The Wholesomeness Evaluation of Irradiated Foods at National and International Levels

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ABSTRACT-The wholesomeness studies on irradiated foods and the evaluation of the data obtained have been conducted at both national and international levels. The conclusion of the Joint FAO/IAEA/WHO Expert Committee on Wholesomeness of Irradiated Food in 1980 that irradiated foods treated with doses up to 10 kGy are safe for human consumption are being significantly influencing on the regulatory circumstances in individual countries as well as a regional economic community. Principles of the wholesomeness evaluation, importance of radiation chemical considerations, methodology of toxicological testing and the interpretation of *in vitro* and *in vivo* toxicity studies are discussed. Emphasis is placed on the progress of methods for wholesomeness studies and data evaluations and also on the importance of comparative assessments together with safety problems concerning other food treatments and environmental factors.

Potentialities of food irradiation are reconized to reduce food losses during storage and to improve food hygienic aspects. The establishment of the wholesomeness of irradiated foods is essential for the regulatory progress and commercialization of this novel technology. The concept of wholesomeness is consisted of two aspects, i.e. (1) the safety or no hazardous factor for human consumption and (2) nutritional adequacy. Approach to the establishment of the wholesomeness of irradiated foods has been made through evaluations at national and international levels.

In this review paper, the outline of the wholesomeness evaluation and its outcome reflecting upon legal regulation in different countries are described. The emphasis will be placed on the progress in the scientific methodology for the wholesomeness evaluation of irradiated foods and the comparative safety assessments of food irradiation together with other food treatments and environmental factors.

Evaluation of wholesomeness at national and international levels

Importance of the wholesomeness aspects of food irradiation was already emphasized at an international meeting sponsored by FAO, IAEA and WHO in Brussels in 1961 in connection with international trading. Technical basis for legislation on irradiated foods was also discussed in an expert committee of these three UN organizations in Rome in 1964.[1)]

At an early stage of research and development, however, actual wholesomeness studies and evaluation of the data obtained were almost conducted at the national level. The world-first clearance in the field of food irradiation was given to irradiation of potatoes in USSR (1958), followed by the treatments of potatoes in Canada (1960) and wheat and potatoes in USA (1963 and 1964, respectively). Thus in recent years, legal permissions of individual countries[2)] have become increasingly

Table 1. Present status of clearances of irradiated foods

(According to an IAEA document, Jan. 1987)[2]

Purpose	Food item	Dose (kGy)	Contry
Radappertization	Spices and condiments	≤30	USA
Radurization and Radicidation	1. Frozen shrimp, 2. chicken and poultry, 3. pork, 4. egg powder, 5. spices, 6. sausage, 7. dried vegetable and fruits, 8. fish, 9. arabic gum, 10. herbs, 11. cereals, 12. enzymes, 13. malt, 14. dried blood protein, 15. cooked meat products	≤10	Australia(1), Bangladesh(2,5), Belgium(5,7,9), Brazil(2,5), Canada(2*,5,7), Chile(2,5), China(6), Denmark(5), France(5,7,9,11), GDR(5,12), Hungary(5), India(1,5), Israel(2***,5), Netherlands(1,4,5,7,8,13,14), New Zealand(5,10), Norway(5), South Africa(2), Thailand(1,5,6), USSR (2*,3*,15*), USA(5,12), Yugoslavia (2,4,7,10,11)
	1. Fish and fish products, 2. cooked shrimp, 3. frozen meat, 4. refrigerated meat, 5. chicken and poultry, 6. froglegs, 7. vegetables, 8. fruits, 9. rye bread, 10. cocoa beans, 11. spices, 12. meat products, 13. powderedbattermix, 14. strawberry	<5.0	Bangladesh(1,6), Belgium(8), Brazil (1,8), Bulgaria(7,8), Canada(1*), Chile (1,8,10), France(5), Hungary(3*,8*,11*,12*), India(6), Israel(14), Netherlands(1*,2,4*,5,6*,7*,8*,9,12*,13*), South Africa(7,8,11), Thailand (1,5,14), USSR(7*,8*)
Disinfestation — Insect	1. Wheat and wheat products, 2. rice, 3. pulses, 4. spices, 5. maize, 6. cocoa beans, 7. almonds, 8. peanut, 9. dates, 10.dried fruits and vegetables, 11. marine products, 12. papaya, 13. mangoes**, 14. food concentrates, 15. cereals, 16. cheese powder, 17. enzyme preparations	≤1.0	Bangladesh(1,2,3,12,13), Brazil(1,2,3,5,11,12), Bulgaria(10*,14*,15*), Canada(1), Chile(1,2,3,4**,6,9,11,13), China(8,15), Israel(3,6,15), South Africa(3,7,10,16), Thailand(1,2,3,6,9,11,12,13), USSR(10.14,15), USA(10,17), Yugoslavia(3,15), Netherlands (2,6*)
Parasite	Pork	0.3～1.0	USA
Sprout inhibition	1. Potatoes, 2. onions, 3. garlic, 4. shallots	<0.15	Argentina(1,2,3), Bangladesh(1,2), Belgium(1,2,3,4), Brazil(1,2), Bulgaria(1*,2*,3*), Canada(1,2), Chile (1*,2), China(1,2,3), Czechoslovakia (1*,2*), Denmark(1), France(1,2,3,4), FRG(1*), GDR(2), Hungary(1*,2), India(1,2), Israel(1,2,3,4), Italy(1,2,3), Japan(1), Netherlands(1,2), Philippines(1,2,3), Poland(1,2), South Africa(1,2,3), Spain(1,2), Thailand(1,2,3), USSR(1,2), USA(1), Uruguay (1), Yugoslavia(1,2,3)

Continued from Table 1

Ripening delay	1. Mangoes, 2. papaya, 3. tomatoes, 4. other, 5. tropical fruits, 6. fresh food (fruits and vegetables)	$\leqslant 1.0$	Bangladesh(1,2), Brazil(2), Chile(1), Israel(5), South Africa(1#,2#,3,4) USA(5)
Growth inhibition	1. Mushroom, 2. asparagus, 3. fresh food (fruits and vegetables)	$\leqslant 3.0$	China(1), Czechoslovakia(1), Hungary (1), Israel(1), Netherlands(1,2), USA (3 *)
Radappertization	Hospital meal	25	FRG, Netherlands, UK

* For experimental batch/test marketing; **10 kGy; ***7 kGy; 1.0 kGy; # 0.5 1.5 kGy

established as indicated in Table 1, although progress in the commercialization of food irradiation has been rather slow.

On the other hand, wholesomeness studies and the evaluation of the data at the international level became being anticipated by several reasons, e.g. (1) to accumulate wholesomeness data most effectively by international cooperation, especially eliminating uneconomical overlapping of extensive and time consuming animal tests, (2) to assist the wholesomeness assessments among developing countries where the implementation of wholesomeness studies is difficult while food irradiation could be a very useful tool of food processing, and (3) to avoid wasteful discussions and confusion within an individual country as have been realized when approval of radappertized bacon (1963) was cancelled in 1968 by the same regulatory agency in USA.

The International Food Irradiation Project (IFIP) established in 1970 had successfully performed its activities to provide the relevant wholesomeness data, the host institute of which was in Karlsruhe, West Germany. Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food (JECFI) met in Geneva in 1969, 1976 and 1980 to evaluate the wholesomeness data at the international level.[3,4,5] The IFIP played an important role in supporting discussions at the 1976 and 1980 JECFIs with its relevant wholesomeness data. In 1980, the JECFI[5] drew the significant conclusion that irradiation of any food commodity up to an overall dose of 10 kGy presents no toxicological hazard; hence toxicological testing of foods so treated is no longer required. The recommendations of the above three JECFIs on individual irradiated food items are listed in Table 2 and desirable applications of food irradiation are indicated in Table 3.

A Joint FAO/WHO Codex Alimentarius Commission (CAC) set up in 1962 with the purpose of protecting the consumer, facilitating international trade and helping the developing countries, has been taking an active part in preparing international food standards and codes of practice. Two documents of the CAC, "Recommended International General Standard for Irradiated Foods" and "Recommended International Code of Practice for the Operation of Radiation Facilities for the Treatment of Foods" were revised to reflect the conclusion of the 1980 JECFI and the revisions were adopted by the CAC in 1983 and circulated to the 122 governments of the CAC member countries.

In this way, evaluation of the wholesomeness of irradiated food was effectively promoted at the international level. In the meantime of such international cooperation mentioned above, approvals of regulatory agencies of individual countries have made great progress, especially after the 1980 JECFI. It should be kept in mind that the outcome of assessment at the international level is not a regulation but a recommendation for governments of individual countries.

Principles of evaluation of the wholesomeness

In the earlier phase of food irradiation develop-

Table 2. Evaluation of irradiated foods by JECFIs[3,4,5]

Food item	Objective	Dose (kGy)	Category of acceptance
Potatoes	Sprout inhibition	⩽ 0.15	Temporary (1969)
		0.03-0.15	Unconditional (1976)
Onions	Sprout inhibition	0.02-0.15	Provisional (1976)
		⩽ 0.15	Unconditional (1980)
Wheat and wheat products	Insect disinfestation	⩽ 0.75	Tempa.ory (1969)
		0.15-1.00	Unconditional (1976)
Chicken	Shelf life extension	2-7	Unconditional (1976)
	Elimination of pathogenic microorganism	5-7	Unconditional (1976)
Fish and fish products	Radurization and radicidation	1.0-2.2	Provisional (1976)
		⩽ 2.2	Unconditional (1980)
	Insect disinfestation of dried fish	⩽ 1.0	Unconditional (1980)
Papayas	Insect disinfestation and ripening delay	0.5-1.0	Unconditional (1976)
Strawberry	Radurization	1-3	Unconditional (1976)
Rice	Insect disinfestation	0.1-1.0	Provisional (1976)
		⩽ 1.0	Unconditional (1980)
Cocoa beans	Insect disinfestation	⩽ 1.0	Unconditional (1980)
	Radurization of fermented beans	⩽ 5.0	Unconditional (1980)
Dates	Insect disinfestation	⩽ 1.0	Unconditional (1980)
Pulses	Insect disinfestation	⩽ 1.0	Unconditional (1980)
Mangoes	Insect disinfestation, ripening delay and radurization combined with heating	⩽ 1.0	Unconditional (1980)
Spices and condiments	Insect disinfestation	⩽ 1.0	Unconditional (1980)
	Reduction of microload and radicidation	⩽ 10	Unconditional (1980)

ment, the wholesomeness was studied with radioactivity induction, toxicity in animal tests, especially carcinogenicity, and destruction of nutrients, followed by the analysis of microbiological safety problem. Referring the progress in related scientific methodology and wholesomeness data accumulated, the JECFIs examined the wholesomeness of irradiated foods with the wider scope of the assessment. The results of examinations are briefly indicated in Table 4.

General and technical aspects—The 1976 JECFI[4] employed a view that irradiation is a physical process for treating foods like heating and freezing and stressed that microbiological, nutritional and toxicological assessments should be based on the concept of food irradiation as a process, but not a food additive. Such appropriate changeover of the basic concept has seriously affected assessments, particularly the toxicological assay methods, as will be discussed later.

From a viewpoint of safety to prevent the induction of radioactivity, it is recommended to res-

Table 3. Desirable use of food irradiation

Low-dose applications (up to about 1 kGy)
Inhibition of sprouting
Insect disinfestation
Delay of ripening
Control of *Trchinella spiralis* in pork
Medium-dose applications (1-10 kGy)
Reduction of microbial load (Radurization)
Control of non-sporing pathogenic microbs (Radicidation)
Improvement in technological properties
High-dose applications (about 10-50 kGy)
Sterilization for commercial purposes
Elimination of viruses

trict the type of radiation and beam energy levels to be used for industrial-scale irradiation as follows: (1) gamma rays from isotopic sources of ^{60}Co and ^{137}Cs (less than 2.2 MeV), (2) electrons up to 10 MeV accelerated in a machine and (3) converted X-rays less than 5 MeV. Besides, desirable objectives of irradiation (Table 3), extrapolation of data from one food to another, application of the correct absorbed dose, dose uniformity, methods of dosimetry, processing conditions for irradiation, methods of identifying irradiated foods, packaging, repeated irradiation, technological efficiency, quality of food to be irradiated and comparisons of energy used for different processes were also discussed.

Radiation-chemical aspects—Irradiation does induce chemical changes in food components. Accordingly, to assess radiation chemical changes must be required as the most important basis of wholesomeness assessments. Yields of radiolytic products and their dose dependence have been demonstrated. It is noteworthy that yields of radiolytic products by doses up to 1 kGy are too low for conducting animal tests of traditional toxicological assay using experimental animals because of their insufficient sensitivity. On the other hand, increase of radiolytic product concentrations in proportion to radiation doses requires the toxicological animal tests for irradiation with doses exceeding 1 kGy. It is also known that the most of radiolytic products identified in irradiated foods are found in various unirradiated foods. Extensive data on free radical reactions induced in irradiated foods and model systems are useful to understand chemical changes of food components by radiation treatments and thus to eliminate fear for human consumption of irradiated foods

Toxicological aspects—Because of very low yields of radiolytic products when irradiated doses up to 1 kGy, traditional animal tests are considered not to be effective for the assessment. However, progress in experimental methodology of genotoxic studies in recent years has brought about various *in vitro* tests as a useful tool for examining mutagenicity and carcinogenicity even at the low-dose treatment level. Types of tests, methodology and protocols for animal tests, parameters to be studied, interpretations of toxicological systems, etrapolation from animal studies to man, toxicological evaluation of radiolytic products and so on have been extensively investigated.

Microbiological aspects—Irradiation for microbiological purposes has been classified into three categories, i.e. radappertization, for achieving commercial sterility of the food with high-dose irradiation at doses more than 10 kGy, (2) radicidation, which can kill all of the specified asporogenic pathogens in foods by doses less than 10 kGy, and (3) radurization to reduce contamination of spoilage microorganisms in foods also by doses below 10 kGy. In low-dose range less than 1 kGy, however, lethal effects of radiations on microorganisms in foods are mostly insignificant. Radiosensitivities of food microorganisms *in vitro* and in foods, change in microflora and spoilage pattern, risks of increase in radioresistance and pathogenicity, the possibility of increased mycotoxin production after irradiation treatments were investigated.

Nutritional aspects—Destructions of nutrients, especially vitamins, were determined. The general conclusion can be drawn that changes by doses less than 10 kGy in macronutrients such as proteins and carbohydrates are not nutritionally significant and overall extents of vitamin losses by irradiation treatments are comparable with those by

Table 4. Wholesomeness assessment of irradiated foods in three dose ranges[4,5,6]

Aspects of evaluation	Low-dose range (up to 1 kGy)	Medium-dose range (1-10 kGy)	High-dose range (10-50 kGy)
General and technical aspects	Types and energy levels of radiations without radioactivity induction: 2.2 MeV gmma rays (from ^{60}Co and ^{137}Cs) 10 MeV electrons from accelerator 5 MeV converted X rays Dosimetry, processing conditions, method of identification of irradiated foods, packaging		
Radiation chemical aspects	Yields of radiolytic products increase in proportion to doses Yield at 1 kGy of: All radiolytic products 30ppm Total unique radiolytic product(URP) 3ppm Single URP 1ppm	Yield at 10 kGy of: Total radiolytic products 300ppm	Concentrations of radiolytic products reach a plateau. Yield of a radiolytic product: 1ppm (up to 6kGy) 1-700 g/kg (at 5.6kGy at -30°C)
Toxicological aspects	Sensitivity of traditional animal tests is insufficient because of too low yield of radiolytic products. *In vitro* tests for mutagenicity and carcinogenicity are effective.	Animal tests are required.	Animal tests are required.
Microbiological aspects	Radiation killing effects on microorganisms in food are minor. Almost no change in spoilage pattern	Effective for radicidation and radurization Change in microflora and spoilage pattern, mycotoxin production, increase in radioresistance and pathogenicity are studied.	Effective for radappertization or similar treatments No public health problems
Nutritional aspects	Nutrient losses are insignificant. No nutritional difference between unirradiated and irradiated foods	Losses of macronutrients are insignificant. Some losses of vitamins may occurr with extents similar to those on cooking.	If irradiation were done under frozen or in the absence of air, losses of nutrients may actually be lower than mediumdose irradiation without such precautions.

cooking, although the sensitivity profiles for both treatments are different. Among vitamins, vitamins A,E and K, thiamine and ascorbic acid are comparatively sensitive to radiations. Changes in immunological properties, bioavailability of nutrients, formation of adverse nutritional consequences of irradiation treatments, e.g. anti-vitamins, have been also assessed. It is realized based on evidences that on low-dose irradiation with doses less than 1 kGy, nutrient losses are insignificant except those of some vitamins and on medium-dose irradiation by doses of 1-10 kGy, decrease in vitamin contents is dependent upon the types and radiation doses, which can be summerized as comparable with heat treatments. For high-dose irradiation (more than 10 kGy), it is recommended that irradiation should be done under specified conditions, e.g. under frozen or in the dry or dehydrated state, to avoid changes in organoleptic quality and destruction of nutrients.

Examples of international disputs so far on the wholesomeness evaluation of irradiated foods

Occurrence of radiotoxins—With respect to potato irradiation, Kuzin and his coworkers[6,7] presented a radiotoxin hypothesis. Irradiation might induce the activation of enzymic oxidation of polyphenols and thus ortho-quinones produced be absorbed by cell nuclei to result in chromosomal aberration. Under such assumption, the radiotoxin hypothesis could be applied to other living plant tissues which contain polyphenols and their oxidizing enzyme. This means that irradiation treatments of vegetables and fruits might be harmful for human consumption. However, all repeated experiments by other authors did not reproduce the occurrence of toxic substances, i.e. in a dominant lethal assay in mice[8], in a micronuclei test in rat[9], and a series of chemical and biological assays including a dominant lethal assay in mice[10,11,12]. In the third experiment[10,11,12], chemical analysis using paper and high performance liquid chromatography and bioassay of different levels, i.e. a prophage induction test, reverse mutation assays in *S. typhimurium*, chromosomal aberration tests *in vitro*, micronucleus tests in mice and a dominant lethal test in mice using 30 males in a group, were carried out with the preparation of alcohol extracts from gamma-irradiated potatoes produced in Hokkaido, Japan. Zajcev *et al*[13]. and Osipova *et al*[14]. faild to find out such toxic activity of the alcohol extracts from tubers cooked or stored after irradiation. Kuzin himself also metioned later in his review paper that there is no fear for human consumption since radiodoxins are reduced or destroyed by cooking or storage[7].

Polyploids arising from intake of freshly irradiated wheat—In 1975, Bhaskaram and Sadasivan[15]† reported that whole wheat freshly irradiated by 0.75 kGy and fed to rats may be associated with (1) an increased incidence of chromosomal aberrations in bone marrow cells, (2) a reduction in germ cells and damage to spermatids, and that (3) the feeding to children suffering from severe protein-calorie malnutrition might induce chromosomal aberrations in cultured peripheral lymphocytes from the children.

In repeated studies in rats conducted by scientists at Life Science Research and Huntingdon Research Centre, England, concerning (1) incidence of polyploid configuration in bone marrow cells, (2) incidence of micronucleated polychromatic erythrocytes in bone marrow cells and (3) dominant lethal mutations in germ cells of male rats, no adverse effect or no mutagenic potential of freshly irradiated wheat was observed[18]. A committee of Indian scientists carefully investigated the experimental techniques, experimental design and the data of the initial observations associated with a toxic effects of freshly irradiated wheat and concluded that no evidence of increase in polyploidy resulted from irradiation can not be confirmed. One of the criticisms directed toward the initial Indian data is the abnormally low control value of polyploidy (0%) and that of the irradiated wheat group (1.8%) which is still in the normal range[19].

Mutagenic activity of irradiated sugar solution and its relation to fruit irradiation—Irradiated sugar solutions were found to be cytotoxic and mutagenic towards bacterial, plant and animal cells[20,21,22] Ehrenberg first observed the increased chlorophyll mutations in barley seeds exposed to irradiated glucose[23]. Abnormal anaphase formation in bean root tips, decreased growth in carrot tissue cultures and increased reverse mutation in *S. typhimurium* were reported[24]. Also in an *in vitro* study, increase in the inhibitory effects of irradiated sucrose solutions on liver mitochondrial oxidative phosphorylation and on the syntheses of lipids, protein and DNA. These toxic effects have been interpreted as the consequence of treatments with irradiated sugar solutions. Such potentially toxic compounds radiation-produced in sugar solutions are mainly dicarbonyl sugars. They occur by a reaction between peroxy radicals and sugar molecules. Dicarbonyl sugars are transformed into unsaturated carbonyl sugars, which are found in unirradiated foods. However, the yield of these carbonyl sugars induced by irradiation would be much lower in foods in comparison with in the simple model system of sugar solution because of reduced oxygen concentrations and reactions with food components.

Since sugars such as glucose and sucrose are widely contained in fruits and vegetables, *in vitro* cytotoxic effects of irradiated sugar solutions have been much attention from a viewpoint of the safety assessment of irradiated foods. In contrast to the *in vitro* observations, short-(8 weeks) and long-term (2- years) feeding studies with irradiated sucrose solution did reveal no adverse effects on growth, organ weights and fine structure of cells in rats and the normal oxidative phosphorylation and incorporation activities for biosyntheses[20]. In addition, animal feeding studies of IFIP and a mutagenicity study in bacterial systems on subtropical fruits containing sugars such as mango and papaya have clearly evidenced the safety of these fruits[4,5]. It is interesting to see that mango fractions abolish the mutagenic activity of glucosone which is found in irradiated sugar solutions[25]. Based on these findings, it is concluded that irradiation of the simple sugar solution produces toxic substances, whilst radiolytic products from sugars in irradiated foods do not reveal their toxic effects in the whole animals. The toxicity *in vitro* of irradiated sugar solutions can be modified by post irradiation treatments or conditions during irradiation. Types and yields of radiolytic products in irradiated sugar solutions are dependent upon radiation dose and the presence of oxygen and metal ions during irradiation.

Recent wholesomeness evaluations of irradiated foods in some countries

USA[26,27]—In order to investigate better methods for evaluating the safety of irradiated foods, USFDA established its Bureau of Foods Irradiated Food Committee (BFIFC) in 1979. The BFIFC estimated based on extensive radiation-chemical data that concentrations of radiolytic products at 1 kGy would be about 30 ppm in total, only 3 ppm of unique radiolytic products (URP), which are not found in unirradiated foods, and less than 1 ppm of any single URP in irradiated foods. The BFIFI concluded that foods irradiated with doses up to 1 kGy are regarded as safe for human consumption without the requirement of toxicological testing because of the extremly low concentrations of URPs produced in irradiated foods and recommended that foods contained 0.01% or less of the daily diet and irradiated with doses up to 50 kGy also be considered safe for human consumption without toxicological testing. These views of the BFIFC are based on radiation-chemical analyses and the insufficient sensitivity of toxicological animal tests for detecting URDs. In 1981, the USFDA agreed to the BFIFC's views and established the Irradiated Food Task Group to review all available toxicological data on irradiated foods. The data review of the Task Group was proceeded in three phases: phase I, collection of 409 references except overlapping; phase II, categorizing references into 3 groups (accepted, accepted with reservation and rejected) by the screening conditions; phase III, examinations in detail of 69 studies of 266 "accepted" references.

Based on the results of investigations by the BFIFC and the Task Group, USFDA concluded that food irradiated at doses up to 1 kGy is safe for human consumption. There are several reasons associated with radiation chemical considerations as well as methodology and sensitivity of traditional toxicological testing for irradiated foods. Subsequently the USFDA had taken the multi-steps of legal and regulatory procedures for amending its regulations of irradiated foods. Eventually, in April 1986, the regulations of the agency were amended with two permissions to allow manufacturers to use irradiation at doses not to exceed 1 kGy for inhibiting the growth and maturation of fresh foods and for disinfectation of food with arthropod pests and to use irradiation at doses not to exceed 30 kGy for disinfectation of dry or dehydrated aromatic vegetable substances (such as spices and herbs. Here, it is noted that the foods permitted are not individual items but the group of foods.

United Kingdom[28]—In the UK, the Advisory Committee on Irradiated and Novel Foods requested to advise Health and Agriculture Ministers on food irradiation stated in its report in 1986 after reviewing the relevant scientific data bearing on the safety and wholesomeness of irradiated foods that the Committee agrees with the conclusion with the conclusion of the 1980 JECFI.

Similarly, the EEC is now making its efforts for the approximation of the laws of the member states concerning irradiated foods and food ingredients. This type of international harmonization is required for trading with irradiated foods in the EEC. Dose ranges and purposes of food irradiation to be recommended by the UK Advisory Committee and the EEC are compared in Table 5 and 6.

Japan—No further regulatory procedure has been taken in Japan since the legal permission for irradiated potatoes, although the commercial irradiation of potatoes has been continued over the past more than ten years at Shihiro Agricultural Cooperative Association in Hokkaido which is the world first success on a commercial scale. The wholesomeness of irradiated foods, i.e. potatoes, onions, rice, wheat, sausage and fish paste product (Kamaboko), which had been studied in the national program were already evidenced.

Table 5. Different purposes and dose ranges for food irradiation recommended by the UK Advisory Committee[28]

Process	Approximate dose range (kGy)
Inhibition of sprouting	0.05-0.15
Delaying ripening of various fruits	0.2-0.5
Insect disinfestation	0.2-1.0
Elimination of various parasites	0.03-6.0
Shelf life extension by reduction of microbial load	0.5-5.0
Elimination of non-sporing pathogens	3.0-10.0
Bacterial sterilisation	up to 50.0

Table 6. Food items and doses for irradiation treatments to be recommended by the EEC[34]

Food commodity	Maximum overall average dose (kGy)
Fruits	2
Vegetables	1
Cereals	1
Bulbs and tubers	0.2
Spices and condiments	10
Fish and shellfish	3
Fresh meats	2
Poultry	7
Arabic gum	

Progress in methods of the wholesomeness evaluation and tasks for further development of food irradiation in this field

When we look back upon the past development of food irradiation for commercialization, we have to understand remarkable progress in the principle and methods of the safety assessments of food irradiation.

As mentioned above, the 1976 JECFI corrected the basic concept of food irradiation as a physical process for treating foods[4]. This change of the basic concept from a food additive to a process influenced seriously on the methods of the wholesomeness evaluation, particularly on the method of toxicological animal tests. The "food additive" approach requires toxicological methods based on the traditional concepts of an acceptable daily intake and safety factors. In animal feeding studies on irradiated food, it is not appropriate to fulfill this requirement by exaggeration of the radiation dose given to foods or the incorporation rate in animal diets. In the national project on food irradiation in Japan, anemia in test animals was observed with both unirradiated and irradiated diet groups fed with onions, which might hinder the toxicological potential attributable to irradiation treatments, if any.

Thus the wholesomeness evaluation of irradiated foods requires a different approach as the assessment method for food itself, not for food additives. One of the answers would be radiation-chemical approach, as being recently employed by the USFDA. Its Bureau of Foods estimated that concentrations of radiolitic products at 1 kGy are very low, about 30 ppm, as indicated in Table 4. Similarly, the UK Advisory Committee stated that the total concentration of the products could be of the order of 300 mg/kg of food at a dose of 10 kGy. Therefore it can be concluded that potential toxicity of irradiated food treated with the lower doses, e.g. up to 1 kGy, can not be detected by traditional animal tests. In recent years, knowledges concerning the time sequence of physicochemical and chemical events following absorption of radiation energy are remarkably increased. Dose response relation and yields of radiolytic products have been extensively determined in both actual foods and simple model systems. Information on the wholesomeness of irradiated foods with common chemical components, for example starch and cereal grains, would be helpful for increasing the safety margin of the assessment on individual food items. It would be also worthwhile to consider toxicological approach using extracts or condensates of irradiated foods prepared so that they may not disturb or pose any problem on animal testing.

Another useful tool of chemical approach to the food safety assessment is advanced methods of chemical analyses. Since it is well known that yields of radiolytic products are generally lower in actual foods as compared with simple model systems, the more sensitive method of chemical analysis is required. At present, it is possible to detect and quantify a component or product in food at a level of ppb by HPLC and LC/MS analyses.[29]

Thus, chemical approach has grown to a useful tool for the safety assessments of food. However, it would be helpful to supplement this chemical approach for low-dose applications with toxicological testing using experimental animals, because it is still meaningful to examine the formation of extraordinarily toxic radiolytic products. In this meaning, various mutagenicity and carcinogenicity tests at cellular levels of bacterial and mammalian systems would be effective for the sensitivity of detecting harmful factors. It should be taken in mind that the wholesomeness evaluation is to be done for human consumption. Therefore, the most important task is the safety assessment for *in vivo* toxicities not for *in vitro* ones. In cases of food additives, the sensitivity of human being is considered higher about 10 times than that of animals. Further careful investigations on this problem are requested together with special attention to the methodological advances in chemical analyses on foods.

With respect to the problem of radioactivity induction in irradiated foods, physical investigations lead us to use in food irradiation the limited radiations of photons and electrons at energy levels indicated in a paragraph of general and technical aspects of wholesomeness evaluation. It would be yet useful to show the experimental data of radioactivity determinations for increasing consumer acceptance, because fear for risks of radioactivity induction by irradiation treatments is widely spread among consumers. No induced radioactivity in the dried vegetable powder irradiated with 10 kGy by ^{60}Co gamma rays has been detected by a germanium detector in our determination, which can detect changes in the background radioactivity along subway rail roads[30].

Toxicity studies on various types of problems associated with agricultural chemicals, food additives, cooked foods and environmental safety have developed effective assay methods, especially *in vitro* tests[31]. Even frying and broiling of meats are found to produce mutagens[32,33]. Although the radiobiological implications of *in vitro* mutagenicity recently found in food processing and evironments have not yet been fully elucidated, it would be of great account to promote comparative studies between the wholesomeness data of food irradiation and those on other safety-assessment subjects in our routine lives from the viewpoint that increase in public acceptance is one of key factors for the success in commercialization of this novel food processing technology. For this purpose, uses of other available safety data, for example, experiences to use radappertized animal diets would be relevant.

Concluding remarks

Toxicological testing—(1) Based on radiation-chemical data, foods irradiated at 1 kGy or less are considered safe for human consumption without toxicological animal tests because of extremely lower concentrations of radiolytic products as compared with the sensitivity of animal tests. (2) Dry or dehydrated foods, such as spices and dried vegetables, irradiated at doses up to about 50 kGy and used in a daily diets with a smaller quantity, are also regarded as safe. (3) Foods irradiated at doses of 1 kGy to about 50 kGy require toxicological tests in principle. With respect to the medium dose applications (1-10kGy), the JECFI in 1980 concluded that toxicological testing is no longer required, reviewing all available toxicological data. Requests of additional toxicological testing for the medium-dose range would be dependent upon conditions of individual countries and types of food commodities.

Establishment of the wholesomeness—On toxicological evaluation, data obtained with different types of tests including model food systems should be properly interpreted from the viewpoint of the safety for human consumption, referring to the past experiences of international disputs. Among others, the *in vitro* mutagenicity test is of great account as the first step of the toxicological assessment because of its higher sensitivity and a close correlation between mutagenic and carcinogenic activities. The fact that recent progress in the methodology of toxicological studies has been demonstrating toxic potentials of various materials in our routine lives and environments but not in food irradiation, could endorse the view that the wholesomeness of irradiated foods has been established at the scientific level.

Current and future tasks—Considering the present developmental stage of commercialization and the existence of consumer fear for the use of ionizing energy, further wholesomeness studies on food irradiation for our deeper understanding should be encouraged to increase public acceptance and subsequently to promote regulatory procedures and commercialization of food irradiation. Finally, it is stressed that international cooperation and harmonization have become more important to develope food irradiation in different countries and to contribute to the improvement of world food supplies and the international trading.

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