

**COMMUNICATION FROM THE COMMISSION ON FOODS AND FOOD INGREDIENTS  
AUTHORISED FOR TREATMENT WITH IONISING RADIATION IN THE COMMUNITY**

(2001/C 241/03)

(Text with EEA relevance)

**Summary**

The food irradiation Directives 1999/2/EC and 1999/3/EC became applicable on 20 September 2000. Since 20 March 2001 all irradiated foods and food ingredients on the Community market must comply with the provisions of the Directives.

Only a single food category is listed on the EU wide positive list for irradiation treatment: 'dried aromatic herbs, spices and vegetable seasonings'. A requirement was introduced in Directive 1999/2/EC that the Commission should forward a proposal by 31 December 2000 to complete this Community positive list of foodstuffs authorised for irradiation, to be adopted through the co-decision procedure. Meanwhile, Member States can maintain existing national authorisations for irradiation of certain foodstuffs and can continue to apply existing national restrictions or bans in compliance with the Treaty.

Before preparing a proposal to the European Parliament and the Council for a Community positive list, the Commission services launched an open discussion with consumer organisations, industry organisations and other interested parties in autumn 2000 on the strategy for drawing up the positive list. A consultation paper outlining a strategy was launched, inviting for comments.

The comments revealed strong views, either in favour or against. The conditions for authorisation as laid down in the Directive, especially technological need, benefit to the consumers and no substitute for hygiene, are subject to a wide range of interpretations.

Given the complexity of this issue, the Commission considers that a broader debate is opportune at this stage.

## 1. INTRODUCTION

The food irradiation Directives 1999/2/EC and 1999/3/EC became applicable on 20 September 2000. Since 20 March 2001 all irradiated foods and food ingredients on the Community market must comply with the provisions of the Directives. However, a major question still remains open:

*Which foodstuffs should be allowed to be treated by ionising radiation in the whole Community?*

During the discussions leading to the adoption of the above-mentioned Directives, the Council and the European Parliament agreed only on a single food category to be authorised EU wide for irradiation treatment: 'dried aromatic herbs, spices and vegetable seasonings'. A requirement was introduced into Directive 1999/2/EC that the Commission should forward a proposal by 31 December 2000 to complete the *Community positive list of foodstuffs authorised for irradiation*, to be adopted through the co-decision procedure. Meanwhile, Member States can maintain existing national authorisations for irradiation of certain foodstuffs and can continue to apply existing national restrictions or bans in compliance with the Treaty.

Before submitting a proposal for a Community positive list to the Council and the European Parliament, the Commission services launched an open discussion with consumer organisations, industry organisations and other interested parties in autumn 2000 on the strategy for drawing up the positive list. A consultation paper outlining a strategy was launched, inviting for comments.

## 2. LEGAL BACKGROUND

Irradiated foods are regulated by:

- the **framework Directive** 1999/2/EC of the European Parliament and Council on the approximation of the laws of Member States concerning foods and food ingredients treated with ionising radiation, which covers general and technical aspects for carrying out the process, labelling of irradiated foods and conditions for authorising food irradiation.

— the **implementing Directive** 1993/3/EC of the European Parliament and Council on the establishment of a Community list of food and food ingredients authorised for treatment with ionising radiation. So far, this positive list contains only a single food category: 'dried aromatic herbs, spices and vegetable seasonings'.

The **framework Directive** requires or provides specifically that:

1. the treatment of a specific food item may only be authorised if
  - there is a reasonable technological need,
  - it presents no health hazard,
  - it is of benefit to the consumers,
  - it is not used as a substitute for hygiene and health practices or for good manufacturing or agricultural practice;
2. *any food irradiated* as such or containing *irradiated food ingredients* has to be *labelled*;
3. a favourable opinion of the *Scientific Committee on Food (SCF)* is needed to place a specific food item on the positive list;
4. the Commission shall forward a proposal by 31 December 2000 to complete the *Community positive list of foodstuffs authorised for irradiation*;
5. *national authorisations* of Member States which allow the irradiation of certain foods *can be maintained* until the completed positive list enters into force;
6. until a completed positive list enters into force, Member States may also *maintain restrictions or bans of irradiated foods*, in compliance with the Treaty;
7. Member States shall ensure that the *analytical methods* used to detect irradiated foods are *validated or standardised*;
8. foodstuffs, including those imported from third countries, may only be irradiated in *approved irradiation facilities*.

### 3. SCIENTIFIC BACKGROUND

On the basis of scientific studies, the Food and Agriculture Organisation, the International Atomic Energy Agency and the World Health Organisation (FAO/IAEA/WHO) concluded in 1980 that the irradiation of any food up to a maximum

dose of 10 kGy is considered to be safe. In fact, WHO encourages the use of the irradiation process in order to reduce the incidence of food borne diseases caused by micro-organisms.

Building upon the work of FAO/IAEA/WHO, the Scientific Committee on Food expressed opinions on irradiated foods in 1986, 1992 and 1998 and gave favourable opinions on irradiation of a number of foodstuffs (fruit, vegetables, cereals, starchy tubers, spices and condiments, fish, shellfish, fresh meats, poultry, camembert from raw milk, frog legs, gum arabic, casein/caseinates, egg white, cereal flakes, rice flour, blood products). The SCF emphasised that food irradiation must not be used to cover negligence in handling foodstuffs or to mask their unsuitability for use as food.

The FAO/IAEA/WHO published in 1999 the report of a study group on the wholesomeness of food irradiated with doses above 10 kGy. This study group concluded that food irradiated with any dose appropriate to achieve the intended technological objective is both safe to consume and nutritionally adequate.

Reliable detection methods are available for most of the foods which can be irradiated. These methods are validated and either already standardised by the European Committee for Standardisation (CEN) or in the process of standardisation. Thus, analytical control of whether irradiated foods are correctly labelled is possible in most cases. In the remaining cases, documentary control is an alternative.

### 4. APPLICATIONS

Although existing authorisations in certain Member States (Annex) allow the irradiation of a number of foods and food ingredients, only few are irradiated in practice. The percentage of a particular food which is treated by ionising radiation is in most cases small.

Irradiation is applied to reduce the number of micro-organisms in food ingredients intended for the production of industrially produced compound foodstuffs in order to extend the shelf life of the final products. This is especially the case for ingredients which are added to products for which the production process does not involve heating, such as yoghurt containing cereals flakes or white cheese containing herbs and spices. The same foods/food ingredients (flakes, dried fruits, etc.) may not need to be irradiated if they are intended as such directly for the final consumers, since the shelf life necessary for home-made products is much shorter and the normal microbial load does not induce health hazards as long as the ingredients are stored and handled by the consumers in a normal and reasonable manner.

Irradiation is also applied to certain foodstuffs which may be contaminated with *salmonella*, *listeria* or other harmful micro-organisms (e.g. chicken meat, eggs, cheese from raw milk) and which are intended for the direct use of the consumer. Some of these products, especially frog legs and shrimps, are often insufficiently heated during preparation to destroy these harmful micro-organisms or ingested without further heat treatment, and may give rise to cross-contamination.

#### 5. EXISTING COMMUNITY MEASURES TO ENSURE HYGIENE BY MEANS OTHER THAN FOOD IRRADIATION

Food hygiene rules are laid down in Council Directive 93/43/EEC on hygiene of foodstuffs and in a number of Council Directives governing the production and placing on the market of products of animal origin. These legislative requirements set a high level of consumer health protection for all foods. These requirements are commonly accepted to be essential to ensure safe food, also at international level through *Codex Alimentarius*. Experience has shown that a strict respect of these rules is efficient without there being a need to rely on other steps such as a final decontamination of food for reasons of food safety. However, experience has also shown that certain foods, due to limits inherent to the production process, may present a residual microbiological risk. In these circumstances, there may be no other option than to allow reduction of the microbial load in the final product or to prohibit the food. This is recognised in the Commission proposals on food hygiene, where additional decontamination steps are foreseen for certain foods presenting a particular high risk profile. Where such steps are applied, it is clearly stated that decontamination is without prejudice to the correct implementation of all food hygiene requirements and that decontamination can only be applied in accordance with conditions of use to be defined by the relevant scientific committee. This aims to avoid improper and inappropriate use of decontamination.

#### 6. CONSULTATION OF CONSUMER ORGANISATIONS, INDUSTRY ORGANISATIONS AND OTHER INTERESTED PARTIES ON A STRATEGY TO DRAW UP THE COMMUNITY WIDE POSITIVE LIST

On 27 September 2000, the Commission services sent a consultation paper on food irradiation to European consumer organisations and European industry associations, addressing in particular the question of which foodstuffs should be authorised for irradiation treatment in the European Community. The paper was also placed on the web site of this Directorate-General to give other interested parties the possibility to comment ([http://europa.eu.int/comm/food/fs/sfp/fi\\_index\\_en.html](http://europa.eu.int/comm/food/fs/sfp/fi_index_en.html)). The paper proposed a strategy for drawing

up the Community-wide positive list and can be summarised as follows:

- the framework Directive requires that there must be a benefit for the consumer. It was argued that a benefit for the consumer could be assumed if possible health hazards are reduced or the shelf life of the products is prolonged. The latter, besides being more convenient, could also have the potential to decrease the price of products;
- the framework Directive requires that there must be a reasonable technological need. It was argued that some products are irradiated in substantial amounts in at least one Member State which could be seen as an indicator of technological need, at least in that Member State;
- the framework Directive requires that irradiation should not be used to substitute good hygiene practices. It was argued that this could be achieved by restricting the authorisations for irradiation to those products for which an unacceptable risk for the health of consumers is associated with the untreated products and for which suitable alternatives to decontamination may be lacking.

The paper indicated that the following products could be included in the positive list when applying this strategy:

- deep frozen aromatic herbs, dried fruit, cereal flakes and germs. These food ingredients are mainly used in compound foodstuffs, such as milk-based products, which are not heated during processing;
- offal of chicken, egg white and gum arabic (additive). These food ingredients may be contaminated and need to be decontaminated to reduce health hazards and to extend shelf life;
- frog legs and peeled shrimps may not meet appropriate microbiological standards by virtue of the methods of collection and preparation. These products are intended for the direct use of the final consumer and decontamination increases the safety of these products.

Based on the same reasoning, the following products might not be included in the positive list although the SCF gave a favourable opinion as to their safety:

- fresh fruits and vegetables, cereals, starchy tubers (potatoes), fish, camembert from raw milk, casein, rice flour and blood products. These products are not irradiated in Member States or only in very small amounts, whenever this is allowed. This can be interpreted as demonstrating insufficient technological need;

— fresh red meat and poultry meat<sup>(1)</sup>. In order not to discourage good hygiene practices, priority should be given to measures which improve the hygiene conditions during the production of these foods rather than the subsequent decontamination of the foods by irradiation.

## 7. RESULTS OF THE CONSULTATION

A total of 33 comments were received from consumer and industry organisations, the US Government, the FAO/WHO International Consultative Group on Food Irradiation, companies and individual persons ([http://europa.eu.int/comm/food/fs/sfp/fi\\_index\\_en.html](http://europa.eu.int/comm/food/fs/sfp/fi_index_en.html)).

### 7.1. Opinions of consumer organisations

The consumer organisations expressed very critical views. They argue that food irradiation is not necessary if good hygiene practices are applied. A 'reasonable technological need' is not defined by the fact that a product is already irradiated in substantial amounts in one Member State. There is the danger that food irradiation might be used as a substitute for good hygiene practices. The benefit of irradiated foods for the consumer has been questioned since extended shelf life of food products would not be in the interest of consumers, but in the interest of producers. Priority should focus on improving food production at primary level, in storage and in manufacturing processes.

### 7.2. Opinions of industry associations and other parties

The views of industry associations and other parties which sent comments are more diverse.

#### *Comments in favour of food irradiation*

The irradiation industry is clearly in favour of authorising all products for which the SCF has expressed a favourable opinion. The FAO/WHO International Consultative Group on Food Irradiation which has the mandate to evaluate and advise on the global activities of food irradiation, the United States Government and some research associations/institutes expressed similar opinions.

<sup>(1)</sup> Since the publication of the Consultation paper, mechanically recovered meat from bovine, ovine and caprine animals has been banned by Commission Decision 2001/233/EC of 14 March 2001 (OJ L 84, 23.3.2001, p. 59).

The main arguments are that according to the scientific community, food irradiation is safe and contributes to increasing consumer protection by destroying harmful organisms in food (red meat, poultry, etc.). The technique, if applied using good manufacturing practice, will not substitute for good hygiene practices. There is no justified reason to prohibit/restrict the application of food irradiation in the EU. The global trade liberalisation through the WTO requires that national authorities base their regulations on Codex Standards, sound science and proper risk analysis. Although it is acknowledged that improvement of hygiene should have first priority, the failure of hygiene measures to avoid the presence of harmful micro-organisms, especially in red meat and chicken, is stressed. Many countries have authorised irradiation of a number of food products, including red meat and poultry. Also, food irradiation is the best substitute for fumigation of fruit and vegetable in order to get rid of pests. Food irradiation has in general the potential to substitute for harmful chemicals. The current low treatment volumes do not indicate that there is 'no technological need' since social, environmental and economic factors have an overwhelming power over technological need, scientific endorsement and consumer benefit.

#### *Comments against food irradiation*

The food producing industry, in particular the producers and traders of meat products, dried fruit/vegetables, potatoes, milk products, cereal flakes and tea are not in favour of the inclusion of their products into the list. Current procedures to ensure good hygiene are considered to be sufficient (no technological need). HACCP systems should get first priority to improve hygiene. The authorisation would affect negatively the image of these products. The irradiation of fresh fruit and vegetables to inhibit sprouting and delay ripening might mislead consumers with regard to age and freshness of the products. The Confederation of the Food and Drink Industries of the EU (CIAA) is of the opinion that it is unlikely that food manufacturers will make use of food irradiation until consumer confidence in the technology is secured. CIAA believes that the negative image of food irradiation will be further reinforced if all the products for which the SCF expressed a favourable opinion were to be authorised for irradiation. Food irradiation could be used to substitute good hygiene practices and could lead to unfair trade practices. Any extension of the list should be accompanied by an information campaign to reassure consumers about the safety of the technology. The issue of extending the list should be postponed.

### 7.3. Summary of the results of the consultation

The conditions for authorisation as laid down in the Community legislation, especially that irradiation should not be a substitute for hygiene practices, that there must be a technological need and a benefit to the consumers, are interpreted in both ways either in favour of the inclusion of certain products or against.

The consumer organisations are either totally against additional authorisations or would like to see this technique applied as restrictively as possible. On the contrary, the irradiation industry, backed by the FAO/WHO Consultative Group, the United States Government and some research associations/institutes, claims that there is no scientific justification not to include all the products for which the SCF expressed a favourable opinion.

Interestingly, most of the food production and trade sectors are against the inclusion of their products into the positive list, mainly because they expect negative consumer reactions. There are also indications that the use of irradiated herbs and spices by the food-producing industry is declining due to the strict labelling requirements of the EU legislation and the increased control of correct labelling by Member State authorities. Only some specific sectors are in favour of authorising irradiation of their products, like shrimps, frog legs, crayfish and blood products.

## 8. OPTIONS FOR DRAWING UP THE PROPOSAL FOR A POSITIVE LIST

### Option 1

The food-producing industry is mainly against the inclusion of the food ingredients proposed in the consultation paper. This can be interpreted as 'no technological need'. The only products for which a clear need has been identified in the consultation are peeled shrimps and frog legs, which could be proposed for authorisation. The conditions in subtropical and tropical countries from which these products are imported are such that a certain microbial load cannot be avoided.

### Option 2

The food-producing industry is against the inclusion of food ingredients mostly because they are concerned about negative consumer reactions. The Commission has the responsibility to draft legislation which is scientifically justified and which increases the safety of food products. There is no doubt that this technology can improve the safety of certain products. Thus, the Commission could propose the products which are irradiated in some Member States in substantial amounts, namely deep frozen aromatic herbs, dried fruit, cereal flakes and germs, chicken offal, egg white, gum arabic (additive), peeled shrimps and frog legs.

### Option 3

Having regard to the divergence of views resulting from the consultation process, a third option might be to regard the current list as complete.

## CONCLUSIONS

Food irradiation arises interest from all parts of society although the actual application of this technique is rather limited. Even in countries — inside and outside the European Community — which allow the irradiation of a lot of different foodstuffs, the treated volumes are in most cases very small in comparison to the non-treated ones. An exception are frog legs which are always irradiated, e.g. in France, and to a certain extent shrimps.

The scientific community, including the Scientific Committee on Food, is of the opinion that food irradiation is safe for the health of the consumers if it is applied under good manufacturing practice. The Community legislation requires labelling of all irradiated foods, even those which contain only a small portion of irradiated products. Enough reliable detection methods are available for the food control authorities to enforce correct labelling.

Directive 1999/2/EC lays down the conditions for authorising foods for irradiation. The conditions are that irradiated foods present no health hazard, that it is not used as a substitute for hygiene practices, that there is a reasonable technological need and that it is of benefit to the consumers. The consultation showed that the latter three conditions can be interpreted in both ways either in favour of the inclusion of certain products or against. The Commission, being aware of the debatable nature of the conditions, had suggested a compromise solution in the consultation paper, focussing on the few products which are already irradiated in substantial amounts in at least one Member State and for which hygiene problems exist. The comments revealed that any proposal on a Community positive list would be susceptible to criticism from one or the other side, and most probably from both.

Given the complexity of this issue, the Commission considers that a broader debate with all, interested parties is opportune before putting forward the proposal for the completion of the positive list.

## ANNEX

**LIST OF MEMBER STATES' AUTHORISATIONS OF FOOD AND FOOD INGREDIENTS WHICH MAY BE TREATED WITH IONISING RADIATION**

(According to Article 4(6) of Directive 1999/2/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation)

| Product  | Authorised at the given maximum dose [kGy] |       |      |    |     |
|--|--|-------|------|----|-----|
|  | BE   | FR    | IT   | NL | UK  |
| Deep frozen aromatic herbs   |  | 10    |      |    |     |
| Potatoes   | 0,15                                       |       | 0,15 |    | 0,2 |
| Yams   |  |       |      |    | 0,2 |
| Onions   | 0,15                                       | 0,075 | 0,15 |    | 0,2 |
| Garlic   | 0,15                                       | 0,075 | 0,15 |    | 0,2 |
| Shallots   | 0,15                                       | 0,075 |      |    | 0,2 |
| Vegetables, including pulses   |  |       |      |    | 1   |
| Pulses   |  |       |      | 1  |     |
| Fruit (including fungi, tomato, rhubarb)   |  |       |      |    | 2   |
| Dried vegetables and fruits  |  | 1     |      | 1  |     |
| Cereals  |  |       |      |    | 1   |
| Flakes and germs of cereals for milk products                                      |  | 10    |      |    |     |
| Flakes from cereals  |  |       |      | 1  |     |
| Rice flour   |  | 4     |      |    |     |
| Gum arabic   |  | 3     |      | 3  |     |
| Chicken meat   |  |       |      | 7  |     |
| Poultry  |  | 5     |      |    |     |
| Poultry (domestic fowls, geese, ducks, guinea fowls, pigeons, quails, and turkeys) |  |       |      |    | 7   |
| Mechanically recovered chicken meat  |  | 5     |      |    |     |
| Offal of chicken   |  | 5     |      |    |     |
| Frozen frog legs   | 5  | 5     |      | 5  |     |
| Dehydrated blood, plasma, coagulates   |  | 10    |      |    |     |
| Fish and shellfish (including eels, crustaceans and molluscs)                      |  |       |      |    | 3   |
| Frozen peeled or decapitated shrimps   | 5  | 5     |      |    |     |
| Shrimps  |  |       |      | 3  |     |
| Egg white  |  | 3     |      | 3  |     |
| Casein, caseinates   |  | 6     |      |    |     |