Wholesomeness of irradiated food

Report of a Joint FAO/IAEA/WHO Expert Committee

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Geneva, 31 August – 7 September 1976

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WHOLESOMENESS 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 31 August to 7 September 1976. The meeting was opened by Dr A. S. Pavlov, Assistant Director-General of WHO, and by Dr H. Glubrecht, Deputy Director-General of IAEA, 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.

1. INTRODUCTION

To meet the increasing need for food throughout the world, many approaches are utilized. One of the most important is the reduction of food loss. This may be achieved by the use of chemicals (e.g., antimicrobials, insecticides, and sprout inhibitors), but such use involves potential health hazards not only of the chemicals themselves but of their metabolic products and interaction products (such as nitrosamines). For this reason, much work has been done on the use of irradiation in the conservation of food and on determining the wholesomeness of the food that has been irradiated.

At the international level, the need to consider the wholesomeness of irradiated food was emphasized at a meeting sponsored by FAO, IAEA and WHO in Brussels in 1961. The appropriate studies required to ascertain the wholesomeness of irradiated food were discussed by an expert committee sponsored by the three organizations in Rome in 1964 (*7*, *28*). A further joint expert committee was convened in Geneva in April 1969 (*30*). Its main task was to assess the wholesomeness of irradiated wheat, potatoes, and onions. In the light of the available data, the Committee recommended temporary acceptance of wheat and wheat products irradiated with doses of up to 0.75 kGy (75 krad) and of white potatoes irradiated with doses not exceeding 0.15 kGy (15 krad).[1] It further specified certain studies to be carried out on

[1] In this report absorbed dose is expressed in terms of the gray (Gy), as recommended by the International Organization for Standardization. Values expressed in terms of the rad are given in parenthesis. Conversion factor : 1 rad = 10^{-2} Gy.

these irradiated foods. The data were considered inadequate to assess the wholesomeness of irradiated onions.

Much additional information has since been provided, notably from studies sponsored by the International Project in the Field of Food Irradiation (IFIP). The studies cover not only the foods specified by the 1969 meeting but also other irradiated foods. In addition, data have been provided in response to a circular letter from WHO to its Member States, which supplement those resulting from a WHO consultation group that met in 1974 to review data on irradiated food and an FAO/IAEA consultants' meeting on microbiological aspects of food irradiation (*34*). The present Expert Committee was convened to review and assess these data.[1]

2. GENERAL CONSIDERATIONS

2.1 Principles

The Committee reviewed the principles and guidelines described in the reports of the 1964 and the 1969 Joint FAO/IAEA/WHO Expert Committees referred to in the previous section and concluded that, for the most part, these were sound and should be followed. The present Committee re-emphasized, however, that the safety for human consumption of irradiated food must be based on the following considerations: (1) the absence of microorganisms and microbial toxins harmful to man, (2) the nutritional contribution to the total diet of the irradiated food, and (3) the absence of any significant amounts of toxic products formed in the food as a result of the irradiation process.

2.2 Irradiation as a food-treatment process

Irradiation is a physical process for treating foods and as such it is comparable to the heating or freezing of foods for preservation. The only unique feature of irradiation is the particular type of energy employed, and it is this feature that has aroused special attention.

The question of wholesomeness has been raised in relation to the irradiation of foods with gamma-rays, yet the wholesomeness of foods treated with radiation of longer wavelengths (heat or microwaves) has not been questioned to the same extent. The Committee stressed that

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[1] A summary of the data considered by the Joint Expert Committee (document WHO/Food Add/77.45) is available from Food Additives, World Health Organization, 1211 Geneva 27, Switzerland.

the microbiological, nutritional and toxicological approaches to the assessment of the wholesomeness of irradiated food must be based on the concept of food irradiation as a process.

In the past the approach has been taken that irradiation " adds " something to the treated food and that it should therefore be considered as a food additive and not as a process. This view was adopted by some national authorities, whereas others regulated food irradiation by controlling it as a process. The " food additive " approach to food irradiation meant that evaluation of the toxicological aspects of wholesomeness had to be based on the concepts of an acceptable daily intake and safety factors, as is the case with food additives or pesticide residues in food. However, the Committee considered that the approach needed in the toxicological evaluation of the wholesomeness of irradiated food differs from that used in the safety evaluation of chemicals. It is impracticable to exaggerate the feeding levels of irradiated foods in animal studies beyond a modest degree, nor is it appropriate to exaggerate the radiation dosage much beyond that to be used in practice. Either of these practices gives rise to effects which are not relevant to the toxicological potential of the irradiated food. The evaluation of the wholesomeness of irradiated foods therefore poses problems of a different kind from those encountered with food additives or contaminants and it consequently requires a different approach.

It is recognized that public concern about the hazards of radiation generally may be reflected in a distrust of irradiated foods. It will be necessary to educate and reassure the public as to the safety of irradiation as a food process, because in many parts of the world and for many commodities there are good reasons to use this process.

2.3 Extrapolation of data from one food to another

The Joint FAO/IAEA/WHO Expert Committee that met in 1964 (*28*) considered that too little information was available at that time to establish general principles for extrapolation of data on the wholesomeness of some irradiated foods. It was expected that this would become possible in time.

The Joint FAO/IAEA/WHO Expert Committee that met in 1969 (*30*) concluded that data on the wholesomeness of one irradiated food had relevance to other irradiated foods. Any generally applicable data that could be identified would add reliability to the evaluation of specific foods treated by irradiation. This approach represented progress compared to the earlier views.

A WHO Consultation held in 1974 considered that data on a specific variety of a food crop were applicable to all varieties of that food crop. For groups of foods exhibiting differences extending beyond intraspecies variety (e.g., the applicability of data collected on wheat to maize, barley or oats) it might be possible to use simpler wholesomeness testing procedures when the radiation dose is below 10 kGy (1 Mrad). Thus studies on a single representative variety of irradiated food could cover other varieties of the same food. Similarly, toxicological and chemical data could be used across a class of related irradiated foods with minimal toxicological testing requirements for new foods in that class.

The Committee was presented with evidence on the great similarity in radiolytic products in related foods treated with radiation doses of the order of 10 kGy and on the uniformity of reaction of the protein, lipid and carbohydrate constituents of foods to radiation (see section 4). It is considered, therefore, that it is possible to generalize to a considerable extent about the radiation chemistry of foods. Most of the radiolytic products identified in irradiated foods can also be found in non-irradiated foods, and many of them are generated in foods by other processing procedures. For those radiolytic products that have been identified, the concentrations of the most abundant, even with radiation doses of up to 60 kGy (6 Mrad), are only in the mg/kg range. With dose ranges below 10 kGy (1 Mrad)—i.e., in the range that achieves the technical requirement for foods considered by the present Committee—the concentrations of radiolytic products are much lower. The available data on the chemical structures of radiolytic products in food and the very low concentrations at which they occur (see section 4) suggest the general conclusion that the health hazard they might represent is negligible.

The Committee agreed with the view that evidence of safety of one form of irradiated food could be applied to other forms of the same food. To the extent that foodstuffs can be placed in a relatively small number of major categories and for doses below 10 kGy (1 Mrad), the Committee accepted that data may be extrapolated from one member of a class to related members. It employed these principles when evaluating the wholesomeness of the starch-containing foods potato, wheat and rice by including in its evaluation information on maize starch. In the case of the wholesomeness evaluation of certain irradiated fresh fish, the evaluation was facilitated by information on a large variety of other irradiated fish and fish products; in future the totality of the data on irradiated fish may allow the acceptance of irradiation for all fish.

From such considerations the Committee envisaged that for doses of up to 5 kGy (500 krad) radiation chemical data (along with negative evidence from animal feeding studies) may eventually indicate that food items in general are safe for consumption by man. If certain radiation chemical and toxicological studies are continued it may even prove possible to use a purely chemical approach to the wholesomeness evaluation of irradiated food. These conclusions regarding the safety of the radiation process may even be extended to dose levels higher than 5 kGy.

However, the acceptance of these principles does not militate against the questions that might be asked about any new process. Thus irradiation must be proved to be an acceptable means of processing food and one that does not impair its wholesomeness, and it may be premature to base an evaluation of a new irradiated food solely on data obtained with other foods, even though they may be of closely related types.

3. TECHNICAL ASPECTS

3.1 Dosimetry

Careful dosimetry is required in the irradiation of test foods to be used in animal feeding studies as well as in the irradiation of foods for human consumption. Satisfactory methods of dosimetry exist and have been used for years in the commercial radiation-sterilization of medical products, laboratory animal diets, and some other items. Suitable procedures are described in detail in a handbook entitled *Dosimetry manual for industrial irradiators*, which is being prepared by IAEA.

In the technical specifications for the irradiation of various foods described in this report, a dose range is given for each food. This indicates that no part of the foods to be irradiated shall receive less than the minimum dose or more than the maximum dose indicated.

Dosage has to be expressed in terms of a range not only because it is impracticable to have a completely uniform dose distribution in an irradiator but also because an optimum average radiation dose cannot be fixed. For instance, different potato varieties require somewhat different doses for optimum sprout inhibition and storage life ; thus one variety may require an average dose of 0.07 kGy (range 0.05–0.09 kGy) and another may require an average dose of 0.12 kGy (range 0.09–0.15 kGy). Similarly, climatic conditions and insect populations prevailing in one country may require wheat to be irradiated with about 0.5 kGy (range 0.4–0.6 kGy) whereas in another country half that dose may suffice. In order to encompass all such variations it is necessary to specify a range of dosage.

As a matter of principle, the applied dose should not be higher than is needed to achieve the desired effect. It is therefore necessary to set maximum dose values. The setting of minimum dose values is critical in those cases where the desired effect is the elimination of pathogenic organisms or of plant pests for which quarantine regulations exist. In other instances adherence to the prescribed minimum dose is necessary to achieve the technological purpose.

3.2 Processing conditions for irradiation

Beyond indicating a dose range and the type of radiation to be used, it is beyond the scope of this report to prescribe all the technologically important details of various radiation processes. To take potato irradiation as an example, some of the factors to be considered are : whether the potatoes are irradiated immediately after harvest or after several weeks of storage ; whether they are irradiated loose or packaged, and if packaged, what sort of packaging material or container should be used ; and whether storage after irradiation is at ambient temperature or at 10°C. The answers to these questions may depend on local needs and conditions. Potatoes to be stored for eight months and to be used for industrial processing into chips will require conditions different from those needed for potatoes to be stored for four months and to be sold for household use.

With regard to the irradiation of a food used in experiments for testing wholesomeness, the irradiation conditions specified should be as close as possible to those to be used when the food is irradiated for human consumption.

On the other hand, radiation chemical data show that extrapolation within a wide range of irradiation conditions (with regard, for example, to water content and dose rate) is permissible ; therefore an evaluation of wholesomeness that is arrived at under one set of conditions will often be valid for practical application under a different set of conditions.

3.3 Methods of identifying irradiated foods

The search for methods that permit the identification of irradiated foods is not without scientific interest, but the availability of such methods should not be made a condition for permitting food irradiation or trade with irradiated foods. Food irradiation cannot be done in a clandestine fashion ; indeed it will be carried out in government-licensed installations. To ascertain the dose, existing methods of dosimetry are more reliable than any analysis of the food. In only a few cases can irradiation of foods be reliably detected by chemical methods.[1]

3.4 Packaging of irradiated food

Irradiation should not adversely affect the functional properties of packaging materials and should not cause the release of deleterious substances that may migrate into the food.

Methods of testing the functional properties of packaging materials and detecting migrating compounds are well established and must be applied to non-irradiated as well as irradiated packaging materials.

3.5 Repeated irradiation

The Committee considers that repeated irradiation of food is to be avoided, for a number of reasons. For example, the evaluations of toxicological and microbiological safety and nutritional quality are in respect of foods treated within specific ranges of radiation ; furthermore, the product should be correctly identified to the consumer in terms of the processing to which it has been subjected.

Even though radiolytic products accumulate with repeated irradiation, the concentrations are so low that the toxicological hazard likely to arise from repeated irradiation is minimal. However, the food is likely to be degraded in terms of organoleptic acceptability and nutritional quality.

Because there are no readily available tests for detecting repeated irradiation of a product, the main procedures for preventing this practice are proper labelling, record-keeping, and surveillance. The records should be sufficiently comprehensive to avoid irradiation of secondary products of previously irradiated foods—for example, of milled products of irradiated grains.

3.6 Quality of food to be irradiated

As a general principle, the process of irradiation should be applied only to those foods that meet appropriate standards of quality before irradiation. The need to affirm this principle arose when the attention of the Committee was drawn to a problem that could arise from irradiation of food contaminated with fecal matter (see section 10.6). In this case, irradiation would probably destroy the common bacterial indicators of fecal contamination, as well as the enteric pathogens, but

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[1] Further information on this point is given in document WHO/FAD/75.3, which is obtainable on request from Food Additives, World Health Organization, 1211 Geneva 27, Switzerland.

pathogenic viruses that may also be present would probably not be destroyed. It is important, therefore, to establish the hygienic quality of foods *before* irradiation if there is any reason to suspect fecal contamination.

3.7 Technological aspects of irradiated food

As part of the technological assessment of irradiated foods, cognizance should be taken of the possible consequences of irradiation for the secondary uses that will be made of the food. For example, if irradiation of wheat produced changes in gluten, this would affect the quality of bread, pasta and noodles prepared from it ; however, in this instance, the level of irradiation accepted by the Committee for wheat falls well below that at which gluten is appreciably degraded.

4. RADIATION CHEMISTRY

The Committee endorsed the recommendations made by the 1974 WHO consultation group[1] concerning the desirability of chemical studies to provide data for the evaluation of irradiated food. However, if the toxicological data are adequate for acceptance of an irradiated food, radiation chemistry studies will not be required as a condition for acceptance.

The analyses of radiolytic products that have been carried out so far have removed much of the previous uncertainty about the validity of extrapolating from one food to another in arriving at an evaluation of the consequences of irradiation (see section 2.3). A previous Expert Committee (*30*) questioned the validity of using toxicological data obtained with foods subjected to higher doses of irradiation than would be used in practice. The objection was based on the theoretical consideration that high doses of radiation might destroy radiolytic products that were formed at low doses. However, the experimental evidence that has since accumulated indicates that the concentrations of radiolytic products generally increase in proportion to radiation dosage until they reach a plateau with radiation doses of about 10 kGy (1 Mrad) (*25*).

It may be concluded, therefore, that when no significant toxic effects have been obtained with a food treated with a high dose of radiation, there will be no effect when the same food is treated with a lower dose

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[1] The report of the consultation group (document FAD/75.3) is available on request from Food Additives, World Health Organization, 1211 Geneva 27, Switzerland.

of radiation. It is not such a straightforward matter to extrapolate from data on foods treated with high doses of radiation that do produce toxic effects; this is because it is not yet possible to give an assurance that *all* the radiolytic products having possible toxicity have been identified and because the biological dose/response relationships of even the known radiolytic products have not been determined with precision. Therefore there is still a need at present for a certain degree of toxicological testing to establish with confidence the safety of irradiated foods. However, the general principle of radiation chemical reactions, as revealed by analytical studies, will reduce considerably the extent to which toxicological testing is needed and will simplify the testing procedures.

In recent years, a considerable number of irradiated foods have been analysed chemically in detail. Most of the radiolytic products that have been identified are also found in various non-irradiated foods (*6*, *17*, *18*). The concentrations formed by radiation with doses of up to 60 kGy (6 Mrad) are generally less than 1 mg/kg (*17*, *19*, *23*). The major radiolytic products, such as carbon dioxide, methane, and hydrogen, are tolerable at considerably higher concentrations. The concentrations of radiolytic products that are formed by doses *below* 10 kGy (1 Mrad) are so low that their reliable identification is possible only in simple food materials such as starch, crystalline sugar, and pure fats.

The evidence so far obtained from radiation chemistry indicates that no acute toxicological effects will occur with irradiated foods. There remains, however, the possibility that more subtle long-term effects (e.g., carcinogenesis, mutagenesis) may occur. Most compounds with such effects either possess an electrophilic reactivity or are metabolized into compounds with such reactivity. In addition, autoxidizable compounds that yield peroxides possibly present a hazard. Considering from these viewpoints the chemical structure of the minor radiolytic products that have been identified, and the low concentrations at which they occur, there are no grounds for suspecting that they represent an actual hazard in irradiated foods.

Studies on the radiation chemistry of proteins, carbohydrates, and lipids have shown that these major food constituents react in uniform ways. This allows the prediction of the major radiolytic products that are likely to be present in more complex foods (*33*), though caution must be exercised in this respect.

It thus appears that the radiolytic products detected in the wide range of foods and individual food constituents that have been studied so far do not pose any toxicological hazards in the concentrations at which they have been detected. It is envisaged that radiation chemical investigations will eventually provide sufficient data (when taken in conjunction with findings from toxicological, nutritional and microbiological investigations) to facilitate greatly the evaluation of irradiated foods (5).

5. NUTRITIONAL ASPECTS

Irradiation, like certain other food-processing techniques, results in physicochemical changes in the product that may alter not only its organoleptic properties, and therefore consumer acceptance, but also its nutrient composition. Because of wide differences in the chemical constitution of different foods, the nature and extent of these changes may depend on the kind of food subjected to irradiation and on the irradiation dose. It is therefore important to :

(1) examine the changes that occur in the nutrient content of foods following irradiation ;

(2) determine whether the bio-availability of nutrients is in any way altered ; and

(3) establish whether changes, if they do occur, would have possible adverse nutritional consequences.

Relatively small changes in nutrient composition or bio-availability in foods that are consumed in considerable amounts in habitual diets may acquire nutritional significance, whereas similar changes in foods that are eaten only in small quantities would be less likely to affect nutritional balance. Thus, alterations in the nutritional quality of meat and fish, where these foods constitute a major part of the diet, would be more serious than changes in foods like papaya, mushroom, and strawberry. In several developing countries, large population groups obtain a very high proportion of several nutrients from a single food source (e.g., wheat, rice, or millet).

Generally, foods are irradiated in the raw state and stored for varying periods of time before they are cooked and consumed. Storage and cooking are among the factors known to result in loss of nutrients, depending on the type and duration of storage and the method of cooking. The extent to which irradiation may contribute to those losses deserves examination. Nutritional evaluation of irradiated foods should be carried out, when feasible, on foods as they are actually consumed.