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FOOD IRRADIATION

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Abstract

A review of recent developments in the field of wholesomeness research and legal clearances is presented. The work of the International Project in the Field of Food Irradiation, the decisions of the 1976 meeting of the FAO/IAEA/WHO Joint Expert Committee on Food Irradiation, and the steps taken by the Codex Alimentarius Commission are mentioned in some detail. On the basis of the developments which have taken place at the international level it is concluded that the chances of world-wide commercial application of food irradiation have improved considerably since this topic was reviewed at the First International Meeting on Radiation Processing.

Introduction

Progress towards commercial use of radiation processing in the food industry depends primarily on the legal clearance of more irradiated food products in more countries. This was a key point of the review paper which I presented at the First International Meeting on Radiation Processing, calling attention to the unfortunate consequences of legally treating irradiated foods as food additives and of requiring separate long-term animal feeding studies for each irradiated food item. The review ended with the statement: "If the old item-by-item testing and petition requirements are still in force at the end of this decade, food irradiation will be a dead issue". (Ref. 1). We are approaching the end of this decade. It will be the purpose of the following presentation to sketch the recent developments in the area of wholesomeness testing and legal clearances, and to discuss how they have affected the outlook for food irradiation as a commercially applicable process.

The 1976 JECFI meeting

The attitude of national health authorities towards irradiated foods has been decisively influenced in the past by the pronouncements of

the FAO/IAEA/WHO Joint Expert Committee on Food Irradiation (JECFI). The principles of judging the wholesomeness of irradiated foods were first laid down by JECFI in 1964 (Ref. 2). At its 2nd meeting in 1969 the Committee pronounced "temporary acceptance" of irradiated potatoes (doses up to 15 krad) and of wheat and wheat products (up to 75 krad), while wholesomeness data on irradiated onions were found to be not satisfactory for an evaluation (Ref. 3). The "temporary" nature of the acceptances for potatoes and wheat meant that the available data were insufficient to fully establish safety and that the Committee required additional evidence within a specified period of time.

The outcome of the 3rd JECFI meeting (Ref. 4), in September of 1976, was indeed encouraging. Irradiated wheat (up to 100 krad) and potatoes (up to 15 krad) now received "unconditional acceptance". Three other items, papayas (up to 100 krad), strawberries (up to 300 krad) and chicken (up to 700 krad) were placed in the same category, while onions (up to 15 krad), rice (up to 100 krad) and fresh cod and redfish (up to 220 krad) received "provisional acceptance". This category means - as the previously used term "temporary acceptance" - that some additional testing is required. The Committee also considered irradiated mushrooms, finding evaluation of this product was not possible with the data available.

Perhaps even more important than the clearance of these irradiated foodstuffs was the Committee's expressly pronounced departure from the food additive concept: "Irradiation is a physical process for treating foods and as such it is comparable to the heating or freezing of foods for preservation ..... The Committee stressed that 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 ..... 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" (Ref. 4).

The JECFI report of 1976 also marks a turning point in the recognition of chemical studies as a basis for evaluating the wholesomeness of irradiated foods: "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 ..... 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 ....." (Ref. 4).

The positive attitude of JECFI towards irradiated foods and its active interest in finding a new, more reasonable basis for wholesomeness evaluation have already had a decisive impact on international developments in this field.

Codex Alimentarius Standards for Irradiated Foods

The most important tool for world-wide harmonization of food legislation is the Codex Alimentarius, a collection of uniformly structured, internationally recognized food standards. FAO and WHO founded the Codex Alimentarius Commission in 1962, and more than 100 nations have in the meantime become members. The Commission's main

aim is to facilitate international trade. Admission of irradiated foods to the Codex should greatly facilitate acceptance by national governments.

Immediately after the JECFI decisions of 1976 an ad hoc Working Group began preparations for establishing a) a General Standard on Irradiated Foods, and b) a Code of Practice for the Operation of Radiation Facilities used in the Treatment of Foods. The Codex Alimentarius Commission, at its 12th Session in April 1978, has accepted a) and b). The drafts now have to go to the member country governments for approval. It appears from the comments received by the Commission so far, that final approval will be possible within a reasonable period of time. The Draft General Standard specifically lists the 8 products given unconditional or provisional acceptance by JECFI and makes clear that no foods other than these shall be irradiated - pending further clearances by JECFI.

Joint FAO/IAEA/WHO Legal Panel on Irradiated Foods

The Codex Standards are primarily concerned with the quality of food commodities. They do not address other important legal problems which also require harmonization at the supranational level, e.g. licensing and registration of irradiation plants, enforcement of regulations, plant control by one country in another country. In order to achieve harmonization in this area, FAO, IAEA and WHO first convened a Consultation Group on the Legal Aspects of Food Irradiation in 1972. The outcome of this meeting was rather disappointing: "The consensus of the Consultation Group on the legal aspects of food irradiation was that it is premature to develop detailed legal guidance for member countries who are concerned with the irradiation of food, because there were still unanswered questions regarding the safety evaluation of irradiated food" (Ref. 5).

Another Consultation Group meeting was convened in November 1977 and its outlook was quite different: "Numerous countries desire that irradiated foods be made available to their people because of the obvious advantages of such foods" - and therefore "it is necessary that systems be developed and implemented by countries that assure that irradiated foods moving in international trade meet internationally acceptable standards of wholesomeness, good manufacturing practice, hygienic quality, and irradiation treatment control" (Ref. 6). At the request of IAEA, Professor A. Gérard of the International Research Center of Food Law in Brussels is preparing a model regulation on irradiated foods, based on the proposed Codex Alimentarius Standards and on the Report of the 1977 Consultation Group. This model regulation will ultimately be submitted to the Member States of IAEA for their consideration - and hopefully for incorporation into their national regulations.

The International Project in the Field of Food Irradiation

Much of the progress achieved at the 1976 JECFI meeting was due to the excellent preparatory work by the International Food Irradiation Project - IFIP for short. The Project was set up under an Agreement signed in Paris on 14th October 1970 for an initial period of five years and was subsequently extended for a further three years until December 1978. The Agreement provides that its signatories shall cooperate in the execution of an international program of wholesome-

ness studies on irradiated foods. Signatories were 19 countries (the number has in the meantime grown to 24 - see Table 1) and three international organizations: The Nuclear Energy Agency of the Organization for Economic Cooperation and Development (OECD/NEA), the International Atomic Energy Agency (IAEA) and the Food and Agriculture Organization of the United Nations (FAO). The World Health Organization (WHO) is associated with the work of the Project in an advisory capacity.

TABLE 1 Member Countries of the International Project in the Field of Food Irradiation

Austria	Italy+
Belgium	Japan
Brazil	Netherlands+
Denmark	Norway
Finland	Portugal
France+	South Africa+
Germany, Fed.Rep.+	Spain
Ghana	Sweden
Hungary+	Switzerland
India	Turkey
Iraq+	United Kingdom+
Israel	United States+

+Major contributor; represented on the Scientific Program Committee.

The Agreement lists the following objectives of the Project:

1) Wholesomeness testing of irradiated food;

2) Research on and investigations into the methodology of wholesomeness testing;

3) Dissemination of information resulting from the work undertaken and of other informations concerning wholesomeness testing of relevance to the program;

4) Assisting national and international authorities in their consideration of the acceptance of irradiated food.

The work on the first one of these objectives is mostly carried out under contract in various institutions in different parts of the world. The contracts are placed by the Project director on the basis of requests for bids and of tenders received. Work on the other three objectives is handled by the Project director and his small staff at the Host Center, i.e. the German Federal Research Center for Nutrition in Karlsruhe. Annual contributions by the signatories, ranging from 5000,-- to over 25000.- US $, provide a current cash budget of about 300 000.- $. With staff positions contributed by IAEA and the German Government, and various services and facilities provided by OECD/NEA and by the Host Center, the total budget amounts to about 500 000.- $.

The results of the work carried out under points 1) and 2) are presented to the signatories in the form of Technical Reports, of which some 50 issues have been turned out to date. The main activity under point 3) is the publication of Food Irradiation Information, whose issue No. 8 has recently been distributed, with a circulation of 2800 copies. Work on point 4), while entailing some correspondence with national authorities, has consisted mostly of giving assistance to FAO/IAEA and especially of compiling information for JECFI.

During the first years of the International Project's existence, animal feeding studies constituted the bulk of the research program. Completed contracts are listed in Table 2. In none of these studies were adverse effects of the irradiated diets observed. Feeding studies not yet completed are concerned with mangoes (WARF, Madison, Wisc., USA), various spices (Central Food Res. Institute, Budapest, Hungary), onions (IFREB, France), and dried dates (Life Science Research, U.K.). It goes without saying that in all of these studies, the groups of animals receiving the irradiated diet are compared with groups receiving the same but unirradiated diet and control groups receiving a standard laboratory diet.

Recently, the traditional animal feeding studies have been increasingly supplemented by work on in-vitro screening procedures, such as the Ames test and tissue culture studies. At the same time chemical studies have received growing attention. Reviews on radiation effects on major food components were written by a number of specialists in the field, under contract with IFIP. The resulting monograph has played an important role in the deliberations of the 1976 JECFI meeting; it is now available in book form (Ref. 7). As mentioned earlier, JECFI foresees that chemical studies will reduce considerably the extent to which toxicological testing of irradiated foods will be needed. Thus, not many more of the costly and time consuming feeding studies of the type listed in Table 2 will have to be carried out.

In my opinion, an important factor in IFIP's success with WHO and the Codex Alimentarius Commission was the decision by the project's sponsors to appoint internationally recognized toxicologists as Project directors. The first two directors, J.R. Hickman (1971 - 1973) and D.J. Clegg (1974 - 1975), were on leave of absence from the Canadian Department of Health and Welfare during their association with the Project. The present director, Dr. P.S. Elias, was Principal Medical Officer at the Department of Health and Social Security in London before joining the Project. All three are beyond suspicion of having a personal interest in the application of radiation processing and all three enjoy the respect and confidence of their peers in national and international health agencies. It may seem surprising that I mention this. Should not the decision on acceptance or non-acceptance of irradiated foods be based strictly on scientific evidence? Ideally it should. But anyone who has closely followed the struggles between scientists, administrators, politicians, industry representatives and consumer advocates on such issues as saccharin, cyclamate, DES etc. has recognized that there are often no easy yes or no answers when it comes to decisions on food safety.

When I mentioned the International Project in my talk at the First International Meeting on Radiation Processing (Ref. 1), I predicted that the signatories of IFIP would probably not be willing to continue the Project beyond the end of 1978 "unless its work will have brought

Table 2 Animal feeding studies completed by the International Project

Product Radiation dose	Percentage of product in diet	Nature of study	Contractor
wheat flour 75 krad ± 5 %	70 % (baked into biscuits)	one year feeding and reproduction studies in mice; teratogenicity and mutagenicity tests	Huntingdon Research Centre, Huntingdon, U.K.
	same	mutagenicity test in rats	Huntingdon Research Centre, Huntingdon, U.K.
	same	mutagenicity test in rats	Life Science Research, Stock, Essex U.K.
potatoes 8.5 - 15.0 krad	35 % (peeled, boiled)	life-time feeding and reproduction studies in rats; teratogenicity and mutagenicity tests	Huntingdon Research Centre, Huntingdon, U.K.
	same	life-time feeding and reproduction studies in mice	CREDO, Saint-Germain-sur-l'Arbresle, France
	-	alcoholic extract of potatoes administered by gavage to mice. Mutagenicity test	Bio-Research Laboratories Ltd., Pointe Claire, Que.,Canada
iced fresh fish cod-redfish mixture 1:1 175 - 340 krad	45 % (boiled)	life-time feeding and reproduction studies in mice; teratogenicity and mutagenicity tests	Huntingdon, Baltimore, USA
	same	life-time feeding and reproduction studies in rats; teratogenicity and mutagenicity tests	Industrial Bio-Test Labs. Inc., Northbrook, Ill., USA
mackerel 200 - 260 krad	same	90-day feeding and reproduction studies in rats; mutagenicity tests	BARC, Bombay, India

Table 2, continued

Product Radiation dose	Percentage of product in diet	Nature of study	Contractor
iced fresh fish European plaice 175 - 340 krad	45 % (boiled)	90-day feeding and reproduction studies in rats; mutagenicity tests	Inveresk Res. International, Edinburgh, U.K.
yellow-tailed flounder 175 - 340 krad	same	same	Cannon Labs. Inc., Reading, Pa., USA
rice 46 - 55 krad	60 % dry wt. (boiled)	one year feeding and reproduction studies; teratogenicity and mutagenicity tests	IFREB, Saint-Germain-sur-l'Arbresle, France

about a fundamental change in the evaluation of the wholesomeness of irradiated foods by that time". Fortunately, this fundamental change has occurred with JECFI's decisions of 1976, and I am happy to report that another 3-year extension of IFIP seems now to be assured.

Other developments and future outlook

So far I have only mentioned developments at the international level. This should not detract from the value of many national food irradiation programs. Details of recent work carried out in the United States will be presented by Dr. Brynjolfsson at this meeting, while Dr. de Zeeuw will speak on the progress of R + D work in other parts of the world. The proceedings of a Symposium on the chemistry of food irradiation have recently been published (Ref. 8).

At least in some countries the national health authorities have shown as much of a positive attitude towards irradiated foods as have JECFI and Codex Alimentarius Commission. The Dutch authorities have given clearance for unlimited quantities of irradiated chicken (up to 300 krad) and for limited quantities of shrimps and fish fillets (up to 100 krad) in 1976. South-Africa has given approval for unlimited irradiation of potatoes (up to 24 krad) and for limited quantities of mangoes and papayas (up to 125 krad), dried bananas (50 krad) and avocados (10 krad) in 1977. Clearance is also expected shortly for the unlimited sale of mangoes and papayas (150 krad) and strawberries (400 krad). France has authorized irradiation of unlimited quantities of onions, garlic and shallots (up to 15 krad) in 1977. Ton quantities of potatoes (10 krad), onions (8 krad) and mushrooms (200 krad) have been test marketed in Czechoslovakia, onions (5 krad) in Hungary,

potatoes (10 krad) in Chile. Considerable quantities of irradiated spices are being commercially used in the Netherlands and in Hungary. Recent evidence for the strong mutagenic effects of ethylene oxide is bound to lead to an increased utilization of radiation processing of spices and other dried commodities in these and other countries.

Another application of the radiation process which should be favored strongly for health reasons is the elimination of Salmonellae and other enteric bacterial pathogens from food and feed of animal origin. In view of the increasing incidence of disease caused by these organisms, Mossel has recently appealed to the public health authorities to permit the use of radiation processing for this purpose (Ref. 9).

As a matter of fact, the health ministries of most countries are still reluctant or even opposed to permitting irradiation of commodities which have not already been permitted by JECFI and sanctioned by Codex Alimentarius. World-wide future developments will therefore continue to depend on the decisions of these international bodies. Progress may be slow - but since the 1976 JECFI meeting I am optimistic that progress will continue. The next JECFI meeting is scheduled for 1980. Unless continued research shows some very unexpected results, the 1980 meeting will in all probability give unconditional acceptance to quite a number of irradiated foodstuffs - and possibly to the radiation processing of food in general, up to a certain dose level, perhaps 500 krad, perhaps higher than that. The results of chemical studies will play as important a role in these decisions as the results of animal feeding studies, of in vitro screening tests for mutagenicity, and of microbiological studies. This approach is clearly outlined in the report of the 1976 meeting: "The available data on the chemical structures of radiolytic products in food and the very low concentrations at which they occur suggest the general conclusion that the health hazard they might represent is negligible ... 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" (Ref. 4).

We should not overlook, however,that future progress in this field depends not only on the continued research work, which will provide the basis for legally permitting a broad spectrum of applications. The active interest of the food industry in making use of the opportunities offered by this process is also required. This interest has been more or less dormant, as most potential users felt it was too difficult to obtain the required permissions. Uncertainty about consumer reaction to irradiated foods also plays a role. I am confident that food industry interest will pick up rapidly with the announcement of Codex Alimentarius Standards for irradiated commodities. The well-oiled machinery of the food industry's advertising departments will sooner or later discover the opportunity of explaining to the consumer the advantages of irradiation over the use of ethylene oxide and the benefits of guaranteed freedom from Salmonellae.

Those who feel that progress in the field of food irradiation should be much faster must be reminded that man generally is quite conservative where his food is concerned - and perhaps that's a good thing. Nicolas Appert discovered his "principle" for conserving foods by heat-sterilization in the early 1790s. French Navy ships successfully tested his conserves in 1806. In the United States canned provisions were first offered in 1822 - but it took another 25 years before heat-sterilized foods were marketed in quantity. During the 19th century canned foods and refrigerated or frozen foods were vigorously attacked by many authors who foresaw grave consequences for public health. One example is the following statement from the Encyclopedia Larousse of 1872: "It is an unfortunate custom that all winter long, and especially during the time of carneval, ice cream is offered at all parties. This habit claims many victims, especially among women. Often fatal pleurisy and pneumonia or the always deadly consumption are the consequence". A British patent on the freezing of fish was issued to H. Benjamin in 1842; the first store houses for frozen food were built in England some 40 years later - but another 40 years went by before frozen products were marketed in the United States, and yet another 30 years in Central Europe. The advantages of storing fruits and vegetables in low oxygen-high carbon dioxide atmospheres were recognized by F. Kidd and C. West in England in 1929 - but it took some 30 years before "controlled atmosphere storage" was generally accepted by the fruit and vegetable trade. Food irradiation is not doing so badly by comparison.

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