Opinion of the Scientific Committee on Food on the irradiation of eight foodstuffs (expressed on 17.09.1998)

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Terms of Reference

The Committee is asked to evaluate the potential risks to public health arising from the treatment with ionizing radiation of 8 foodstuffs submitted by the authorities of a Member State in consistency with the Committee's opinion published in its 1986 Report on the irradiation of food(1).

Background

The Commission, in pursuance of its objectives to propose a Directive on the approximation of the laws of Member States concerning foods and food ingredients treated with ionizing radiation (framework directive) and a Directive on the establishment of a Community list of foods and food ingredients treated with ionizing radiation (implementing directive), has informed the Scientific Committee for Food, that on 27.10.1997 the Council adopted a Common Position 46/97(1) on the framework directive proposal and a Common Position 47/97(2) on the implementation directive proposal.

Article 4, paragraph 4, of the framework Directive requires that until the entry into force of the Directive which will complete the Community positive list of the implementing Directive, Member States may maintain existing authorisations concerning irradiated foods provided, amongst other requirements, that the treatment for the foodstuff concerned has been given a favourable opinion by the Scientific Committee for Food.

Following a request from a Member State, the Commission committed itself, that before the entry into force of the framework Directive, it will obtain the opinion of the Scientific Committee for Food on the products for which treatment with ionizing radiation is authorised in the Member State.

Introduction

In 1986 the Scientific Committee for Food expressed its views on the irradiation of food in its 18th series of reports (3), that on the basis of all then available evidence considered the Committee could recommend that in the context of an overall assessment of the wholesomeness of irradiated foods only those specific irradiation doses and food classes should be endorsed that were indicated as appropriate, not only from the strict toxicological point of view, but also from the chemical, microbiological, nutritional and technological standpoint. The Committee listed 8 food classes and the corresponding radiation doses submitted to it as acceptable from a public health standpoint. The Committee believed that the health significance of any changes which may take place in the listed foods at the indicated radiation doses is not different from the health significance of the changes which are induced by heat treatment. In principle the Committee saw no objection to considering an extension of the list to other applications provided that appropriate information is given for evaluation following the criteria considered in the SCF report of 1986.

In 1992 the Committee agreed that the treatment of Camembert cheeses manufactured from raw milk with gamma radiation at doses up to 2.5 kGy was acceptable from a health point of view and that therefore Camembert cheeses manufactured from raw milk could be added to the food classes listed for which irradiation was considered acceptable(4).

Evaluation of the dossiers submitted

General comments:

The Committee noted that all the dossiers submitted were of unsatisfactory quality, and did not comply with the criteria described in the 1986 report (1). They contained only outdated information on economic, technological and safety aspects but no recent information on the present situation with regard to the microbiological quality of the marketed products and their nutritional role in the present diet of the population of the EU. No recent safety studies have been submitted on the irradiated foodstuffs now requested nor do the submissions contain sufficient information on the present nutritional role for the European consumer in accordance with the criteria previously considered appropriate for evaluation by the Committee. Recent data are missing on the nutritional quality of the macro- and microconstituents of these irradiated foodstuffs. The description of the test methods are frequently inadequate to evaluate the validity of the reported results.

The Committee is aware that since publication of its 1986 Report WHO has issued a further review of the safety and nutritional adequacy of irradiated food in 1992(5) which concluded that the then available scientific literature and reports indicated that food irradiation was a thoroughly tested food technology. Safety studies had so far revealed no deleterious effects. In the opinion of WHO irradiation could help ensure a safe and more plentiful food supply by extending shelf life and by eradicating pests and pathogens. As long as good manufacturing practice controls were in place and implemented, irradiation of foods was considered safe and effective.

The Committee also noted, that in 1997, WHO issued a further report(6) on the conclusions of a WHO study group on high dose irradiation (above 10 kGy), which stated that food irradiated to any dose appropriate to achieve the intended technological objective was both safe to consume and nutritionally adequate. Hence no upper limit needed to be imposed for food irradiation. This WHO study group was also of the opinion, that the application of risk assessment in the currently accepted sense was not appropriate to the safety assessment of foods preserved by high dose irradiation and suggested, that in this context the concept of substantial equivalence may be more appropriate. It also suggested that compromising the organoleptic properties of a foodstuff by irradiation would automatically limit the irradiation dose which could be applied and would then act as a guide for orientating the technological application of food irradiation.

The Committee had no opportunity so far to consider fully the data base on which the WHO reports of 1992 and 1997 were based. It noted, however, that the opinions expressed in these WHO reports did not overrule the opinions expressed in its own report of 1986.

The Committee also wishes to reemphasize that in common with other food processes it is necessary to follow GMP and GHP and obligatory to follow HACCP principles when irradiation of foods is contemplated and carried out .

Individual evaluations:

1. Frogs' legs

The dossier (undated)(7) reports for 1985, that a considerable tonnage of frogs' legs has been imported into Europe to satisfy consumer demand, which could not be met by national production. The biggest hazard arises not from the consumption of cooked frogs' legs but from cross-infection of utensils and other foodstuffs at the place of culinary preparation through contact with thawed material befor *e* cooking. The most important hazard arises from contamination with *Salmonella* and other faecal organisms naturally present in frogs' legs, which cannot be removed entirely from the raw material before being deep-frozen for export from South Asian producing countries. As pasteurisation or chemical decontamination cannot be applied to thawed frogs' legs without either causing unacceptable organoleptic changes or leaving residues of chemicals which infringe food regulations, an alternative is the destruction of the potentially pathogenic flora of the deep-frozen material by irradiation with either -rays or accelerated electrons at an average dose of 5 kGy which has been shown to be effective for decontamination.

Some early experimental work has been submitted to show that at this dosage no nutritionally relevant radiolytic changes occur which are likely to cause a toxicological hazard. A microsomal reverse mutation test was negative on a sample of irradiated frogs' legs. The irradiation-induced losses of vitamins are nutritionally negligible as frogs' legs are unlikely to be a major dietary source for them. As the dosage of irradiation necessary is within the limits accepted as appropriate to the treatment of foodstuffs by WHO in 1981, there is no safety reason not to permit the decontamination of frozen frogs' legs by irradiation up to an average maximum dose of 5 kGy.

2. Shrimps

A dossier (undated)(8) states that most European countries have insufficient production of quick frozen, peeled and decapitated shrimps. They therefore satisfy their market requirements by importation predominantly from South Asia. These imported products, by virtue of locally existing conditions for collection, preparation, storage and exportation in the countries of origin do not always meet the microbiological standards set for European producing countries. Decontamination by a method which does not affect the organoleptic properties and quality of shrimps is required to avoid toxic infections of the consumer, as thawed products are often ingested without further heat treatment. Furthermore, it is essential that indirect contamination of the utensils and working areas and personnel handling imported goods contaminated with pathogens, such as *Salmonella,* be avoided to prevent any outbreaks of disease. Irradiation with doses of 5 kGy of the imported, quick frozen, packaged products has been shown to be an effective and technologically acceptable method of decontamination without any toxicological or nutritionally relevant risks, as this foodstuff is not a major source of macro- and micronutrients in the European diet.

3. Gum arabic

Gum arabic(9), being a plant product, produced only in tropical or subtropical areas of the world, tends to be contaminated by sand and wood particles by virtue of the method of its collection and preparation for shipping abroad. Storage at the harbours before shipping causes microbial contamination in the locally existing humid and hot climate. When it is to be used in pharmacy, the gum preparation must comply with the very strict microbiological specifications of the pharmacopoeias. There is experimental evidence that irradiation with doses of 3 kGy will reduce the microbiological contamination to the appropriate level for use in foodstuffs and pharmaceutical products as specified in AFNOR V 08-11-14. This dosage does not cause any significant changes in the chemical composition of the gum nor does it affect the toxicological and technological properties to any significant extent.

4. Casein/caseinates

Microbiological analysis of acid casein, rennet casein and caseinates(10), manufactured in dehydrated form under European conditions has shown, that despite good hygienic control the final products may still contain *Enterobacter sakazakii, Escherichia coli, Salmonella spp* and *Klebsiella pneumoniae*. To avoid cross-contamination of other food products not pasteurised as a final step before being sold to the general public, it is necessary to decontaminate these casein products by irradiation with a dose up to 6 kGy to avoid any incidence of toxic infection of the consumer. At that dosage, it has been shown that no significant chemical or physico-chemical changes occur in casein products which would constitute a health risk through ingestion of food products containing these products as ingredients.

5. Egg white

The submission (11) points out that in general the raw material may be contaminated. Treatment of egg white, whether liquid, frozen or dehydrated with doses up to 3 kGy assures a bacteriological quality as needed by the food industry and avoids secondary contamination of the decontaminated product during packaging, storage and transport. In accepting these products the Committee is relying on the general safety clearance of the wholesomeness of foods, irradiated up to doses of 10 kGy, as evaluated by the Joint FAO/IAEA/WHO Expert Committee on the wholesomeness of irradiated food in 1981 and the opinion expressed in the SCF report of 1986.

6. Cereal flakes

It has been demonstrated(12) that the cereal flakes and germ intended for use as ingredients in yoghurts made from whole milk cannot be freed from contaminating *Bacillus* spores by heat treatment. As some of the species are pathogenic for man and can produce toxins, they have to be eliminated from the cereal carrier before the cereal is added to the final ingredient mixture, which is subsequently pasteurised prior to its addition to the yoghurt preparation. An efficient method capable of destroying the spores of pathogenic *Bacillus* species is irradiation of the cereal ingredients with doses of 10 kGy before these are added to the final ingredient mixture. Irradiation is therefore acceptable in these special circumstances as an appropriate measure to protect the health of the consumer.

7. Rice flour

For rice flour(13) used in special foods for infants and other sensitive sections of the population, requiring food of special microbiological quality not achievable with normally available products, it may be necessary to use irradiation up to 4 kGy to achieve the desired microbiological purity of rice flour when used as an ingredient of baby foods during their manufacture, even though most food products involved are likely to be cooked before consumption. Starches irradiated up to 1 kGy have already received general clearance by the SCF in the 18th Report. The acceptability of irradiation of legume flour is based on the demonstration that all starches, irrespective of their plant origin, behave similarly when irradiated in respect of production of radiolysis products and physico-chemical behaviour and irradiation up to 4 kGy is acceptable.

8. Blood products

According to the submission, a considerable tonnage of blood(14) collected from animals killed in slaughterhouses is wasted because of its poor initial microbiological quality due to the method of collection and the poor hygiene conditions existing in the small slaughterhouses which at the time of the submission represented the majority of such premises in France. As blood, plasma and packed cell mass, when dehydrated, constitute a source of nutritious proteins used by the food industry for the production of human food, some method of decontamination is needed to reduce wastage of this protein and to reduce costly imports of other protein sources. In the absence of official microbiological standards, the industry has developed its own quality standards for fresh and dehydrated blood and its byproducts. These may be met by the use of irradiation of prepackaged dehydrated blood and its byproducts with doses of 5 kGy. The submission requests however treatment with an overall average dose of 10 kGy. Chemical analysis has not revealed any significant production of radiolytic products or loss in the nutritional quality of the proteins in the dehydrated products, but the use of blood as a source of bioavailable iron has not been taken into consideration. The irradiation dosage proposed for efficient decontamination is within the limits established as safe treatment for the wholesomeness of irradiated foods by the 1981 Joint FAO/WHO/IAEA Expert Committee(15) and the Scientific Committee on Food in its 1986 report. The microbiological quality of the irradiated products has been shown to be satisfactory by appropriate investigations of samples taken from the production line.

The application of doses of ionizing radiation that would be adequate to kill bacteria would not, of course, inactivate any contaminating viruses or prions.

Conclusions

The Committee evaluated eight irradiated products which have been marketed and used as food ingredients in at least one Member State for almost 20 years without reported problems.

The Committee, in its evaluation, took into account the general safety clearance of the wholesomeness of foods, irradiated up to doses of 10 kGy, as evaluated by the Joint FAO/IAEA/WHO Expert Committee in 1981. The Committee is aware that the effects of ionizing radiation on the major components of food, e.g.: proteins, carbohydrates, fats, minerals, and vitamins have been investigated thoroughly and published. These data formed the basis of the various reports on irradiated foods by international authoritative bodies and the Scientific Committee for Food.

In the light of the opinion expressed by the SCF in its 1986 report , the data now submitted and the recent developments regarding the assessment of the safety of irradiated foods by international authorities such as WHO, the Committee accepts that the irradiation of these eight food products does not pose a risk to public health. The Committee has no objections to add the submitted 8 food items to the already published list of acceptable irradiated food classes at the overall average radiation doses requested in the submissions for technological reasons.

The Committee reiterates the opinion expressed in its 1986 report that food irradiation technology must not be used to cover negligence in handling foodstuffs or to mask their unsuitability for use as food.

References

1. Council of the European Union. Common Position (EC) No. 46/97 adopted by the Council on 27 October 1997 with a view to adopting Directive 97/…./EC of the European Parliament and of the Council of ….. on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionizing radiation . Official Journal of the European Communities C 289, 22-12-97 p.36.

2. Council of the European Union. Common Position (EC) No. 47/97 adopted by the Council on 27 October 1997 with a view to adopting Directive 97/…./EC of the European Parliament and of the Council of ….. on the establishment of a Community list of foods and food ingredients treated with ionizing radiation. Official Journal of the European Communities C 289, 22-12-97, p.47.

3. SCF (1989) Report on the irradiation of food. Opinion given in March 1986. 18th Series of Reports of the Scientific Committee for Food, EUR 10840, European Commission, Luxembourg.

4. SCF (1994). Report on irradiated Camembert cheese. 32nd Series of Reports of the Scientific Committee for Food, EU Commission, Luxembourg.

5. WHO (1992) Review of the Safety and Nutritional Adequacy of Irradiated Food. WHO. Geneva.

6. WHO (1997). Conclusions of the Joint FAO/IAEA/WHO Study Group on High Dose Irradiation. Weekly Epidemiological Record. 16 Jan 98, 73 rd year.

7. FICUR, (undated). La pasteurisation par traitement ionisant des cuisses de grenouille congelées. Unpublished dossier submitted by the French Permanent Representation to the EU.

8. SSNCEPCS (1985). La pasteurisation des crevettes décortiqués ou étêtées, congelées ou surgelées par traitement au rayonnement gamma. Unpublished dossier submitted by the French Permanent Representation to the EU.

9. CNI (1983). Traitement par rayonnement ionisant de la gomme arabique. Unpublished dossier submitted by the French Permanent Representation to the EU.

10. Besnier Proteines,Conservatome SA (1986). La débactérisation des caséines et caseinates alimentaires par traitement au rayonnement gamma. Unpublished dossier submitted by the French Permanent Representation to the EU.

11. CECAR DELAUNAY, Conservatome SA (1984). La débactérisation des blanc d'oeuf liquide congelé ou deshydraté par traitement au rayonnement gamma. Unpublished dossier submitted by the French Permanent Representation to the EU.

12. IFF (undated). Fruit et cereales sur sucre pour yaourts, demande d'autorisation de traitement par irradiation. Unpublished dossier submitted by the French Permanent Representation to the EU.

13. GMFF (undated). Pasteurisation des farines de riz et de légumineuses par traitement ionisant. Unpublished dossier submitted by the French Permanent Representation to the EU.

14. Europroteine SA, Van Hees, Conservatome SA, (1984). Débactérisation de sang, plasma et cruor deshydratés par traitement au rayonnement gamma. Unpublished dossier submitted by the French Permanent Representation to the EU.

15. WHO (1981). Report of a Joint FAO/IAEA/WHO Expert Committee on the wholesomeness of irradiated food. WHO Technical Report Series No. 659. (1981).