Wholesomeness of irradiated food

Report of a Joint FAO/IAEA/WHO Expert Committee

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WHOLESMENESS OF IRRADIATED FOOD

Geneva, 27 October–3 November 1980

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WHOLESONENESS OF IRRADIATED FOOD

Report of a Joint FAO/IAEA/WHO Expert Committee

A Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food met in Geneva from 27 October to 3 November 1980. The meeting was opened by Dr T. Fülöp, Director of the Division of Health Manpower Development, on behalf of the Directors-General of the Food and Agriculture Organization of the United Nations, the International Atomic Energy Agency, and the World Health Organization. He mentioned that, as a result of recommendations from previous Joint Expert Committees and of the conclusions of other technical or legal expert consultations organized by these agencies, the FAO/WHO Codex Alimentarius Commission had adopted a general standard for irradiated foods as well as a code of practice relating to food irradiation facilities. Once the recommended general standard is accepted by Governments, foods evaluated by the Expert Committees would be permitted to be irradiated. These would include chickens, papaya, potatoes, strawberries, wheat and ground wheat products, cod and redfish, onions, rice, mangoes, dates, cocoa beans, spices, and pulses. A number of these products are of special interest to developing countries.

1. INTRODUCTION

The world’s food requirements continue to grow, but in an environment of scarce resources and of limitations on methods of food production. In addition, the problems of food storage and processing make it necessary to search for effective alternative methods of food preservation, particularly where existing methods are costly because of the energy requirements and may be difficult to provide in some areas. Accordingly, it is reasonable to consider the use of ionizing radiation for food storage and preservation as one alternative, provided that it does not adversely affect the wholesomeness of food.

The need to consider the wholesomeness of food processed by irradiation was emphasized at an international level at a meeting sponsored by FAO, IAEA and WHO in Brussels in 1961 (1). The studies required to ascertain the wholesomeness of irradiated food were discussed by a Joint FAO/IAEA/WHO Expert Committee on Irradiated Food in Rome in 1964 (2). Taking as a premise that the
irradiation of food resulted in the production of radiolytic products in the food, the Committee adopted the view that these products represented additions to the food. It therefore concluded that the establishment of the safety of irradiated foods should follow procedures similar to those generally used for evaluating the safety of food additives and should be pursued on a food-by-food basis.

A subsequent Joint Expert Committee, which met in 1969 (3), had available for consideration the results of a number of toxicological studies carried out on three specific foods on the basis of the recommended procedures. It reviewed the comparative data on several varieties within a major crop, and accepted extrapolation of data from a major variety to all varieties of that crop. The Committee recommended temporary acceptance of irradiated wheat and potatoes as wholesome, and specified further studies on onions. The next Joint Expert Committee, convened in 1976 (4), reviewed a large number of animal studies on various irradiated foods. Unconditional or provisional acceptances were recommended for most of them. The Committee also reviewed the results of radiation chemistry studies on the major components of food; it noted that many of the radiolytic products identified were present in food treated by heat and other processes and considered that the health hazard from the concentrations found was probably negligible. It therefore encouraged further studies on the chemical changes in food components associated with irradiation.

A large number of data on irradiated foods and food components have since been generated. The present Committee was convened to evaluate the wholesomeness of the irradiated foods for which data were available. It was also asked to review the acceptability of irradiated food in general, in the light of all the toxicological data and the data from radiation chemistry studies, and to make suggestions for further studies where desirable.

2. GENERAL CONSIDERATIONS

2.1. Principles

The principles and guidelines set out in the reports of the 1964, 1969, and 1976 Joint FAO/IAEA/WHO Expert Committees formed the basis for the present Committee's approach to its consideration of the wholesomeness of irradiated food.
2.2. Reasons for the use of food irradiation

The Committee was aware that irradiation of food may be used to achieve a variety of desirable objectives including the following, which are classified according to the average radiation dose required to achieve the objectives in question:

Low-dose applications (up to about 1 kGy)
- Inhibition of sprouting
- Insect disinfestation
- Delay of ripening

Medium-dose applications (about 1–10 kGy)
- Reduction of microbial load
- Reduction in the number of non-sporing pathogenic microorganisms
- Improvement in technological properties of food

High-dose applications (about 10–50 kGy)
- Sterilization for commercial purposes
- Elimination of viruses

The sections that follow (3–7) summarize the evidence which enabled the Committee to assess the effect of the irradiation process on the wholesomeness of food and to arrive at conclusions on the acceptability of irradiated foods.

3. TECHNICAL ASPECTS

3.1 Radiation sources

The Committee stressed the importance of using appropriate radiation sources. From the point of view of safety, the energy level of the radiation applied to food is the most important characteristic that has to be regulated in order to prevent the possible formation of induced radioactivity in the irradiated material. In practice, this is only of importance when considering machine sources, since the most commonly used isotopic sources (\(^{60}\)Co and \(^{137}\)Cs) emit radiation of a maximum energy (\(\leq 1.33\) MeV) which is lower than that causing induced radioactivity. The Committee examined a recent unpublished report (5) showing that, with machine sources, induced activity is negligible and very short-lived below an energy level as high as 16 MeV. In this respect the Committee reconsidered and endorsed a
statement (in the report of a Joint FAO/IAEA Advisory Group on International Acceptance of Irradiated Foods (6)) that the radiation permitted for food irradiation should have a maximum energy level of (a) 10 MeV for electrons and (b) 5 MeV for gamma rays and X-rays. On the basis of that statement and the report of the Expert Committee that met in 1964, which indicated X-rays as a suitable type of radiation, the present Committee decided to recommend the inclusion of X-ray sources in the list of acceptable radiation sources.

3.2 Absorbed dose

The present Committee reiterated the view of the Expert Committee of 1976 (4) that, as a matter of principle, the applied dose of ionizing radiation should not be higher or lower than is needed to achieve the desired effect. Finding and applying the appropriate dose level is the key to the technologically and economically proper application of the irradiation process to food.

It was stressed that the application of the correct dose would be taken care of, wherever there was good irradiation practice. It was recognized that advice on the doses necessary for the treatment of specific food items and the procedures involved would assist those concerned. Such advice could be included in a code of technological practice.

The Committee noted that no new method for the determination of absorbed dose in the food itself, or indeed for the identification of irradiated food, had become available since 1976. It therefore upheld the view of the Expert Committee that met in 1976 (4) that effective dose control can only be exercised in the irradiation plant. The operation of irradiation facilities should be subject to supervision by the appropriate national authorities in order to ensure that proper dose control is exercised. In this respect it was noted that assistance in the calibration of dose control is offered by the IAEA through its programme on High- and Low-Dose standardization and inter-comparison for industrial radiation processing.

As regards setting an overall average dose\(^1\) for the process of irradiation, it was considered that, contrary to the opinion expressed

\(^1\) The overall average dose is the arithmetic mean value of all dosemeter readings in a given irradiation run. To determine this mean value, an adequate number of dosemeters must be randomly distributed in the food as it is exposed to the radiation. The number of dosemeters is considered adequate if it permits estimation of the dose distribution in each portion of the food material of different density and if the measurements are representative for all dose and density fluctuations during a usual run.
by the Expert Committee that met in 1976 (4), it is practical (for reasons such as the technical design of the irradiation facility) to stipulate an average value rather than to require that no part of the food shall receive less than a minimum, or more than a maximum, dose. Taking into account the ratio of maximum to minimum dose absorbed by the product (i.e., the “dose uniformity ratio”) in pilot and currently used commercial facilities, the overall average dose may result in a small fraction of the food receiving a maximum absorbed dose up to 50% higher.

3.3 Processing conditions for irradiation

It is expected that, with wider application of food irradiation, processing conditions will be designed to meet specific technological requirements. Plant design should attempt to minimize the dose uniformity ratio to ensure appropriate dose rates and, where necessary, to permit temperature control during irradiation (e.g., for the treatment of frozen foods) and also control of the atmosphere. It is also necessary to minimize mechanical damage to the product during transportation, irradiation, and storage, as well as to ensure the maximum efficiency in the use of the irradiator. Where the food to be irradiated is subject to special standards for hygiene or temperature control, the facility must permit compliance with these standards.

3.4. Packaging of irradiated food

The packaging method and the packaging material used must be safe and appropriate to the food to be irradiated. Irradiation must not adversely affect the functional properties of the material chosen, nor must it render the material unsafe as determined by appropriate test methods of the kind applied to the unirradiated material.

3.5 Repeated irradiation

While adhering to the view that irradiation of food should normally be carried out once only in each case, the Committee agreed that in certain circumstances repeated irradiation might be justified. This is a departure from the statement in the report of the Expert Committee that met in 1976 that any repetition of irradiation is to be avoided. In deciding upon this change, the present Committee took account of the following findings: (a) the concentration of radiolytic products is
a linear function of dose; \( b \) there is a considerable and rapid reduc-
tion in the concentration of some of these radiolytic products follow-
ing irradiation; and \( c \) an overall average dose based on toxicological
and other considerations could now be established (see section 10).
Consequently, a repetition of irradiation within this overall average
dose would not be harmful, provided that no significant impairment
of nutritional or technological properties occurred. The Committee
agreed that, at the present stage of knowledge, the acceptability of
repeated irradiation should be limited to the case of food commodities
of low moisture content, in which reinfestation by insects could not
be effectively prevented under practical conditions of storage and
transport.

Two other types of repetition of the irradiation process were also
considered acceptable: \( a \) when the food to be irradiated is a pro-
cessed form of food that has already undergone low-dose treatment (for
example, dried onion prepared from onions treated to inhibit sprout-
ing); \( b \) when it includes irradiated minor ingredients (for example,
meat products or dehydrated soup containing irradiated spices). In
both cases, it was considered that the additional amounts of radiolytic
compounds formed in the final products would be insignificant.

By analogy with tyndallization, fractionated irradiation (i.e., when
the full dose has to be applied in two or more instalments) should not
be considered as repeated irradiation.

3.6 Technological efficacy

The Committee stressed that, like other food processing techniques,
food irradiation is justified only if it serves a useful purpose. Results
of studies on the efficacy of the irradiation of the food items specifi-
cally examined by the present Committee clearly showed that the
applications in question are technologically justified and effective.

3.7 Requirements of quality assurance and labelling

The use of sound raw materials and proper handling and proces-
sing techniques, as well as strict maintenance of the wholesomeness
and other desirable qualities of foods are a necessity when irradiation
or any other form of processing is applied. Furthermore, users and
consumers are entitled to expect that the quality and safety of food is
not adversely changed either by irradiation or by other currently
accepted forms of treatment.
The Committee understood that irradiated foods would be subject to regulations covering foods generally, and to any specific food standards relating to individual foods. It was therefore not thought necessary on scientific grounds to envisage special requirements for the quality, wholesomeness, and labelling of irradiated foods.

4. ASPECTS OF RADIATION CHEMISTRY

4.1 Chemical analysis and wholesomeness evaluation

Treatment of foods with electrons (of energies up to 10 MeV) or gamma-rays and X-rays (of energies up to 5 MeV) does not produce radioactivity in the foods so treated. The need for toxicological evaluation of irradiated foodstuffs stems from the fact that the application of radiation energy results in chemical changes. The nature of the radiation-induced compounds depends primarily on the chemical composition of the food. The concentration of radiation-induced compounds generally increases with increasing radiation dose, but can be modified by factors during irradiation such as temperature, presence or absence of air, and the water content of the sample. The energy taken up by the irradiated food is much less than that taken up by heated foods. It is therefore not surprising that chemical changes caused by irradiation are quantitatively much smaller than those caused by heating. For instance, an absorbed dose of 10 kGy (1 Mrad) corresponds to a temperature rise of only 2.4 °C in a food having the heat capacity of water (4.184 J/°C; 1 cal/°C). This is about 3% of the energy needed for raising the temperature of water from about 20 °C to 100 °C.

The Expert Committee that met in 1976 concluded that the radiolytic products detected in the wide range of foods and individual food constituents that had been studied did not appear to pose any toxicological hazards in the concentrations at which they were detected. That Committee also accepted that, for doses below 10 kGy (1 Mrad), data may be extrapolated from one member of a food class to related members (p. 10 in that Committee’s report (4)) and, furthermore, that if certain studies in radiation chemistry and toxicology were continued, a purely chemical approach to the wholesomeness evaluation of irradiated food may prove to be possible (p. 11 in the report (4)).
4.2 Recent studies

The above proposals stimulated a great deal of chemical research on irradiated foods and on model systems, which has confirmed the earlier assumptions and enabled more radiolytic products to be identified and quantitatively determined. Thus, the mechanisms of radiation chemical reactions in carbohydrates, lipids and proteins are now known in greater detail.

A study of the radiolytic products in beef, pork, ham and chicken has shown that formation of volatile hydrocarbons depends on the fat content of the meat, regardless of origin. The electron spin resonance spectra from the four types of meat irradiated at −40°C were identical, indicating the production of common free radical intermediates (I. A. Taub & C. Merritt, unpublished observations).

Another study showed radiolytic products from various starches (derived from maize, amylomaize, waxy maize, wheat, manioc, potatoes, rice, and beans) to be qualitatively identical. Small quantitative differences were related to known properties of these starches, such as the ratio of amyllose to amylopectin. These results were confirmed by electron spin resonance which showed that the nature of the radical intermediates is the same in all the irradiated starches (J. Raffi & L. Saint-Lébe, unpublished observations).

A study of radiation-induced changes in a fruit model has shown that the extent to which these changes take place is in accord with well established kinetic laws. These changes may be calculated using digital computer methods to solve the differential equations which describe the reaction probabilities. Chemical analysis confirmed the prediction that the radiolytic products present in greatest yield in the irradiated fruit were derived from the major constituents of the fruit, i.e., from sugars. Yields of products derived from minor constituents such as protein, malic acid, phenolics, and nicotinamide were much lower (R. A. Basson and co-workers, unpublished observations).

The products of radiolysis in beef (irradiated with an average dose of 56 kGy (5.6 Mrad) at −30°C ± 10°C) have been studied in detail. Over 100 volatile compounds have been identified at concentrations varying from 1 to 700 μg/kg, with a total yield of 9 mg/kg. Most of the compounds are known to occur also in unirradiated foods. The Committee noted that this subject had been reviewed recently (7, 8) and agreed that there were no grounds for suspecting these products of being a hazard to the consumer.
4.3 Conclusions

Since similar radiolytic reactions occur with the same constituents of different foods (protein, fat, carbohydrates, water, etc.), common radiolytic products are formed in roughly predictable yields when these foods are irradiated. Although only approximate predictions of product yields are possible at present, these are sufficiently accurate to enable estimates to be made of the upper limits of yields. Thus there is now considerable additional evidence to support the view that information obtained from toxicity tests on one irradiated food can be extrapolated to other foods of similar chemical composition, or to other processing conditions for the same food.

5. NUTRITIONAL ASPECTS

None of the evidence published since 1976 necessitates a change in the advice on the nutritional aspects of irradiated food given by the Joint Expert Committee that met in that year (4). The salient points are as follows:

Evidence from most studies suggests that in the low-dose range (up to 1 kGy) used for the irradiation of food, nutrient losses are insignificant. In the medium-dose range (1–10 kGy), losses of some vitamins may occur, if air is not excluded during irradiation and storage. In the high-dose range (10–50 kGy), the technology used to avoid effects on organoleptic quality (i.e., irradiation at temperatures below freezing and in the absence of air) also partially protects nutrients, so that losses may actually be lower than in the medium-dose range if such precautions have not been taken.

Conflicting results have been reported concerning the effect of radiation on vitamin C levels in foods. Some authors have determined only ascorbic acid, without taking into consideration that radiation converts some of this acid to dehydro-ascorbic acid, which is also biologically active. In future studies, both ascorbic and dehydro-ascorbic acid should therefore be determined.

The extent of losses of nutrients due to the irradiation of foods depends on many factors, such as the composition of the food, the radiation dose, the temperature, and the presence or absence of air during irradiation and storage.

Whether or not the loss of a nutrient in an irradiated food is of importance depends on circumstances, such as the contribution that
this food makes to the total diet. For instance, a partial loss of thiamine in fish would be of concern if that was the key source of thiamine to a particular population. Other relevant factors include the nutritional status and requirements of the population for which that food is intended. Some other areas of uncertainty (i.e., folic acid losses) require further investigation.

In 1976 the Joint Expert Committee suggested that the reduction of nutritional value produced by irradiation alone should be compared with that produced by other processes and during storage, and by combinations of irradiation with other processes (4). A considerable body of evidence is now available in this regard and the results give no cause for particular concern.

6. MICROBIOLOGICAL ASPECTS

The microbiological safety achieved by the food irradiation process is fully comparable with that of other currently accepted food treatments. No findings have been published during the past four years which would necessitate a reconsideration of the views expressed by the Joint Expert Committee in 1976 (4) regarding the microbiological implications of irradiation of food. The results of theoretical and practical work carried out since 1976 have not revealed any new microbiological problems besides those already reviewed.

The results of both field and “inoculated pack” studies have shown that the microbiological safety evaluation of a specific irradiated food can be based only on studies that have specifically been designed to reflect all the circumstances encountered in commercial irradiation. Furthermore, it is important that the hygienic aspects of each individual commodity should be examined separately and that the post-irradiation storage conditions should be carefully and adequately designed to control microbial growth.

6.1 Variations in radiation resistance

The natural radiation resistance of microorganisms and the consequences of their possible survival after irradiation have been re-investigated with regard to some highly radiation-resistant microorganisms. No new health hazards arising from these organisms have been identified.
Additional experience has also been gained in the application of potentially useful and technologically acceptable combined treatments. For example, it has been demonstrated that the use of irradiation, in conjunction with heat and/or salt treatment, achieves a more efficient reduction in the number of organisms, especially the highly radiation-resistant organisms.

6.2 Radiation-induced genetic variations

Since 1976 there have been no reports to justify the concern, expressed before that time, about the development of irradiation-induced mutations under good operating conditions. As already stated in 1976 (4), the risk of inducing greater radiation resistance has only been shown under laboratory conditions.

Changes of taxonomically relevant characteristics, due to mutation, have not been observed under practical conditions of food irradiation and thus do not pose specific problems. Methods for the isolation and enumeration of damaged cells from heated or dried foods may be used for these purposes in the examination of irradiated food, but their applicability should be tested in each case.

No evidence has been reported of enhanced irradiation-induced pathogenicity of foodborne microorganisms, or of increased toxin formation, or induction of antibiotic resistance in irradiated bacteria. Accordingly, the Committee continues to hold the opinion expressed in 1976 that irradiation of food does not increase the pathogenicity of bacteria, yeasts and viruses.

Because of the intrinsic genetic variability of moulds, experimental results should be interpreted with caution. Laboratory experiments, carried out under conditions which differed greatly from those occurring in practice, have shown that mycotoxin production by moulds derived from irradiated spores may vary (in either direction) in comparison with the parent non-irradiated strain. Other laboratory experiments have shown increased mycotoxin production only if heavy inocula are incubated in irradiated, autoclaved moistened foods. These observations have no relevance to food irradiation under present conditions of practice, in which increased formation of mycotoxins has not been found (see section 8.3).

6.3 Microbiological aims of food irradiation

It has been demonstrated that irradiation can reduce the microbial load of a food, thereby increasing the useful life of a perishable food product. The efficacy of irradiation of spices for reducing microbial
load is well documented and this process may be a useful alternative to fumigation treatment. Laboratory animal diets have been irradiated successfully for a number of years on a large scale to render them commercially sterile. *Salmonella* occurs in livestock and is derived from feed and other sources. Since the incidence of such *Salmonella* can be reduced by irradiation of the feed, this process may afford a means of controlling *Salmonella* in poultry and some egg products and of dealing with this common public health problem in many parts of the world. The on-shore irradiation of fish and seafood has received much attention because, among other reasons, *Vibrio parahaemolyticus* is one of the most important foodborne disease agents in warmer climates.

In all, properly designed irradiation processes have been shown to be capable of achieving their intended microbiological objectives (e.g., commercial sterilization, destruction of pathogens). Problems of a microbiological nature that had before been thought might exist have not materialized. Nevertheless, in the case of irradiation, as in any other method of food processing, the gains in microbiological quality must be safeguarded by proper care of the product after processing.

7. TOXICOLOGICAL ASPECTS

7.1 Re-evaluation of provisional acceptances and new evaluations

The Committee reviewed data on fish, onions and rice for re-evaluation and on cocoa beans, dates, mangoes, pulses, and spices and condiments for evaluation. These data were developed in accordance with the guidelines set out in earlier reports of previous Joint Expert Committees. In making its evaluations the Committee used the principles and categories of acceptance, as set out in the previous report (4).

The Committee noted that, in the case of cocoa beans, onions, and spices, the presence of natural constituents exerted toxicologically significant effects when these commodities were fed at high levels in the test diet. These effects were found, whether or not the food had been irradiated. The information available on irradiated vegetables was insufficient to make an evaluation, using the principles previously
established. The data on all these commodities were also used in considering the acceptance of irradiated food in general (see section 10).

7.2 Considerations arising from a review of data on irradiated laboratory animal diets and other diets

Concern was expressed by the 1976 Joint Expert Committee about the increasingly common practice of using irradiated prepared feeds for laboratory animals, because of the possible effect on control groups used in toxicological testing (4). Data requested on animal colonies reared on irradiated diets were made available to the present Committee, as summarized below.

Studies comparing diets (sterilized by autoclaving or irradiation at 25–44 kGy or treated to eliminate pathogens at 15 kGy) have been published by institutes in Austria, Denmark, France, Hungary, the Netherlands, and the United Kingdom. These included multigeneration studies in rats (9–14), mice (15–17), and pigs (18). In two of the studies (10, 13), some of the parent and F1 generation animals were kept for the whole lifespan for information on carcinogenicity. The numbers of animals examined ranged from 5000 to 500 000.

The Committee concluded from these data that the rearing of test animals on laboratory diets sterilized by irradiation at doses of 15 to 45 kGy was unlikely to obscure any differences if a non-irradiated, hygienically acceptable feed had been used.

The Committee also reviewed information on the results of feeding commercial livestock on feedstuffs irradiated at doses of the order of 8 kGy to reduce organisms belonging to the Enterobacteriaceae, especially Salmonella. Breeding and performance studies in poultry (19), and pigs (20, 21) produced no evidence to show that feeding of irradiated diet to commercial livestock had any adverse effects.

The Committee was aware of the practice of using totally irradiated diets for maintaining patients on immunosuppressive therapy as the only practical means of supplying palatable food under these conditions. No published systematic investigations or accounts were available to the Committee for evaluation. The absence of reports of adverse effects suggests that this practice is not deleterious, and this fact was taken into account in the general assessment of the toxicological acceptability of irradiated food. The Committee recommended that if possible there should be a systematic collection and review of information relating to the use of radiation-sterilized human diets.
7.3 Toxicological evaluation of radiolytic products

The Committee reviewed a study in which the principal radiolytic products from irradiated polysaccharides were fed to rats for 6 months at 1700 times the concentration found after irradiation at 3 kGy. No toxic effects were noted (22). These data also support the conclusion set out in section 10 (See also section 4.2).

8. RE-EVALUATION OF FISH, ONION, AND RICE

8.1 Teleost fish and fish products

Purpose of irradiation

(a) To control insect infestation of dried fish during storage and marketing.
(b) To reduce the microbial load of the packaged or unpackaged fish and fish products.
(c) To reduce the number of certain pathogenic microorganisms in packaged or unpackaged fish and fish products.

Average dose

For (a) up to 1 kGy, and for (b) and (c) up to 2.2 kGy.

Temperature requirement

During irradiation and storage the fish and fish products referred to in (b) and (c) should be kept at the temperature of melting ice.

Microbiological aspects

Vibrio parahaemolyticus is the agent, infectious for man, that is most typically associated with fish and other seafoods. However, infectious agents derived from the intestines of man or other warm-

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1 Summaries of the data used in the evaluations and the references are given in a separate document entitled "Wholesomeness of irradiated food. Summaries of data considered by the Joint FAO/IAEA/WHO Expert Committee, Geneva, 27 October to 3 November 1980". Copies of this document are available, on request, from Division of Environmental Health, World Health Organization, 1211 Geneva 27, Switzerland.
blooded animals may be present in fish because these agents were present in the water in which the fish grew or, as sometimes happens, because they were present in the only water that was available for cleaning fishing equipment (including holding compartments on the ship) or the catch. In addition to infectious agents, toxigenic, spore-forming bacteria such as *Clostridium botulinum* type E may well be present in the fish as caught.

No microbiological problems are likely to arise from irradiation for purpose (a). *V. parahaemolyticus* will be eliminated in the product by the doses recommended for purposes (b) and (c), while the levels of other pathogens and spoilage agents will at least be reduced. Irradiation that does not exceed 2.2 kGy (average dose) is expected to leave enough spoilage organisms to render the food unacceptable before cells derived from surviving *C. botulinum* spores can produce enough toxin to constitute a hazard. However, maintenance of the temperature of melting ice throughout the period of storage of the product has been specified as an additional safeguard against botulism; salting, drying, or other effective measures would have to be substituted if this temperature could not be maintained reliably.

**Nutritional aspects**

More recent studies have shown that after irradiation at 3 kGy, about 15% of thiamine and 25% of pyridoxine is lost, while riboflavin, niacin and vitamin B₁₂ remain unaffected. Higher doses confirmed the particular sensitivity of thiamine and pyridoxine to destruction, the other B complex vitamins remaining practically unaffected. Further studies have confirmed the stability to irradiation of the amino-acid content, particularly of tryptophan. The protein quality of mackerel and hake remained unaltered even by doses of the order of 5 kGy.

The lipids extracted from salted dried irradiated mackerel showed no evidence of adverse nutritional effects at radiation doses of up to 8 kGy. Irradiation up to a dose of 2.2 kGy does not appreciably change the usefulness of fish as a good dietary source of protein, B vitamins, and iodine.

**Toxicological aspects**

The Committee noted that the results of the studies (ongoing in 1976) had now become available—i.e., short-term, long-term, reproduction, and dominant lethality studies in mice; a short-term study in
rats, investigating changes in serum alkaline phosphatase levels when rats were fed on mixed eviscerated cod and redfish; and short-term and reproduction studies in rats fed on other fish varieties. These did not reveal any evidence suggesting that the feeding of irradiated fish to these animals caused any deleterious effects.

A large number of other feeding studies in which rats and mice were fed on other varieties of fish and fish products have also been reported since 1976. These consisted of short-term and long-term feeding studies and also reproduction, dominant lethality, and a number of mutagenicity studies. These new toxicological data, taken together with the results of previously evaluated studies on various types of irradiated fish, do not indicate any adverse effects arising from the administration of irradiated fish to test systems.

*Evaluation*

The previous provisional acceptance for cod and redfish is changed to unconditional acceptance for fish and fish products irradiated for the purpose of disinfection, reducing the microbial load, and reducing the number of pathogenic organisms, at an average radiation dose of up to 2.2 kGy.

### 8.2 Onions

*Purpose of irradiation*

To inhibit sprouting during storage.

*Average dose*

Up to 0.15 kGy.

*Microbiological aspects*

No special microbiological problems of public health significance are known to be associated with irradiated onions.

*Nutritional aspects*

Recent studies have confirmed the previously reported lack of effect of irradiation, with doses of up to 0.15 kGy, on the ascorbic acid content of onions even after 10 months of storage. The content
of reducing sugars increased in irradiated onions to a smaller extent than in untreated onions. No changes occurred in the amino-acid composition.

Toxicological aspects

The requirement of the previous Committee for a multigeneration study in rats, at feeding levels below that causing biological changes due to the biologically active substances that were naturally present, has now been met. In addition, a number of short-term, reproduction, teratogenicity, and dominant lethality studies in rats have now been reported. None of these studies has shown any adverse effects when irradiated onions were incorporated at a 2% level in the diet of rats and mice. Additional corroborative evidence has been obtained from many mutagenicity studies on onions treated (for the prevention of sprouting) with doses of radiation of up to 0.15 kGy and from similar studies on dried onion powder treated with radiation doses of up to 15 kGy.

Evaluation

The previous provisional acceptance is changed to unconditional acceptance of onions irradiated, for the purpose of controlling sprouting, at an average dose of up to 0.15 kGy.

8.3 Rice

Purpose of irradiation

- To control insect infestation in stored rice.

Average dose

- Up to 1 kGy.

Prevention of reinestation

Rice, whether prepackaged or handled in bulk, should be stored, as far as possible, under such conditions as will prevent reinestation.
Microbiological aspects

If the moisture content of stored rice is too high, fungi such as *Aspergillus flavus*, which are sometimes toxigenic, may grow. Such moulds cannot grow in rice that is stored in a properly dry condition; however, there has been concern over some results that suggested that irradiation could enhance the toxigenic potential of the moulds. It has been shown that toxin-producing fungi are more susceptible than other fungi to irradiation; that a higher water activity is required for the growth of toxin-producing aspergilli than for that of other aspergilli; and that, even at a high water activity, non-toxin-producing strains of *Aspergillus* overgrow the toxin-producing strains and suppress their formation of toxin. Storage of rice at a sufficiently low level of moisture is critically important; the potential mycotoxin hazard is not enhanced by irradiation under practical conditions.

Nutritional aspects

The loss of thiamine on cooking, noted in the report of the 1976 Joint Expert Committee (4), may make any further losses due to irradiation relevant where rice is a staple item of the diet and a major source of thiamine. However, a recent study has shown that irradiation at dose levels up to 0.5 kGy did not alter the content of B vitamins or the amino acid composition.

Toxicological aspects

The Committee noted that the results of the long-term study in rats and the short-term study in monkeys, requested in 1976 (4), were now available. These showed that the ingestion of irradiated rice caused no adverse effects on the test animals. Another multigeneration study and a dominant lethality study in mice, as well as cytogenetic investigations of the bone marrow of mice and hamsters that had been fed irradiated rice in their diet, showed no adverse effects. These additional results, taken together with the results of the previously reviewed studies, do not indicate any adverse effects from the ingestion of irradiated rice.

Evaluation

The previous provisional acceptance is changed to unconditional acceptance of rice irradiated, for the purpose of controlling insect infestation, at an average dose of up to 1 kGy.
9. NEW EVALUATIONS

9.1 Cocoa beans

Purpose of irradiation

(a) To control insect infestation in storage.
(b) To reduce the microbial load of fermented beans with or without heat treatment.

Average dose

For (a) up to 1 kGy, and for (b) up to 5 kGy.

Prevention of reinfestation

Cocoa beans, whether prepackaged or handled in bulk, should be stored, as far as possible, under conditions that will prevent reinfestation and microbial recontamination.

Microbiological aspects

Members of 11 genera of moulds, some of which are toxigenic, have been found to be natural contaminants of the cocoa bean embryo and are a major factor limiting the storage life of the product. Mould growth flourishes at moisture levels exceeding 8%. Irradiation with doses of 0.5 kGy eliminates moulds in young (under 2 months) beans, whereas a dose of 5 kGy eliminates moulds even in older beans. Pretreatment of cocoa beans with heat (100°C for 10–15 minutes) enhances the radiosensitivity of the moulds they contain.

Nutritional aspects

Beans irradiated with doses in the range of 0.1 to 5 kGy showed no significant differences from unirradiated beans with regard to their content of reducing sugars, total amino acids, total fat, and protein. Analysis of cocoa fat in the irradiated material showed no detectable chemical difference from that in unirradiated material.

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1 See footnote 1 on page 20.
Toxicological aspects

The available results of the short-term and reproduction studies in rats do not indicate any adverse effect due to the irradiation treatment of the cocoa beans. Both irradiated and unirradiated cocoa beans depressed growth and reduced the food intake when incorporated at high levels in the diet of test animals. The observed toxic effects of the cocoa bean diet on fetal development and survival are related to the high theobromine content of the diet. This has been confirmed by cross-fostering experiments and specific studies using theobromine alone. A number of mutagenicity studies have shown the absence of any mutagenic potential in irradiated cocoa beans.

Evaluation

Unconditional acceptance of cocoa beans irradiated, for the purpose of controlling insect infestation or of reducing the microbial load, at an average radiation dose of up to 5 kGy.

9.2 Dates

Purpose of irradiation

To control insect infestation in stored dates.

Average dose

Up to 1 kGy.

Prevention of reinfestation

Prepackaged dried dates should be stored under conditions that will prevent reinfestation.

Microbiological aspects

No microbiological objectives are being pursued by irradiation of dried dates and no public health problems of a microbiological nature are envisaged.

Nutritional aspects

Irradiation of dried dates with doses in the range of 0.3 to 5 kGy had no effect on the reducing sugar content and on major carbohydrate components. No malonaldehyde was detected. No effect on the
protein content was discovered. Irradiation of dates with doses of up to 10 kGy induced no appreciable changes in the amino-acid composition.

Toxicological aspects

The available short-term study in rats revealed no adverse effects that could be related to ingestion of irradiated dates. The results of the reproduction study in rats and of many mutagenicity studies, including a study for induction of recessive lethals in Drosophila, revealed no adverse effects that could be ascribed to the irradiation treatment.

Evaluation

Unconditional acceptance of dates irradiated, for the purpose of controlling insect infestation, at an average dose of up to 1 kGy.

9.3 Mangoes

Purpose of irradiation

(a) To control insect infestation.
(b) To improve the keeping quality by delaying ripening.
(c) To reduce the microbial load by combining irradiation and heat treatment.

Average dose

Up to 1 kGy.

Microbiological aspects

Microbial species isolated from mangoes do not appear to be a threat to human health. Germination of naturally occurring or experimentally inoculated Gloeosporium fusarium and G. singulata is reduced by increasing the doses of irradiation, but complete inhibition requires a dose of 4 kGy, which is technologically unacceptable.

Nutritional aspects

Several studies have shown that irradiation at dose levels of up to 2 kGy caused only slight losses in ascorbic acid and carotene, compared with the effects of freezing or heat treatment. The contents of
riboflavin, niacin and thiamine are not affected. The levels of fat, protein, sugar, and minerals remain unaffected by irradiation.

Toxicological aspects

The available investigations included short-term, long-term, multi-generation, and teratogenicity studies in rats as well as a number of mutagenicity studies. The results indicated that the incorporation in the test diets or irradiated mangoes produced no adverse effects.

Evaluation

Unconditional acceptance of mangoes irradiated for the purpose of controlling insect infestation or for delaying ripening or reducing the microbial load at an average radiation dose of up to 1 kGy.

9.4 Pulses

Purpose of irradiation

To control insect infestation in stored pulses.

Average dose

Up to 1 kGy.

Prevention of reinfestation

Pulses, whether prepackaged or handled in bulk, should be stored, as far as possible, under conditions that will prevent reinfestation.

Microbiological aspects

No specific microbiological problems arise with pulses, whether irradiated or not.

Nutritional aspects

Pulses are a major source of dietary protein in certain parts of the world. Any deleterious effects of irradiation on the nutritional quality of these crops would therefore be of importance. Conflicting results
appear in studies of the protein efficiency ratio (PER)\textsuperscript{1} and the effects on B-complex vitamins have not been well established for different pulses. These possible effects should receive consideration wherever irradiated pulses are used as staple items of the diet.

\textit{Toxicological aspects}

The available short-term studies in mice and rats, as well as a reproduction study in rats, did not indicate any adverse effects due to irradiation of several varieties of dried beans and cowpeas. There was a reduction in the growth rate of rats after the ingestion of high dietary levels of both irradiated and unirradiated beans. A number of mutagenicity studies, including a dominant lethality study in mice, did not reveal any mutagenic potential in several varieties of irradiated dried beans.

\textit{Evaluation}

Unconditional acceptance of pulses irradiated, for controlling insect infestation, at an average radiation dose of up to 1 kGy.

\textbf{9.5 Spices and condiments\textsuperscript{2}}

\textit{Purpose of irradiation}

\begin{itemize}
  \item[(a)] To control insect infestation.
  \item[(b)] To reduce the microbial load.
  \item[(c)] To reduce the number of pathogenic microorganisms.
\end{itemize}

\textit{Average dose}

For (a) up to 1 kGy, and for (b) and (c) up to 10 kGy.

\textit{Microbiological aspects}

Fungal contaminants, some of which are likely to be toxigenic, occur in untreated spices at an average level of $10^7$/g. Other agents of possible concern to human health include the food-poisoning species

\begin{flushright}
\textsuperscript{1} The protein efficiency ratio is a rough measure of the nutritive value of proteins, obtained by dividing the gain in body mass by the mass of the protein consumed. It is usually measured in young rats, fed on a diet containing 10% protein under standard conditions.
\end{flushright}

\begin{flushright}
\textsuperscript{2} Inclusive of "dehydrated onion" and "onion powder".
\end{flushright}

29
Bacillus cereus and Clostridium perfringens; Salmonella and Shigella have been reported. Aerobic spore-formers and thermophilic bacteria at levels of up to $10^6$/g must be dealt with by some means other than heat. Because the majority of the flora are radiosensitive, irradiation doses of 4–5 kGy reduce the total bacterial counts to less than $10^4$/g. Commercial sterility can be achieved at doses of 15–20 kGy, depending on the initial microbial load. The flora that survive irradiation have a lower heat and salt tolerance, so that the subsequent heat treatment of products containing the irradiated spices can be reduced.

Nutritional aspects

Irradiation of paprika at temperatures in the range of 0°C to 22°C, with doses of 5–50 kGy, and subsequent storage for 6 months had practically no effect on the carotenoid content.

Radiation treatment with 5 and 15 kGy affected the relative concentrations of some fatty acids but not always in a dose-dependent manner. In some spices there is a small reduction in the proportion of some unsaturated fatty acids. Since spices do not contribute significantly to the nutritional quality of food, these changes are of no nutritional significance.

Toxicological aspects

The available reports of feeding studies in rats (including short-term, reproduction, and teratogenicity studies) are less comprehensive in the case of irradiated spices and condiments than for other irradiated foods. Some of the adverse effects observed in the test animals are related to the ingestion of high dietary levels of spices, both irradiated and unirradiated. No untoward effects, attributable to the irradiation treatment, were reported in these studies. The results of several mutagenicity tests revealed the absence of any mutagenic potential. In evaluating the safety of this commodity, the Committee took into consideration the low levels of spices used in the human diet.

Evaluation

Unconditional acceptance of spices irradiated for the purpose of controlling insect infestation, or of reducing the microbial load and the number of pathogenic microorganisms, at an average radiation dose of up to 10 kGy.
10. CONCLUSIONS ON THE ACCEPTABILITY OF IRRADIATED FOOD

10.1 Toxicological acceptability of irradiated food

The Committee, having reviewed new evidence, was able to formulate a recommendation on the acceptability of food irradiated up to an overall average dose of 10 kGy (see sections 2 and 3). This development follows logically from the approaches to the assessment of the wholesomeness of irradiated food adopted in the past by previous Joint Expert Committees, as described in the Introduction. The following considerations led to this development:

(a) All the toxicological studies carried out on a large number of individual foods (from almost every type of food commodity) have produced no evidence of adverse effects as a result of irradiation.

(b) Radiation chemistry studies have now shown that the radiolytic products of major food components are identical, regardless of the food from which they are derived. Moreover, for major food components, most of these radiolytic products have also been identified in foods subjected to other, accepted types of food processing. Knowledge of the nature and concentration of these radiolytic products indicates that there is no evidence of a toxicological hazard.

(c) Supporting evidence is provided by the absence of any adverse effects resulting from the feeding of irradiated diets to laboratory animals, the use of irradiated feeds in livestock production, and the practice of maintaining immunologically incompetent patients on irradiated diets.

The Committee therefore concluded that the irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazard; hence, toxicological testing of foods so treated is no longer required.

10.2 Microbiological and nutritional acceptability of irradiated food

The Committee considered that the irradiation of food up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems. However, the Committee emphasized that attention should be given to the significance of any changes in relation to each particular irradiated food and to its role in the diet.
10.3 High-dose irradiation

The Committee recognized that higher doses of radiation were needed for the treatment of certain foods but did not consider the toxicological evaluation and wholesomeness assessment of foods so treated because the available data are insufficient for this purpose. Further studies in this area are therefore needed.

11. FUTURE RESEARCH

The Committee considered that future research is needed in the following areas in order to increase existing knowledge about the effects of irradiation on food and to facilitate future evaluations:

— The technological and economic feasibility of conducting food irradiation on a larger scale and with a wider variety of foods should be established (see section 3).
— Further studies in the area of wholesomeness assessment of certain foods irradiated at higher doses are desirable (see section 10.3).
— If possible, there should be a systematic collection and review of information on the effects of using irradiation-treated human diets (see section 7).
— The conflicting results published on the effect of radiation on the biological value of proteins and B complex vitamins in pulses should be clarified because of their importance as staple foods in many countries (see section 9.4).
— As there is little recent information on the effect of radiation on folic acid, future work should be carried out on representative folate-containing foods, since the diets in some parts of the world have a marginal folic acid content (see section 5).
— Further work on the effects of combination of irradiation with other processes on the nutritional value of foods so treated is desirable (see section 5).

12. RECOMMENDATIONS

The technological and economic feasibility of food irradiation on an industrial scale should be established. A wider variety of foods should also be studied with respect to their suitability for processing
by irradiation. IAEA and FAO should facilitate such studies and collect data for the purpose of making recommendations.

The use of high-dose radiation for the treatment of certain foods has been recognized as being technologically feasible. To assess the safety of this process, further information is needed on its nutritional, microbiological and toxicological implications. Such information is being generated and should be brought together by FAO, IAEA and WHO for future evaluation.

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