Register;

(c) The Commissioner of the Food and Drug Administration decides upon the petition after fair evaluation of the data given within a period of no more than 180 days; under certain conditions he has to deny the petition;

(d) Safety investigations are carried out in accordance with a protocol on animal feeding tests;

(e) The regulation, established by order, is published in the Federal Register and is effective for everybody upon publication;

(f) Within thirty days after publication any person may file objections with the Commissioner of Food and Drugs who decides upon these objections after a public hearing;

(g) Any person who will be adversely affected by the decision may have recourse to the United States Court of Appeals for the circuit in which he resides;

(h) The Secretary of Health, Education and Welfare may, upon his own initiative, issue a regulation;

(i) Regulations issued may be cancelled for cause, following the same procedure as is used for establishing them.

The Food and Drug Administration inspects the irradiation of food and requires that records pertaining to the production of irradiated food be retained for a period of one year (21 CFR 101.3003, 101.3007).

Annex 7

MODEL REGULATIONS FOR THE CONTROL OF AND TRADE IN IRRADIATED FOOD

Prepared by A. Gérard, Consultant*

SUMMARY

Chapter I	Scope and definitions
	Art. 1. Scope
	Art. 2. Definitions
Chapter II	Control of irradiation facilities
	Art. 3. Special approval of facilities
	Art. 4. Certificate of approval
	Art. 5. Periodic inspection of facilities
	Art. 6. Suspension or withdrawal of the certificate of approval
Chapter III	Control of food irradiation
	Art. 7. General and particular restrictions governing the irradiation of food
	Art. 8. Updating of technical conditions for irradiation
	Art. 9. Record of food irradiation
	Art. 10. Irradiation voucher
	Art. 11. Food irradiation treatment inspectors
	Art. 12. Powers of inspectors or inspection services
	Art. 13. Inspection reports
	Art. 14. Inspection procedures
	Art. 15. Appeal by the operator

* Lecturer at the University of Brussels, Director of the Food Law Research Centre (E.J. Bigwood Centre), Secretary General of the European Food Law Association.

Chapter IV

Control of trade in irradiated food

- Art. 16. Principles
- Art. 17. Provisions relating to labelling, presentation and packaging
- Art. 18. Commercial documents relating to irradiated food
- Art. 19. Optional information
- Art. 20. Certificate of irradiation for products involved in international trade
- Art. 21. Request for certificate of irradiation
- Art. 22. Issue of certificate of irradiation
- Art. 23. International co-operation in the control of irradiated food

Chapter V

General and final provisions

- Art. 24. Civil liability of the operator
- Art. 25. Penal provisions
- Art. 26. Annulment provisions
- Art. 27. Entry into force

CHAPTER I

SCOPE AND DEFINITIONS

Scope

Art. 1 – The object of this law (1) is to control the intentional exposure of food to ionizing radiations, in so far as the absorbed dose is equal to or greater than 50 rad or 0.5 Gy (2), 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 relating to food (3) or agricultural (4) 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, provided that the absorbed dose is equal to or greater than 50 rad or 0.5 Gy (2);
- (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 . . . (5);
- (b) They have been specially approved by . . . (6) after verification of the safety and efficiency criteria set out in the Draft Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods, adopted 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 . . . (6). This certificate shall specify the national and international reference number (7) of the irradiation facility or unit, the name and address of the operator, the description of the food 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 . . . (6) (8). 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 Draft Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods, adopted by the Codex Alimentarius Commission, the . . . (6) 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 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 (9). 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 (10);
- (b) The irradiation must be carried out in accordance with the general conditions laid down in the Draft Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods, adopted 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. These specific conditions are set out in the Draft General Standard for Irradiated Foods

approved by the Codex Alimentarius Commission. The packaging materials used during the treatment should likewise conform to the provision of these Standards;

- (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 a subsequent irradiation;
- (e) The irradiation must be carried out by personnel meeting the requirements as to training and qualifications laid down by . . . (6);
- (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 . . . (6), 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 . . . (6) 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 (11);
- (f) Where appropriate, all supplementary information required by the specific irradiation conditions provided for in Article 7(c);
- (g) 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 (7) 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 . . . (6) 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 (7) 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 (8) designated or delegated for the purpose by the . . . (6) and meeting the conditions as to training and technical qualifications

established by the said . . . (6) 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 food is subjected;
- (b) They shall require to see all documents relating to the irradiation facility and to the batches of food which has been, or is 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 has been, or is 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 (12) shall apply;
- (d) When batches of food which has been, or is to be, irradiated do not satisfy the requirements of Article 7(a), or when their treatment 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 (13).

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 representative.

This report shall be sent as soon as possible to the . . . (6) and, if appropriate, to the judicial authority (14).

The provisions concerning the procedure for establishing the fact of infringements relating to foodstuffs (15) shall be applicable.

Inspection procedures

Art. 14 – . . . (6) 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 . . . (6) within the time limit fixed by the said . . . (6).

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.

Provisions relating to labelling, presentation and packaging

Art. 17

- (a) Without prejudice to the application of legal provisions relating to the labelling and packaging of food products (16), irradiated food must carry on the package, in readable and indelible letters, the words: *Product treated by irradiation*, accompanied by information 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 the treatment is indicated by the month and the year, except as otherwise laid down by the (6).
The (6) shall establish the style and form of the labelling entries and code references required by the present sub-paragraph (17);
- (b) When food which is irradiated is not packaged, it must 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) 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 provisions of sub-paragraphs (a) and (b) of this Article.

Commercial documents relating to irradiated food

Art. 18 – The wording and references required by Article 17(a) must appear in the invoices, waybills, consignment notes or any other commercial documents accompanying food which has been irradiated or which contains irradiated ingredients.

<i>Optional information</i>	<p>Art. 19 – In addition to the obligatory wording referred to in Article 17(a), the labelling on food which has been irradiated may also mention the advantages sought from the irradiation, a reference to the present law (1) as a guarantee of irradiation control and, where appropriate, the expected shelf-life of the product in its initial state (18).</p> <p>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, nor any reference to medical preventive or healing properties.</p>
<i>Certificate of irradiation for products involved in international trade</i>	<p>Art. 20 – Food which has been irradiated and which is either imported or intended for export must be accompanied, for each batch of food undergoing 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 (7) 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 . . . (6) shall draw up the standard model for the certificate of irradiation referred to above (19).</p>
<i>Request for certificate of irradiation</i>	<p>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 . . . (6). 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.</p>
<i>Issue of certificate of irradiation</i>	<p>Art. 22 – The issue of the certificate of irradiation may be made dependent on verification of the irradiation conditions on the basis of the data contained in the</p>

record of irradiated food referred to in Article 9.
A copy of the certificate of irradiation shall be kept by the . . . (6), who may, on request, issue duplicates.

*International
co-operation in the
control of irradiated
food*

Art. 23 – The . . . (6) shall take all appropriate measures to develop international co-operation 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 a facility, the frequency of the 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 (7), 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 (19).

When the size of the facility, or the danger resulting from its use justifies such a step, the . . . (6) 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 (20), who contravenes the provisions of Article 7 of the present law (1), or who obstructs the execution of the inspection measures provided for by Articles 5 and 12, will be liable to . . . (21).
In the case of repeated offences, the special approval granted by the . . . (6) in fulfilment of Article 3(b) may be suspended or withdrawn (22);
- (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 . . . (21);
- (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 . . . (21);
- (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 . . . (21);
- (e) Any person who contravenes the provisions of Article 16 of the present law (1) will be liable to . . . (21).
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 (23).

<i>Annulment provisions</i>	Art. 26 – The present law (1) annuls the provisions of (24).
<i>Entry into force</i>	Art. 27 – The present law (1) will enter into force on

NOTES AND REFERENCES

- (1) Or (as appropriate): “The present decree”, “. . . . order”, ”regulation”, etc.
- (2) Figure proposed by the Codex Alimentarius Commission on Food Additives (Draft General Standard for Irradiated Foods, Appendix VII, Alinorm 78/12, 1977).
- (3) Where applicable, make reference to the general law on food products. Reference can likewise be made to the “Model food law” proposed at the FAO/WHO Regional Conference on Food Standards in Asia, Bangkok, 1975 (Ref.: CX/Asia 75/7).
- (4) Where applicable, make reference to the law governing the trade in and control of agricultural raw materials.
- (5) Where applicable, make reference to the law governing the approval (authorization) and inspection of nuclear facilities or undertakings.
- (6) 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.
- (7) 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).)
- (8) 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).

- (9) 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.
- (10) Where applicable, make reference to the national regulations concerning materials destined to come into contact with food products.
- (11) 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.
- (12) 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 (3) above.
- (13) The seizure that is referred to here is a preventive 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 (12) above.
- (14) Indicate the judicial authority concerned with preventing the evasion of food laws.
- (15) Same comment as in Note (12) above.
- (16) Where applicable, make reference to the national regulations concerning the labelling of food products. Reference may likewise be made to the General Standards for Labelling Food Products proposed by the Codex Alimentarius Commission of the Joint FAO/WHO Food Standards Programme.
- (17) As regards the obligatory wording on the labelling, the competent Minister should establish, in particular, the language in which the information is to be given, the size of the lettering and the position on the label.
- (18) 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 the present law)".

- (19) 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.

- (20) 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.
- (21) 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".
- (22) This is an additional penalty to be pronounced by a judge and not the administrative measure provided for in Article 6.
- (23) 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).
- (24) 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.

HOW TO ORDER IAEA PUBLICATIONS

An exclusive sales agent for IAEA publications, to whom all orders and inquiries should be addressed, has been appointed in the following country:

UNITED STATES OF AMERICA UNIPUB, 345 Park Avenue South, New York, N.Y. 10010

In the following countries IAEA publications may be purchased from the sales agents or booksellers listed or through your major local booksellers. Payment can be made in local currency or with UNESCO coupons.

ARGENTINA	Comisión Nacional de Energía Atómica, Avenida del Libertador 8250, Buenos Aires
AUSTRALIA	Hunter Publications, 58 A Gipps Street, Collingwood, Victoria 3066
BELGIUM	Service du Courier de l'UNESCO, 112, Rue du Trône, B-1050 Brussels
C.S.S.R.	S.N.T.L., Spálená 51, CS-113 02 Prague 1
FRANCE	Alfa, Publishers, Hurbanovo námestie 6, CS-893 31 Bratislava
	Office International de Documentation et Librairie, 48, rue Gay-Lussac, F-75240 Paris Cedex 05
HUNGARY	Kultura, Bookimport, P.O. Box 149, H-1389 Budapest
INDIA	Oxford Book and Stationery Co., 17, Park Street, Calcutta, 700016
	Oxford Book and Stationery Co., Scindia House, New Delhi-110001
ISRAEL	Heiliger and Co., 3, Nathan Strauss Str., Jerusalem
ITALY	Libreria Scientifica, Dott. Lucio de Biasio "aeiou", Via Meravigli 16, I-20123 Milan
JAPAN	Maruzen Company, Ltd., P.O. Box 5050, 100-31 Tokyo International
NETHERLANDS	Martinus Nijhoff B.V., Lange Voorhout 9-11, P.O. Box 269, The Hague
PAKISTAN	Mirza Book Agency, 65, Shahrah Quaid-e-Azam, P.O. Box 729, Lahore-3
POLAND	Ars Polona-Ruch, Centrala Handlu Zagranicznego, Krakowskie Przedmiescie 7, Warsaw
ROMANIA	Ilexim, P.O. Box 136-137, Bucarest
SOUTH AFRICA	Van Schaik's Bookstore (Pty) Ltd., P.O. Box 724, Pretoria 0001
	Universitas Books (Pty) Ltd., P.O. Box 1557, Pretoria 0001
SPAIN	Díaz de Santos, Lagasca 95, Madrid-6
	Díaz de Santos, Balmes 417, Barcelona-6
SWEDEN	AB C.E. Fritzes Kungl. Hovbokhandel, Fredsgatan 2, P.O. Box 16358 S-103 27 Stockholm
UNITED KINGDOM	Her Majesty's Stationery Office, P.O. Box 569, London SE1 9NH
U.S.S.R.	Mezhdunarodnaya Kniga, Smolenskaya-Sennaya 32-34, Moscow G-200
YUGOSLAVIA	Jugoslovenska Knjige, Terazije 27, POB 36, YU-11001 Belgrade

Orders from countries where sales agents have not yet been appointed and requests for information should be addressed directly to:



Division of Publications
International Atomic Energy Agency
Kärntner Ring 11, P.O.Box 590, A-1011 Vienna, Austria

INTERNATIONAL
ATOMIC ENERGY AGENCY
VIENNA, 1979

SUBJECT GROUP:
Miscellaneous/Nuclear Law
PRICE: US \$8.00