



October 2, 2017

Feedback from the International Irradiation Association on the Evaluation and Fitness Check Roadmap regarding the European Directives on irradiation of food.

Europe was a leader in food irradiation research and commercial applications until the late 1990's. As the yearly reports of the European Commission (EC) show, the quantities of food being irradiated in the EU have declined substantially since the European Directives on irradiation of food and food ingredients, 1999/2/EC and 1999/3/EC entered into force. In America (USA, Canada and Mexico), Africa (mainly South Africa), Asia-Pacific (especially in China, but also Australia, New Zealand, India, Vietnam and Thailand) and the Russian Federation the quantities of irradiated foods on sale are increasing. A dozen countries have deployed the technology to meet the sanitary and phytosanitary requirements of their trading partners. Experience outside and even inside the EU has demonstrated that many consumers are willing to buy irradiated food when they are available, *i.e.* when they are given an opportunity. The complexities of Directives 1999/2/EC and 1999/3/EC and the non-harmonized approach across the EU are in stark contrast to the situation for irradiated non-food commodities. For irradiated non-food items there is a diverse and buoyant market in the European Community. The legislation controlling the market in non-food products has not proven to be a barrier to the application of the irradiation process. The process is trusted to add safety for essential non-food items that include medical devices, drugs, pharmaceutical and cosmetic ingredients, packaging or pet toys, to improve the properties of industrial wires and cables, automotive parts, electronic components and plastic films, or to preserve historical artifacts.

Reputable national and international organizations including the World Health Organization, the Food and Agriculture Organization of the United Nations, and the International Atomic Energy Agency consider that irradiated food pose no toxicological, microbiological or nutritional hazard. Science and decades of experience have proven that food irradiation is safe. However, the European Directives on irradiation of food reflect a lack of confidence in the process and are much more restrictive than the Codex Alimentarius *General Standard for Irradiated Foods* (CODEX STAN 106-1983, REV.1-2003) that served as the model regulation in several countries.

The harmonized list of food products that can be irradiated across the EU has never been extended beyond dried aromatic herbs, spices and vegetable seasonings even though there have been several requests to extend this list. In seven Member States the national authorizations issued prior to 1999 for many irradiated foods are still in force. Therefore foods that may be legally irradiated in some Member States are banned in other Member States. This appears contrary to the spirit and principles established under the Treaty of Rome for a common market. The Association's view is that it is not possible to be both in compliance with the Treaty and at the same time have a national restriction on the sale of a product that is safe and freely permitted in another member state of the European Union.

Despite their stated aim of adopting measures aimed at the smooth operation of the internal market 1999/2/EC and 1999/3/EC are in practice hindering the free movement of foodstuffs and creating conditions of unequal competition. The European Directives created a barrier to the trade of irradiated food within the EU and with third countries and have had a global negative effect on the expansion of a beneficial technology. They hamper the diffusion of innovative European technologies such as new compact and cost efficient recirculation electron beam units and the use of lamps producing low energy electron beams or X rays that can be used to irradiate food.



The European Directives create a barrier to the international trade of irradiated food. This barrier is keenly felt in some developing countries that are seeking to expand their trade with the EU. Most of all, the application of 1999/2/EC and 1999/3/EC have deprived European consumers of the benefits of the process: improved microbiological safety, improved biosecurity (protection against harmful organisms and invasive species), reduced wastage, and replacement of several pesticides and preservatives. Recent cases of meat recalls, food poisoning outbreaks and propagation of harmful organisms show the need to use all possible tools to ensure consumers' safety and irradiation should be one of them.

The Directive 1999/2/EC uses the concept of "maximum overall average dose", a concept that was useful in its time to assess the safety of irradiated foods. In commercial practice, quantities that can be measured directly are used to control the irradiation process the minimum processing time or minimum dose at which the desired effect is obtained and the maximum processing time or dose above which the quality of the product is impaired. These values are defined by testing the irradiated food items. They are self-regulating by nature and do not need to be stated in regulations. The Directives set a maximum value of 10 kGy that was conservatively suggested in 1980 by the Joint WHO-FAO-IAEA Committee on the Safety of Irradiated Food [1]. In 1999, this upper limit of 10 kGy was considered no longer necessary [2] and the 2003 revision of the Codex Alimentarius *General Standard for Irradiated Foods* no longer mentions it.

The Directives have given irradiation a unique particular status among physical food processes that no scientific reason justifies. In particular, the mandatory mention of irradiation for very minor ingredients amounts to a warning. Paradoxically, chemical processes that leave potentially harmful residues do not have to be indicated. Because they found this particular requirement unacceptable, European manufacturers and traders of spices and herbs that used irradiation before 1999 now recourse to cumbersome heat processes that result in products of inferior microbial and sensory quality in comparison to their irradiated counterparts.

The International Irradiation Association, represents nearly 80 organizations engaged in the provision of irradiation services and the supply of irradiation equipment, commercial users of irradiation processing, as well as a dozen research and technological institutes across the world. About a third of the members are based in the EU.

The Association calls for a complete revision of the European Directives on irradiation of food and requests the European Commission:

- To base the revisions on scientific and technological information;
- To put the Directives in conformity with the Codex Alimentarius *General Standard for Irradiated Foods* (CODEX STAN 106-1983, REV.1-2003) and in particular:
 - To abandon the positive list system and permit irradiation of any food, subject to compliance with Good Manufacturing Practice;
 - To abandon the concept of maximum overall average dose;
 - To remove the upper limit of 10 kGy for food treatments.
- To remove the obligation to mention irradiation for ingredients that are a minor component of the food.



References:

(1) Wholesomeness of irradiated food

Report of a Joint FAO/IAEA/WHO Expert Committee

World Health Organisation Technical Report Series 659, Geneva 1981

http://apps.who.int/iris/bitstream/10665/41508/1/WHO_TRS_659.pdf

(2) High-dose irradiation: wholesomeness of food irradiated with doses above 10 kGy

Report of a Joint FAO/IAEA/WHO Study Group

World Health Organisation Technical Report Series 890, Geneva 1999

[http://apps.who.int/iris/bitstream/10665/42203/1/WHO_TRS_890_\(part1\).pdf?ua=1](http://apps.who.int/iris/bitstream/10665/42203/1/WHO_TRS_890_(part1).pdf?ua=1)