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CONSUMER CONCERNS ABOUT THE SAFETY OF IRRADIATED FOOD

The WHO reply to questions raised by the International Organization of Consumers Unions

FOOD SAFETY UNIT

DIVISION OF ENVIRONMENTAL HEALTH

WORLD HEALTH ORGANIZATION

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INTRODUCTION

The "International Conference on the Acceptance, Control of, and Trade in Irradiated Food"

In response to requests from governments, FAO, IAEA, WHO, and ITC[1] jointly convened an international conference on food irradiation, held in Geneva from 12-16 December 1988. The conference, which brought together some 250 participants, was attended by official delegations from 54 countries, comprising government officials at the senior policy-making level, experts in law, health, energy, and food, and representatives of consumer unions, as well as by representatives from 11 international organizations.

The objective of the conference was to produce an internationally agreed document addressing consumer attitudes to irradiated food, the regulation and control of the irradiation process, and the control of international trade in irradiated foods, based on a careful consideration of the particular conditions under which food irradiation should be allowed to play a part in ensuring the supply of wholesome food. The conference achieved its objective. The document reproduced as Annex 1 was adopted by consensus on the final day of the conference.

A complete record of the conference, including texts of the keynote addresses (see Annex 2) and offical statements from governments, will be published by IAEA in late 1989 or early 1990.

The IOCU questions and the WHO reply

During the course of the conference, representatives of the International Organization of Consumers Unions (IOCU) raised a number of questions concerning the safety of irradiated foods[2]. Many of these questions were recorded in an IOCU paper, "Outstanding Questions on the Safety of Irradiated Food," which was distributed to participants during the conference. The IOCU paper is reproduced here in the form in which it was made available during the conference.

The IOCU paper expressed concern over several seemingly unresolved issues of safety, nutrition, and the control of the irradiation technology, and specifically asked WHO "to produce a comprehensive fully referenced report covering all aspects of the *safety, nutrition and public health* aspects of food irradiation."

Such a report was published by WHO in 1981 under the title, *Wholesomeness of Irradiated Food*[3].

In further compliance with the IOCU request, *D.O. Cliver, J.F. Diehl, J. Hawthorn,* and *E.H. Kampelmacher,* acting in their capacity as WHO Temporary Advisers to the Secretariat of the Conference, prepared a point-by-point reply to the specific questions raised in the IOCU paper. These "Comments on the IOCU Paper", prepared during the conference and distributed to participants, were subsequently revised in order to substantiate statements and comply with the IOCU request for "fully referenced" answers. The "Comments" reproduced in the present document incorporate these revisions.

In keeping with the rules of procedure pertaining to intergovernmental meetings convened by UN agencies, the IOCU, which enjoys official relations with WHO, was admitted to the conference in the status of an observer. A special evening session, held outside the official framework of the Conference, was convened in order to permit IOCU representatives to express their concerns.

The importance of consumer views

The document adopted by the conference acknowledges the vital importance of consumer attitudes to food irradiation and recommends that "clear and adequate information about the technology" be made available to the general public.

On its part, WHO regards public understanding of what food irradiation can and cannot do as the most promising path towards general acceptance and fuller use of this technology for the benefit of mankind. In collaboration with FAO, WHO has recently published a book[4] explaining the uses and limitations of food irradiation to the general public.

In reproducing and distributing these "comments" and the questions to which they respond, WHO again lends its authority to the public debate about the wholesomeness of irradiated foods, hoping that the information presented in these pages will help reassure consumers that all of the "outstanding questions" raised by the IOCU have clear, authoritative, scientific answers.

Food Safety Unit
Division of Environmental Health
World Health Organization, Geneva

1 Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, World Health Organization, and the International Trade Centre (a joint sub-organ of the United Nations Conference on Trade and Development and the General Agreement on Tariffs and Trade)
2 The term "safety" is used by IOCU to include toxicological, microbiological, and nutritional issues. The term "wholesomeness", as used by WHO, refers to these same issues.
3 Wholesomeness of irradiated food. Report of a joint FAO/IAEA/WHO expert committee. *Technical Report Series*, No. 659, World Health Organization, Geneva (1981).
4 Food irradiation: a technique for preserving and improving the safety of food. World Health Organization, Geneva (1988).

Note about WHO publications referred to in the IOCU paper

The numbered "WHO Reports", cited in the IOCU paper, refer to the following publications:

"WHO Report 316"
The technical basis for legislation on irradiated food. Report of a Joint FAO/IAEA/WHO expert committee. *Technical Report Series*, no. 316, World Health Organization, Geneva (1966).

"WHO Report 604"
Wholesomeness of irradiated food. Report of a joint FAO/IAEA/WHO expert committee. *Technical Report Series*, no. 604, World Health Organization, Geneva (1977).

"WHO Report 659"
Wholesomeness of irradiated food. Report of a joint FAO/IAEA/WHO expert committee. *Technical Report Series*, no. 659, World Health Organization, Geneva (1981).

THE IOCU QUESTIONS

OUTSTANDING QUESTIONS ON THE SAFETY OF IRRADIATED FOOD

There are unresolved issues of safety and nutrition associated with irradiated foods and problems with control of the technology resulting in abuse occurring in the food trade in some commodities.

These issues will need to be resolved before there can be widespread consumer acceptance of the process and should be resolved before there is any further use or development of the irradiation of food.

The World Health Organization should be asked to produce a comprehensive fully referenced report covering all aspects of the safety, nutrition and public health aspects of food irradiation. The process of review of data should exclude organizations such as the IAEA/FAO joint division on radioisotopes in agriculture and other organizations which have a vested interest in the outcome.

The terms of reference for the WHO investigation should specifically include the need to produce reports on the following :-

1. **Outstanding issues previously identified by WHO**

   The WHO should produce a summary of the evidence on:

   1.1 The effect of irradiation on packaging material in contact with food (WHO Report 316, 1966).

   1.2 The effect of combinations of irradiation and other processes on the nutritional value (WHO Report 604, 1977).

   1.3 Chemical, nutritional and toxicological studies on the radiolytic products of lipids with reference to peroxide and epoxide formation and cis-trans isomerization (WHO Report 604, 1977).

   1.4 The effect of irradiation on the biological value of proteins and B complex vitamins (WHO Report 659, 1981).

   We are unable to trace where this additional work, identified in the earlier WHO reports as requiring further study, has been undertaken and reviewed.

2. **Pesticide residues, additives and contaminants**

   WHO should produce a summary of the evidence and identification of work needed on the effect of irradiation on pesticide residues, food additives and contaminants.

   These areas were identified by the UK government advisory comittee as lacking scientific data.

3. **Adverse effects in animal studies**

   WHO should produce a comprehensive evaluation of the data and methodologies used in studies that found for and against the following adverse effects:

- lowered immune response
- increased dominant lethal genetic damage
- reduced spermatogenesis
- increased incidence of polyploidy
- lower birth weights
- lower growth rates
- kidney damage
- heart lesions
- reduced blood clotting
- increased incidence of tumors

In the event that studies are found methodologically deficient, the WHO should specify the faults in the experimental design and define the appropriate methodology for resolution of the controversy on these issues.

4. Freshly irradiated grains

The WHO should specifically review the data and the evidence available on both sides of the controversy surrounding the studies suggesting adverse effects associated with feeding freshly irradiated as opposed to stored grains. It is now clear that the arguments put forward to dismiss these findings do not stand up to reasoned criticism based on the facts.

5. Free-radical/antioxidant vitamin reactions and vitamin supplementation

The WHO should also specifically review animal trials against the background of scientific evidence indicating the free radical induction effects of irradiation, the role of specific vitamins in terminating free radical reactions, the particular susceptibility of these same vitamins to damage by irradiation and the apparently massive vitamin supplements used in various animal feeding trials, particularly those which are cited as not having found adverse effects.

In its review of methodologies, the WHO should clarify:

a) the purpose of the supplementation of the animal feed when used in each of the relevant studies.

b) whether the level of vitamin and/or mineral supplementation was appropriate or excessive for the purpose.

6. Dietary impact of irradiation on foods

The WHO should review, summarise and if necessary commission research to provide comprehensive data on the effect of irradiation on each of the foodstuffs considered for clearance, indicating the range of vitamin and other nutrient losses that might be expected with different irradiation doses and food storage times.

7. Control of irradiation and prevention of abuse

The WHO should assess the potential public health problems associated with the use of irradiation to reduce microbial loads on foods, considering particularly the problem of bacterial toxins remaining as a result of earlier contamination.

The WHO should publish comprehensive guidelines for:

a) research into appropriate methods of detection of irradiation suitable for public health agencies.

b) research into appropriate tests for bacterial toxins and viruses in foods that have been irradiated.

c) microbiological standards appropriate for foods prior to irradiation so that there can be some clear guidelines as to what is "good manufacturing practice".

d) appropriate controls on storage and handling of foods after irradiation.

e) training for public health/food control and enforcement personnel to meet the changed situation created by irradiation where current laboratory methods for assuring the wholesomeness of food are now largely obsolete.

8. Food poisoning

The WHO should review the extent and causes of food poisoning and develop a comprehensive approach to eliminating the problem based on education, food/water hygiene standards, and appropriate technologies for remedying the root causes of the problem. The limited role for irradiation should be placed within this wider context.

9. World hunger

The WHO and FAO should together develop a comprehensive program for alleviating the problems of world hunger, malnutrition and food losses with attention to dependencies of poorer countries, availability of appropriate finance, a full range of appropriate technologies and measures for food distribution and storage. Discussion of irradiation should be placed within this wider context.

IOCU

INTERNATIONAL ORGANIZATION OF CONSUMERS UNIONS
Regional Office for Asia and the Pacific
P.O. Box 1045, 10830 Penang Malaysia
Phone: 04-20391 Telex: MA 40164 APIOCU

THE WHO REPLY

Comments on the International Organization of Consumers Unions (IOCU) Paper "Outstanding Questions on the Safety of Irradiated Food"

Prepared by
D.O. Cliver
Professor, Food Research Institute and
Department of Bacteriology
University of Wisconsin, Madison
(United States of America)

J.F. Diehl
Director and Professor
Federal Research Center for Nutrition, Karlsruhe
(Federal Republic of Germany)

J. Hawthorn
Emeritus Professor of Food Science
University of Strathclyde, Scotland
(United Kingdom)

E.H. Kampelmacher
Emeritus Professor of Food Microbiology and Hygiene
Agriculture University, Wageningen (The Netherlands)
and former Deputy Director-General
National Institute of Public Health and Environmental Protection, Bilthoven
(The Netherlands)

WHO Temporary Advisers to the Secretariat of the
Joint FAO/IAEA/WHO/ITC-UNCTAD/GATT International Conference
on the Acceptance, Control of, and Trade in Irradiated Food
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Comments on the International Organization of Consumers Unions (IOCU) Paper "Outstanding Questions on the Safety of Irradiated Food"

"Outstanding issues previously identified by WHO"

The IOCU paper claims that there are "unresolved issues of safety and nutrition associated with irradiated foods" and, moreover, that various WHO reports have identified these issues as "requiring further study". In fact, the WHO reports clearly differentiate between *required* studies and *recommended* or *suggested* studies. There are no required further studies. The following four points listed in the IOCU paper all belong to the category of recommended studies. All these studies have been carried out.

1. **Packaging materials**

   The packaging industry is continuously developing new packaging materials for a variety of applications. When newly developed materials are considered for use in radiation processing, their suitability must be adequately studied. In this context, it should be noted that the dose range now under discussion for food irradiation (up to 10 kGy) produces negligibly small effects on plastic materials. Where sterilizing doses of radiation are used, for instance in treating medical equipment, the selection of appropriate packaging materials is more critical. The functional properties of some plastic materials are actually improved by irradiation and this has led to the extensive use of ionizing radiation in the plastics and cable manufacturing industries.

   Numerous studies on irradiated packaging material in contact with food have been carried out, particularly in the United States of America *(1)*. These studies included investigations on the migration of packaging material extractives into food *(2)*. The US Food and Drug Administration, having carefully evaluated the results of these studies, approved a list of materials, some of which are suitable even when sterilizing doses of radiation are to be used *(3)*. The latest FDA rule on food irradiation has confirmed the validity of this list. *(4)*.

2. **Irradiation combined with other processes**

   Effects of combinations of irradiation and other processes on the nutritional value of foods have been extensively studied. Findings from these studies, which were discussed at a 1980 IAEA Symposium devoted to "Combination Processes in Food Irradiation" *(5)*, have shown that vitamin losses caused by high doses of irradiation can be largely prevented by combination methods (e.g. irradiation at low temperatures or in the absence of oxygen).

3. **Radiolytic products of lipids**

   Numerous studies on the radiolytic products of lipids are available. *W.W. Nawar* at the University of Massachusetts, Amherst (USA), has published a long series of papers on the radiation chemistry of pure fats *(6)*. In interpreting the findings of these and other studies *(7)*, it is important to understand the crucial distinction between results following the irradiation of pure lipids and those following the irradiation of lipids present in complex foods, between the conditions of experimental design and those under which irradiation is actually applied to treat foods that reach consumers. Some of the findings, such as cis-trans-isomerization observed at a dose level of 1000 kGy, are of theoretical importance but have little to do with the practice of food irradiation at dose levels of up to 10 kGy (8).

   In particular, it is important to understand that lipids present in complex foods react to irradiation under the protection of other food constituents, such as proteins and antioxidant vitamins. Thus, when pure herring oil was irradiated with a dose of 50kGy, polyunsaturated fatty acids showed 37-50% destruction. Yet when herring fillets were irradiated with the same dose, no destruction was observed *(9)*. Effects of radiation-induced oxidation of lipids on the nutritional value of protein were examined in rat-feeding studies which again demonstrated the important role of the degree of unsaturation of the lipids and of the presence or absence of oxygen during irradiation and storage *(10, 11)*. Other studies have been reviewed by *Delincée* (12) and *Nawar (13)*.

4. Proteins and B complex vitamins

WHO Technical Report Series, No. 659 *(14)* suggested additional studies on the biological value of proteins and B complex vitamins in irradiated *pulses* — not in irradiated foods in general, as IOCU implies. Additional data on pulses are now available. The chick growth bioassay shows slightly *improved* protein nutritional value in beans *(15)* and lentils *(16)* irradiated with a very high dose of radiation (210 and 180 kGy, respectively). There is no reason to assume that doses in the range of up to 10 kGy would have any adverse or beneficial effect on protein quality of pulses. Irradiation of red gram *(Cajanus cajan)* with a dose of 10 kGy caused losses of B-complex vitamins of 7% (thiamin, niacin) or less (riboflavin) when uncooked samples were analyzed. However, irradiation allows shorter cooking time and heating partially destroys B-vitamins; analysis of B-complex vitamins after cooking showed slightly higher levels of B-vitamins in the irradiated samples as compared to unirradiated samples *(17)*. Studies on other pulses do not seem to be available, but there is no reason to assume that they would show very different results.

"Pesticide residues, additives and contaminants"

Pesticide residues are present in foods only at very low levels, usually fractions of one part per million. *Contaminants* may range from traces of lubricants from food processing machinery or products leached into the food from the container to environmental pollutants such as PCBs. *Additives* are likewise generally present in low levels, usually less than 500 mg/kg.

Concerning the case of food additives, a look at the situation using a worst-case approach provides an idea of the relative risk involved. Consider the case of an additive in pure form (as opposed to present in food and protected by other food constituents) irradiated at 10 kGy. In the worst case, 300 mg/kg of the additive would be converted into radiolytic products *(18)*. If the additive is present in a food at the level of 500mg/kg, the amount of radiolytic products from the additive in one kg of the food would be about 0.15 mg. In reality, however, the known protective effect of the food constituents means that the result would almost certainly be less.

In this theoretical "worst-case" situation, the total quantity of radiolytic products associated with the use of additives would therefore be measurable in parts per billion. In the case of pesticides and contaminants the levels of reaction products would be two or three orders of magnitude lower.

Beyond these theoretical considerations, numerous experimental studies are available on the radiation chemistry of food additives and pesticides. These studies have shown that the destruction within the dose range below 10 kGy is very small. As far as the decomposition products have been identified, they have raised no toxicological concerns.

The natural toxins present in many plant foods present much higher risks, and it would be an abuse of experimental animals and scarce toxicological resources to spend effort on such a trivial problem. Once again, it is important to distinguish between theoretical — and improbable — risks and the real situation. As far as the authors of this paper are aware, additives are only occasionally used in a limited number of foods now being commercially irradiated.

"Adverse effects in animal studies"

Comprehensive evaluations of results of animal feeding studies were carried out by the

Joint FAO/IAEA/WHO Expert Committee on Food Irradiation (JECFI). New evaluations by WHO, as demanded by IOCU, would not lead to new information. The "adverse effects" mentioned in the IOCU paper refer to studies carried out many years ago as shown in the following two examples.

Heart lesions
This apparently refers to experimental work on mice reported by *H. Monsen* almost 30 years ago. When the *Monsen* study was repeated by a multi-author group using a much larger number of mice, not a single case of the heart lesion was found *(19)*. There is no scientific reason to review any aspect of these studies.

Reduced blood clotting
This points to another study carried out some 30 years ago. Rats were fed a diet containing 35% of radiation *sterilized* beef in a long-term study. Rats in the study group developed internal bleeding (hemorrhagic diathesis), a finding that caused considerable concern at the time. Subsequent studies showed that the level of vitamin K in this diet was very low, even before irradiation, and that the high dose of irradiation required to sterilize the diet reduced these already very low levels enough to cause symptoms of vitamin K deficiency (reduced blood clotting, internal bleeding). Addition of vitamin K to the diet completely prevented the bleeding *(20,21)*. There is no scientific reason to review any aspect of this comprehensive work.

"Freshly irradiated grain"

Between 1975 and 1978 authors at the National Institute of Nutrition (NIN), Hyderabad, India, published several papers in which they claimed that the feeding of freshly irradiated wheat to mice, rats, monkeys and malnourished children caused adverse effects which were not seen in groups receiving stored irradiated wheat. These findings were disussed at length by JECFI and by various national agencies and expert groups, who came to the conclusion that the NIN studies did *not* demonstrate adverse effects. The claimed effects were based on small numbers, were of questionable statistical significance, or were not considered to be an indication of a pathological situation. As far as these studies were repeated by other groups (with much larger numbers), the results were not confirmed *(concerning polyploidy: 22 concerning intrauterine death: 23)*. No mutagenic effect was observed in a study with monkeys, fed wheat only 24 hours after irradiation, using a different type of assay *(24)*. Apart from the convincing weight of scientific evidence refuting the NIN studies, the need for more repeat studies is further ruled out by the simple fact that the purpose of irradiating wheat is to store it.

"Free-radical/antioxidant vitamin reactions and vitamin supplementation"

IOCU demands information as to the purpose of the supplementation of animal feed used in toxicological studies, and whether the level of vitamin and/or mineral supplementation was appropriate or excessive. The need for vitamin supplementation in long-term studies with diets treated with a high dose of radiation should be obvious from what was said above concerning vitamin K deficiency. The purpose of such long-term feeding studies is to discover possible toxic effects of the test diet. If the test animals are sick from vitamin deficiency, researchers will be hard pressed to determine whether observed adverse effects have been caused by irradiation or stem from the symptoms of vitamin deficiency. In studies designed to look for long-term toxic effects it is therefore essential to bring the vitamin levels of the test diet up to that of the control diet. Therefore, and in keeping with the principles of good experimental design, tests of high-dose irradiated diets have been routinely supplemented with vitamins. When medium- or low-dose irradiated diets were tested such supplements were often not needed because radiation-induced vitamin losses were small. Mineral supplements were always the same in control diets and test diets.

Free radicals are not only found in irradiated foods; they widely occur in biological materials. As a matter of fact, they are continuously produced in the human body. A long term feeding study especially designed to look for possible effects of an irradiated diet containing a high concentration of free radicals produced no indication of harmful effects with regard to tumour formation *(25)* and mutagenic effects *(26)* in rats.

"Dietary impact of irradiation on food"

Reviews of effects of irradiation on the nutritional value of foods are available *(27)*. It is well known that some vitamins are partially destroyed by irradiation, that the losses increase with increasing radiation dose, and that these losses can be ameliorated by irradiating at low temperature and/or in the absence of oxygen. Such vitamin losses are insignificant in all food irradiation processes now being commercially practiced anywhere in the world, including the irradiation of spices and other dried vegetable materials, grains, potatoes, onions, frozen sea food, etc. There is no good reason to prevent the irradiation of these commodities with the argument that some other products irradiated with relatively high doses under unfavourable conditions may show a substantial loss of this or that vitamin. Moreover, if foods now undergoing commerical irradiation were to be distinguished by nutritional losses greater than foods processed by other methods, the problem of finding a detection method for irradiated foods would be solved, since it is well known that highly sensitive methods are available for detecting nutritional changes in foods.

"Control of irradiation and prevention of abuse"

It must be recognized that questions regarding the microbiology of irradiated foods are relevant only to applications in the 1-10 kGy range. Lower doses will have minimal effects on the microflora, whereas higher doses are not yet endorsed by WHO. It should also be noted that the reason nations have food control laws — with criminal penalties — is that the food supply has been abused occasionally since long before modern methods of food preservation were developed. No single food process is any more or less vulnerable to abuse than others.

1. **Methods for detection of irradiation**

   It appears that methods of determining that certain foods have been irradiated are in prospect. Other test methods are being sought in many laboratories. However, it is unlikely that a universal method will emerge, since the biochemical changes produced by irradiation are extremly small and certainly much less than those induced by other methods, such as heat treatment. If a solution to this dilemma is to be found, it may have to come from public trust of the same food control authorities and responsible industries that bear the burden for the many other problems of food safety.

2. **Bacterial toxins and viruses**

   It is true that bacteria can be killed and leave toxins behind them in a food — the problem has long been recognized, for example, in the heat pasteurization of milk. There are tests for the toxins and, in the case of *Staphylococcus aureus*, a fairly simple and rapid "thermonuclease test" exists. Clearly, the important precaution here is to avoid excessive levels of bacteria in the food before irradiation *(see paragraph 3 below)*. Growth of toxin-producing bacteria, mainly *St. aureus*, occurs only when the food is mishandled, i.e. held at temperatures much higher than refrigeration.

   Present methods for the detection in foods of viruses significant to human health leave much to be desired. In that viruses present a very small target, they will be only slightly inactivated (and apparently not mutated) by food irradiation. However, known instances of virus transmission through foods have not involved foods likely to be irradiated, or the contamination occurred during final preparation and serving. Neither bacterial toxins nor viruses have any special significance with respect to food irradiation. The main target of food irradiation is the vegetative bacterial cell, known to cause millions of cases of disease each year.

3. **Microbiological standards for foods to be irradiated**

   Codes of "Good Manufacturing Practice" often include microbiologic criteria for foods that are to be processed. We have been informed that WHO has already scheduled a 1989 meeting to establish microbiologic criteria for foods to be irradiated. Meanwhile, it may be noted again that low-dose (below 1 kGy) applications do not require such criteria.

4. **Controls on storage and handling**

   Methods of record-keeping for this purpose are already in operation in the food control systems of many countries. Aside from specific labelling requirements, irradiated foods present no special problems in this regard. If some countries do not already have such record-keeping systems in place, the matter can doubtless be covered (and probably already is) in training courses discussed in the following section.

5. **Training for public health/food control personnel**

   Training for these purposes goes with the training in food irradiation technology that is offered by the International Facility for Food Irradiation Technology (IFFIT) at their facility in the Netherlands. However, it should be noted that:

   • the food control system that is already in place in many countries can readily be extended to include irradiated foods; and

   • the statement that food irradiation has changed the situation such that "current laboratory methods for assuring the wholesomeness of food are now largely obsolete" is patently false.

   Excepting the wished-for test to show that a food has been irradiated, such foods present no analytical problems that have not already been encountered with other foods.

"Food poisoning"

WHO has reviewed the extent and causes of foodborne disease during the last 35 years. A great number of reports have been issued; many of these reports are available from WHO Headquarters, Geneva. A list of current WHO literature has recently been compiled *(28)*. Moreover, the extent and causes of foodborne disease have been described in thousands of publications from all over the world. Epidemiological studies and surveillance programmes have greatly enlarged our knowledge of agents causing foodborne disease.

At the same time, international organizations, and WHO in particular, as well as national authorities and the food industry, have developed programmes for control and prevention of food contamination by pathogens. The fight against foodborne diseases can be summarized in three lines of defense.

1. **Pathogen-free animals for food production**
   The rearing of pathogen-free animals for food production is, in principle, possible and has been achieved on an experimental basis. In practice, however, this line of defense cannot be applied on a large scale. Due to the increased contamination pressure from the environment (soil, surface water, rodents, insects, birds, etc), raising of pathogen-free food animals is not to be expected in the near future.

2. **Food processing**
   Use of this second line of defense depends on such processes as heat application, freezing, drying, chemical preservation, and irradiation.

3. **Information and education**
   The third line of defense includes information for and education of consumers and all those who handle or prepare food.

It should be clearly understood that all measures briefly summarized as first and third lines of defense have so far not resulted in a reduction of foodborne diseases. The contrary is true: many countries for which data are available have shown a constant increase in the incidence of foodborne diseases over the last 30-40 years. In addition, "new" organisms (e.g. *Campylobacter, Listeria*, etc) have emerged as causative agents of foodborne diseases. This does by no means imply that the measures summarized as first and third lines of defense should be abandoned. On the contrary, all efforts should and must be applied for the production of safe foods.

However, in protecting the consumer, processing methods are undoubtedly important. This is especially true for consumer groups with a heightened susceptibility to foodborne infections, including babies and young children, the diseased, especially those with compromised immunity (AIDS patients, persons on cancer therapy, transplant recipients), patients in hospitals, and the very rapidly growing population of the elderly. Processing methods have already proved their effectiveness as measures to prevent foodborne disease. For example, following the introduction of milk pasteurization in the Netherlands, no single milk-borne disease outbreak has been observed since the Second World War. In Scotland, 18% of all salmonellosis cases were due to contaminated milk. Since pasteurization has been legally required, this percentage has fallen to nearly zero in recent years.

The decontamination of high-risk foods, such as poultry, raw meat sausages, shrimps, frog legs, and spices, to name the most important ones, will without a doubt contribute to the prevention of foodborne diseases, especially as far as the above-mentioned sensitive consumer groups are concerned. In this respect it should be underlined that, worldwide, a large percentage of all foodborne diseases are due to *Salmonella* and *Campylobacter*, two organisms which can be killed in foods with irradiation doses between 2.5-5 kGy.

"World food problems"

The health and development problems caused by food shortages and food losses have been continuously monitored by WHO and FAO for the past 40 years, and many other international, technical, economic and voluntary agencies have been increasingly involved. Food shortages and the probability of future famines are more likely in the developing countries than in industrialized societies. The problems are seen in their most acute form in the tropical regions of the world. In these areas high temperatures, often associated with high humidities, create extreme problems for food storage. For example, grain and pulse losses due to insect and microbial infestations have been variously estimated as being between 20 and 50%.

Over the past several decades, every known preservation technique and a huge scientific effort have achieved little more than a stabilization of the overall situation, although there have been notable improvements in specific geographic areas. Against this background, food irradiation has only a minor part to play in the immediate future, but perhaps a growing one.

Specific situations have to be looked at from a strategic point of view. The main problems arise in the poorest parts of the world, and establishing priorities for such expenditure as is available usually means that, for example, the provision of a clean and safe water supply is far more important than a nuclear irradiator. It is difficult for many people to realize what acute poverty means. As one example, acute poverty often means that there are neither bags nor other insect-proof containers available, so grain goes on the floor in a mud hut, protected from rain but accessible to rodents, insects, and fungi. A family must store a year's supply of grain from a single harvest. To feed a family of five would require, for example, the storage of three metric tonnes of grain. Even if the grain is sound going into storage, insect losses will normally have reached 20 to 30% in the last three months before the next harvest. Irradiation and proper storage would eliminate this loss, but in the extremes of poverty, the provision of proper bags for storage is perhaps the first step.

Thus irradiation is far from being a primary step in dealing with food security under conditions of extreme poverty. The technique has its more proper place in those areas where economies have shown a measure of growth and whose infrastructure of administration, communications and services is well developed. Effective administration is essential since the process involves high and sustained levels of technology; communications are important because a single irradiator requires a constant and substantial supply of raw materials and outlets for the products; services such as refrigeration, power and water are of obvious importance. In large areas of the world, these fundamental prerequisites simply do not exist.

It is in the later stages of socioeconomic development that irradiation has a part to play as an enabling process which will permit the export of such exotic food items as mangos and papayas, which will extend the life of protein staples such as meat and fish, and which will reduce grain and pulse losses caused by infestation.

The IOCU document suggests that FAO and WHO should develop a comprehensive programme for alleviating the problems of world hunger, etc. In so stating, the International Organization of Consumers Unions seems to be unaware that that is precisely what both of these organizations have been engaged upon for the past 40 years, and that irradiation is now seen as but one resource — and in relative terms not a major one — for tackling the panorama of problems involved.

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ANNEX 1

Document on Food Irradiation

Adopted on 16 December 1988 by the
FAO/IAEA/WHO/ITC-UNCTAD/GATT*
International Conference on the
Acceptance, Control of, and Trade in Irradiated Food
Geneva, 12-16 December 1988

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*Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, World Health Organization, and the International Trade Centre (a joint sub-organ of the United Nations Conference on Trade and Development and the General Agreement on Tariffs and Trade)

INTRODUCTION

1. All governments bear a responsibility to ensure sufficient supplies of safe, nutritious and acceptable food to meet the needs of their people. Such supplies should be of high quality and should comprise a wide variety of foodstuffs. Governments should also feel responsible towards contributing to the improvement of the global food supply.

2. In no country can these objectives be achieved without dependence on food processing and preservation technology to a greater or lesser degree. The problems of achievement are compounded by differing agro-climatic conditions, levels of technology, seasonality of production and the perishable nature of many crops. The application of food processing technology is therefore necessary for two important reasons. One is to prolong the availability of seasonally produced crops and to minimize food losses; the other is to reduce the incidence of illness caused by food-borne pathogens. Each country will have differing requirements in these two areas, but the overall trend towards increasing urbanization of the world's population results in an increasing need for processed food, and for the development of appropriate processing and preservation technologies.

3. In the case of certain food imports, additional specialized treatment may be applied to satisfy quarantine requirements necessary to exclude insect pests of economic or environmental significance from the importing country. Lack of acceptable quarantine treatments can result in the loss of foreign exchange earnings, which in turn could affect the ability of an exporting country to provide basic food supplies and socio-economic development for its own population. Irradiation, as a process to ensure that a pest is unable to become established in the importing country, can be an alternative to chemical fumigation and other physical methods.

4. No treatment of food can be employed in the long term unless it has the acceptance of the consumer. In many cases, acceptance can be expected because the palatability of the original food is maintained or because the choice is between the treated food and no food at all (because untreated food would be spoiled). Given the choice, many consumers would generally prefer that food should be unprocessed if at all possible, but such an ideal is not a practicable possibility in many cases, nor is it always desirable.

5. The foregoing requirements for treatment or preservation of food are currently being addressed by a variety of processes, some of which such as drying and salting are of considerable antiquity, while others such as fumigation, canning and freezing are of more recent origin. Treatment by ionizing radiation is now beginning to be used to supplement existing technologies for certain applications. One of these applications, which has potential for beneficial public health effects, is the reduction of pathogenic microorganisms in solid foods.

6. The Conference therefore devoted itself to a careful consideraton of the particular conditions under which food irradiation should be allowed to play a part in ensuring the supply of wholesome food in association with existing and already widely used food preservation and food quarantine treatments. In this context, the Conference recognized the Codex General Standard for Irradiated Foods and Recommended International Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods. The Conference also considered consumer attitudes, inter-governmental and governmental activity, process control and trade.

CONSUMER ATTITUDES TO IRRADIATED FOOD

7. The potential for food irradiation to help maintain a safe and adequate food supply cannot be attained unless irradiated foods are accepted by consumers. On one level of acceptance, the final food product must be of satisfactory quality at a reasonable cost. On a deeper level, however, a consumer who is satisfied with the food currently available should not be expected to be enthusiastic about any change in the current food production system, especially if that change is perceived to be significant.

8. A consumer has a right to expect that food available in commerce is safe and wholesome; that is, the food promotes health because it is nutritionally adequate, microbiologically safe, and does not contribute to toxic effects due to chemicals either produced in the food during processing or added to food by some other means. The terminology used for food irradiation is sometimes confused with that used to describe radioactive contamination. This confusion can best be addressed by proper information. Consumers may also be concerned that introduction of ionizing radiation technology into food processing may lead to an increased probability of accidents leading to environmental contamination or worker hazards.

9. Although wholesomeness of the food is a necessity, it is difficult for a consumer to determine when the criterion of wholesomeness is met. Food is a complex mixture of components and its safety and nutritional adequacy cannot be judged outside the context of the diet of which it is a part. As with any other food processing technique, the matters of safety and nutrition related to food irradiation must continue to be monitored inter alia through further international cooperation and research. As new information becomes available, it should be considered by the authorities concerned.

10. Illness due to food-borne microorganisms is often difficult to trace to a particular food. Its usual incidence is often underestimated by consumers. If the facts on illness resulting from food-borne microorganisms are not understood by consumers, they may not be able to understand the potential impact of food irradiation and other methods for microbial control.

11. As part of the control of the irradiation process, consumers need to be convinced that the potential accomplishments of food irradiation are not negated by a misuse of technology. Although irradiation cannot reverse the effects of spoilage, consumers need reasons for confidence that irradiation will not be used to mask deficiencies of an inferior product. Such confidence can result from a better understanding of the capabilities and limitations of the various individual uses of irradiation and knowledge that irradiation is not being used as a substitute for otherwise achievable good manufacturing practices. Furthermore, like any other process, food irradiation must in no way be used to mislead consumers, and in this respect governments have a major role to play.

12. Information about irradiated food products and processing should be presented to consumers in an objective and clear manner on a continuous basis. The need for such information is particularly important at the time of introduction of irradiated food products when consumer interest and curiosity are expected to be greatest. If necessary, such information should include any special instructions on handling, storage and preparation of irradiated food at home.

13. In cases where irradiated foods are permitted, consumers should be able to make their own choice between irradiated and nonirradiated food. To enable them to make this choice, there must be clear and unambiguous labelling. It is for individual governments to meet this

need in their own countries. International standards for labelling are being developed by the Codex Alimentarius Commission*. Documentation must be sufficient to ensure transfer of information through international trade so that national labelling requirements can be met.

14. It is well known that the changes associated with food irradiation are difficult to detect. However, it is recognized that detection methods, if available, would augment standard regulatory procedures and would thereby help assure consumers that processors and distributors are adhering to government control procedures. Research on detection methodology should be continued.

15. Consumer confidence can be bolstered when there is clear evidence that the food irradiation process is being effectively controlled by a responsible industry and a governmental regulatory process. Because the factors needed to control the irradiation process effectively are the same everywhere, it is reasonable to expect substantial harmonization of national approaches.

INTER-GOVERNMENTAL AND GOVERNMENTAL ACTIVITY

16. In 1980, a Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food declared that the irradiation of any food up to an overall average dose of 10 kGy causes no toxicological hazard and introduces no special nutritional or microbiologial problems.

17. Some concerns about the effects of irradiation on microorganisms in food had been raised earlier at a meeting of the Codex Committee on Food Hygiene in 1979. Therefore the microbiological safety of irradiated food was further considered at a meeting of the Board of the International Committee on Food Microbiology and Hygiene of the International Union of Microbiologial Societies in Copenhagen in December 1982 in order to provide a second opinion. In its conclusions, the Board was satisfied that there was no cause for concern. Food irradiation was said to be an important addition to the methods of control of food-borne pathogens and not to present any additional hazards to health.

18. Following these expert meetings, the Codex Alimentarius Commission, then representing 122 countries, in 1983 adopted the Codex General Standard for Irradiated Foods and the Recommended International Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods. There was broad consensus among the representatives for this adoption, except for two countries which expressed their reservations.

19. The Codex General Standard for the Labelling of Prepackaged Food contains provisions on the labelling of irradiated foods (CODEX STAN. 1-1985, section 5.2). However, as many countries have not yet taken a final position as to how the fact of irradiation should be declared, this section remains under review until the next session of the Codex Committee on Food Labelling and of the Codex Alimentarius Commission in 1989.

20. At the request of over 60 Member States to continue a forum of international co-operation with emphasis on harmonization of national regulations based on the principles of the Codex General Standard for Irradiated Foods and its associated Code of Practice, an International Consultative Group on Food Irradiation (ICGFI) was established under the aegis of FAO, IAEA and WHO in May 1984. The main functions of the Group are to evaluate global developments, provide a focal point of advice and furnish information on food irradiation as required to Member States and the Organizations. The Group now has 28 member countries contributing either in cash or in kind to its activities, which include the maintenance of international inventories of food irradiation

**Codex General Standard for the Labelling of Prepackaged Food (CODEX STAN. 1-1985)* facilities, product clearances and national legislations and regulations, as well as the organization of workshops and task forces, and the preparation of technical guidelines for irradiation processing of various food groups. At its fifth meeting the Group noted that 20 countries are using irradiation for processing food and food ingredients; commercial and demonstration irradiators for treating food are being constructed or are in the advanced planning stages in fourteen countries. The Secretariat of the Group anticipated that some 25 countries will be applying the technology on a commercial scale by 1990.

21. The attitudes of governments towards irradiation of food range from those which have accepted and are applying the technology to those which are interested and exploring it, to those which have decided not to permit the technology at the present time, and to those which have no definite opinion. Some governments consider that there is no need for the technology in their countries. In general, however, countries which express reservations, such as potential misuse of the technology, have not disagreed in principle on the safety of food treated in accordance with adequate standards, such as the Codex General Standard for Irradiated Foods.

22. To a large extent the attitude of governments is influenced by consumer acceptance. If there is widespread opposition among consumers, this may be taken as a reason not to accept the method. Governments share the view that if the sale of irradiated foods is permitted in their countries, the foods would have to be labelled to inform consumers about the irradiation. Adequate regulatory control is generally regarded as the basic responsibility of governments to engender consumer confidence in the process.

23. Governments share the view that all food irradiation facilities should conform to internationally agreed standards of radiation protection, including worker and public safety, transport and disposal of source material and environmental protection.

PROCESS CONTROL

24. Facilities which are intended to carry out irradiation of food should meet appropriate standards of safety and good hygiene conditions for processing. Therefore, such facilities should be operated in accordance with the principles of the Codex General Standard for Irradiated Foods and associated Code of Practice; operational control of such facilities should be subject to inspection by competent authorities.

25. Facilities for irradiating food should be properly designed and constructed. Operation should be by appropriately trained personnel. It is necessary to have an infrastructure that includes support facilities and equipment, and a well-established regulatory system.

26. Food intended for treatment by irradiation should be of a quality acceptable for Good Manufactuing Practices (GMP). Hygienic practices which are needed in GMP for other processes are also necessary in the process of irradiation, but irradiation should not be used as a substitute for such practices. Wherever necessary, pre-treatment of food such as cooling, chilling and freezing should be carried out in such a manner as to achieve effective treatment. Suitable packaging materials are currently available for use when prepackaging is required to prevent recontamination after irradiation.

27. The effectiveness of the irradiation process depends on proper application of dose, and its measurement. Initial dose distribution measurements should be carried out to characterize the process for each product, and thereafter dosimeters should be used routinely to monitor correct execution of the process in accordance

with internationally accepted procedures. The dosimetry should be traceable to national or international standards and thus provide an independent control of the process.

28. Simple radiation indicators which can help the processor in identifying the food which is treated, applied to the product pack prior to treatment, are available for certain dose ranges.

29. As with all food processing, it is important to apply effective quality control, not only at the irradiation process level but also in production, storage, transport and retail sales. It is also necessary to identify critical control points and methods for monitoring by operators and regulatory authorities. The regulatory personnel and those responsible for food irradiation should be trained in quality control. The personnel responsible for controlling the plant should have proper training in operation of the facilities as well as in handling of the foods concerned. The quality control system would also include proper packaging suitable for the product and appropriate temperature control in storage and handling. Products which could become infested by insects or contaminated by microorganisms after treatment should be packed and stored in such a way that reinfestation or recontamination is prevented. Food should be handled, stored and transported according to GMP before, during and after irradiation.

TRADE

30. Control of food in trade by public authorities is essential, whether or not the food is treated by any process, to ensure that any treatment, if applied, is done in a safe and proper manner, and with adequate safeguards against abuse. Proper controls are particularly relevant to both national and international trade in irradiated food. Control should be exercised at all stages of handling up to the point of sale to consumers.

31. Because of the nature of the process, which makes it difficult at present to determine the circumstances of irradiation by examination of the food, control of irradiated food has to be established through legally-based administrative procedures. These procedures, whether the product is intended for domestic use or export, should include on the one hand a system of documentation allowing each batch of irradiated food to be identified with the irradiation facility and with the treatment given, and on the other hand a system of labelling. Other methods of control and compliance should be considered as technology progresses; therefore research on analytical methods for identification of radiation-processed food in trade should be encouraged.

32. The purpose of labelling need not merely be to inform the consumer of the fact of irradiation, but may also indicate the purpose for which treatment has been given (see also paragraph 19). The additional use of a logo to identify irradiated food should be encouraged.

33. The system of control should apply to both domestically produced and imported foods. Internationally recognized standards of control which allow adequate account to be taken of the needs and policies of individual countries would help to avoid the creation of unnecessary obstacles to trade.

34. The harmonization of Standards and Codes of Practice for regulating irradiated food and irradiation facilities by public authorities, and for the training of inspectors, plant operators and food control officials according to an internationally accepted and certified curriculum, would also help to achieve acceptance of irradiated foodstuffs by consumers in the importing country. The principles embodied in the Codex General Standard for Irradiated Foods and associated Code of Practice are considered to form a suitable basis for the harmonization of national procedures.

CONCLUSIONS

35. The Conference recognized that:

35.1 Food irradiation has the potential to reduce the incidence of food-borne diseases through the reduction of pathogen contamination in foods, especially in solid foods.

35.2 Food irradiation can reduce post-harvest food losses and make available a larger quantity and a wider variety of foodstuffs for consumers. It can also be an effective quarantine treatment for certain foods and thus contribute to international trade.

35.3 Regulatory control by competent authorities is a necessary prerequisite for introduction of the process in accordance with the principles of the Codex General Standard for Irradiated Foods and Recommended Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods. Food irradiation is not to be used as a substitute for Good Manufacturing Practices.

35.4 International trade in irradiated foods would be facilitated by harmonization of national procedures based on internationally recognized standards for the control of food irradiation.

35.5 Acceptance of irradiated food by the consumer is a vital factor in the successful commercialization of the irradiation process, and information dissemination can contribute to this acceptance.

RECOMMENDATIONS

36. The Conference recommended that:

36.1 Consideration should be given to the application of food irradiation technology for public health benefits, especially for products where this process would seem advantageous.

36.2 Consideration should be given to the application of food irradiation technology where it can, in appropriate cases, reduce post-harvest losses of foods and serve as a quarantine treatment.

36.3 Governments should ensure that, as a prerequisite to any processing of food by irradiation or sale of irradiated food, regulatory procedures for control are introduced. Key principles which should be incorporated are the registration/licensing, regulation and inspection of food irradiation facilities, documentation and labelling of irradiated food, training of control officials, and employment of Good Manufacturing Practices.

36.4 Regulatory procedures for control of the food irradiation process should be consistent with internationally agreed principles as embodied in the Codex General Standard for Irradiated Foods and associated Code of Practice. Dosimetry traceable to national or international standards should be applied during the irradiation process, providing a means of independent verification.

36.5 Governments should encourage research into methods of detection of irradiated food so that administrative control of irradiated food once it leaves the facility can be supplemented by an additional means of enforcement, thus facilitating international trade and reinforcing consumer confidence in the overall control system.

36.6 Labelling of irradiated food for international trade should be in line with the provisions as adopted by the Codex Alimentarius Commission.

36.7 Governments should ensure that all phases of planning and operation of food irradiation facilities are subject to a regulatory structure consistent with relevant internationally accepted standards for human health, safety and environmental protection.

36.8 Governments, especially those that envisage authorization of food irradiation, are encouraged to provide clear and adequate information about food irradiation to the public. The active participation of all interested parties, including consumers, should be encouraged.

ANNEX 2

Keynote addresses and speakers

International Conference on the Acceptance, Control of, and Trade in **Irradiated Food**

"The Safety and Wholesomeness of Irradiated Foods"	**Prof. J. Hawthorn** Professor Emeritus University of Strathclyde Glasgow United Kingdom
"Food Irradiation — Its Contribution to Public Health "	**Prof. E.H. Kampelmacher** National Institute of Public Health and Environmental Hygiene Bilthoven The Netherlands
"Food Irradiation — A Contribution to Food Security"	**Dr. B.A. Amla** Director Central Food Technology Research Institute Mysore India
"The Impact of Technological Advances in Food Processing and Preservation, in Particular Irradiation, on International Food Trade"	**Dr. K.A. Gilles** Assistant Secretary Department of Agriculture Washington, D.C. U.S.A.
"Regulatory Control of Food Irradiation Process for Consumer Protection"	**Dr. P. Pothisiri** Deputy Secretary-General Food and Drug Administration Bangkok Thailand
"Food Industry's Views on the Acceptance of Irradiated Foods"	**Mr. P. Moog** Société de Produits Alimentaires et Diététiques S.A. Courbevoie Cedex France
"Consumer Views on the Acceptance of Irradiated Food"	**Ms. J. Taylor** Commissioner Queensland Consumer Affairs Bureau Brisbane, Queensland Australia