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Viewpoint

ISO 14470:2011 and EU legislative background on food irradiation technology: The Italian attitude

Aldo Parlato[a,*], Marcella Giacomarra[b], Antonino Galati[c] and Maria Crescimanno[c]

[a]Department of Energy, Information Engineering and Mathematical Models, University of Palermo, Viale delle Scienze, Ed. 9, 90128 Palermo, Sicily, Italy (Tel.: +39 09123897359; e-mails: aldoparlato@gmail.com; aldo.parlato@unipa.it)

[b]Department of Economic, Financial and Statistical Sciences, University of Palermo, Viale delle Scienze, Ed. 2, 90128 Palermo, Sicily, Italy (e-mail: marcella.giacomarra@unipa.it)

[c]Department of Agricultural and Forest Sciences, University of Palermo, Viale delle Scienze, Ed. 4, 90128 Palermo, Sicily, Italy (e-mail: antonino.galati@unipa.it) (e-mail: maria.crescimanno@unipa.it)

Our work aim is to produce an overview of food irradiation technology at European Union level, with a focus on the Italian context, by specifying the legislative background, detection methods and labelling obligations. We highlight how consumers are too often misinformed about this technology and its benefits. For this purpose, a series of tools aimed at improving the amount of information have been proposed, allowing the consumer to make a free choice about whether or not to buy irradiated food based on the correct information received, independent from socio-economic factors. Finally, we show the common effort at EU and International level, represented by the **ISO 14470:2011** quality standard.

Introduction

Food irradiation is physical treatment of food with high-energy ionizing radiation, that produces the same benefits as when it is processed by heat, refrigeration, freezing or treated with chemicals. The process is useful to inactive micro-organisms, viruses, bacteria or insects, preventing the germination and sprouting of potatoes, onions and garlic, slowing down ripening and ageing of fruit and vegetables, prolonging the shelf life, reducing pathogens in food and thus helping to ensure the protection of consumers' health. Its use is limited but authorized in many countries, and formally approved in 55 countries around the world. A latest review study on the food irradiation status showed a wide spread diffusion of this technique across the world. According to the data in year 2010, about 285,223 tons of food products were irradiated in Asia, 103,000 tons in the United States, and 9264 tons in the European Union. A comparison with the data in 2005 revealed an increase (Kume & Todoriki, 2013). In the EU the use of this technology is recommended for foods frequently contaminated and/or infested with organisms which are harmful to public health, considering that such contamination and/or infestation can no longer be treated with fumigants such as ethylene oxide because of the toxic potential of their residues, therefore, supporting the use of ionizing radiation as an effective means of replacing the previously mentioned substances. Although properly irradiated food is safe and wholesome, consumers are not yet well informed about the technology, and they are currently unable to make their own free choice between irradiated and non-irradiated food. This review aims to present the European legal regulations that has regulated the matter since 1999, with a focus on the situation in Italy. Consumer acceptance of the technology has been reviewed and considered, together with an introduction to the last ISO norm and International commitments.

Food irradiation treatment according to the European Union legislation

At European level, the framework Directive 1999/2/EC of the European Parliament and of the Council of 22 February

* Corresponding author.

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1999, regulates the aspects concerning foods and food ingredients treated by ionizing radiation. It became applicable on the 20th September 2000 and since 20th March 2001 all irradiated foods on the EU market have to comply with its requirements (art. 15). According to art. 7, Member States shall forward the results of checks carried out at the irradiation facilities to the Commission every year, including the categories and quantities of products treated and the dose administered, together with the results of checks carried out at the product marketing stage, as well as the methods used to detect irradiated foods (see Section 2). Moreover, food is only allowed to be irradiated in *approved irradiation facilities* (art. 3). To obtain the approval, facilities have to comply with the requirements of the Joint FAO/WHO Codex Alimentarius Commission Recommended International Code of Practice for the operation of irradiation facilities used for the treatment of foods (FAO/WHO/CAC, Vol. XV – 1st ed.), and any supplementary requirements which may be adopted in accordance with the procedure laid down in art. 12 of the Directive.

A second Directive (1999/3/EC), the Implementing Directive, was issued immediately after the first one, establishing a Community list of foods and food ingredients that can be treated with ionizing radiation. Initially, the EU identifies dried aromatic herbs, spices and vegetable seasoning (such as basil, bird pepper, black pepper, cinnamon, etc.) as food frequently contaminated and/or infested with organisms, which are harmful to public health and for this purpose such contamination and/or infestation can no longer be treated with fumigants such as ethylene oxide because of the toxic potential of their residues. The use of ionizing radiation is presented as an effective means of replacing the substances mentioned above.

Since 2001, the EU irradiation legislative framework came into force, and its effects initiated new legislative acts and accreditation all over the world. According to art. 3 (Directive 1999/2/EC), through the Decision 2002/840/EC, the EU started the approval of facilities, located in third countries, for the irradiation of foods: the first three were located in Hungary and South Africa. Between 2002 and 2012, the Decision will be subject to three amendments: in 2004 Hungary became an EU Member State and was moved from the list produced with the 2002/840/EC to the list approved with Directive 1999/2/EC, while Switzerland and Turkey asked for the approval of their facilities (2004/691/EC). In 2007, a Thai facility was approved (2007/802/EC); in 2010, there was the inclusion of three new Indian facilities (2010/172/EU); the last modification was done in 2012, because the Thai facility changed its official name (2012/277/EU).

Apart from the countries cited above, other extra EU countries still treat food with ionizing irradiation (Food Irradiation Treatment Facilities Database – FITF) without asking for EU approval (for example Republic of Korea, China and Vietnam), meaning that food irradiated in those facilities cannot be commercialized inside the EU market but only abroad. The imposed EU limit does not mean that a facility that irradiates without the EU approval is irradiating illegally. As for other economic issues, the EU needs harmonized framework that allows its single market to work well and under standardized setting, the same regulatory treatment was applied to the irradiation technology. From a commercial point of view we can hazard saying that, maybe, the need of EU approval could reduce the import in some EU countries of irradiated foods treated in third countries without approved facilities. This is a matter of EU concern giving that irradiated food may only be imported from a third country when it has been irradiated in an approved facility. Nowadays, a lot of foods (illegally irradiated and/or not correctly labelled) cross the EU National borders on a daily basis and enter the internal market, without consumer awareness or appropriate scrupulous controls at border levels, from competent National Authorities. According to our study, this aspect represents an input to go further in the subject, not only to raise awareness among consumers, but also to promote more thorough checks at national borders, with the main purpose of limiting the trade of illegally irradiated foods.

In Italy, the implementation of the EU Directives 1999/2/CE and 1999/3/CE occurred through the Legislative Decree No. 94 of January 30, 2001. So starting from March 20, 2001, irradiated food on the Italian markets must comply with the previous mentioned Directives. Member States are requested to implement methods to detect treatment with ionizing radiation at the product marketing stage. For this purpose, the Italian Decree mainly relies on the Istituto Superiore di Sanità – ISS (Italian National Institute for Health) for the duty to select and perform detection methods to be applied on a regional scale (Boniglia, Onori, & Sapora, 2003, 2004): each region can perform checks at territorial level, even if the final evaluation, must be sent to the ISS in case of doubts. Local Sanitary Laboratories usually work together with Local Branches of Zooprophylactic Institutes (IZS) and other Public Laboratories (Chiaravalle, Mangiacotti, & Marchesani, 2011) at regional level in terms of implementing these controls.

According to the EU Regulation n. 882/2004 (art. 33), the Ministry of Health, as a Competent Authority, identifies Laboratori Nazionali di Riferimento – LNR (National Reference Laboratories) with the aim to carry out analysis of food and feed quality (in conjunction with EU Reference Laboratory – EURL). The identification of these LNR takes into account the actual presence of National Reference Centres (CRN). In case of absence of related CRN, the selection of the other LNR takes into account the experience gained in the field from Official Laboratories. Those previously mentioned generally coincide with an IZS or with the Italian National Institute for Health. In the specific case of irradiated food controls, a CRN is currently operative in Italy, specialized in radioactivity (CRN per la ricerca della radioattività nel settore zootecnico – veterinario IZS Puglia e Basilicata – Sede Centrale Foggia) that, in 2010 and 2011, performed controls from abroad free of charge at the marketing stage in a series of Italian regions that offered the service (Lazio, Campania, Liguria, Emilia Romagna, Umbria, Piemonte, Trentino Alto Adige, Marche and Puglia). All the information, tables, sample quantities, etc. are finally reported on the Integrated Plan, drawn up on a yearly basis, by the Ministry of Health in collaboration with ISS, regional bodies engaged in sanitary tasks, Port Authorities, Policy, Customs Agency, and Inland revenue corps. The information concerning the checks at marketing stage contained in National Plans are the same as Italy sends to the EU Commission on a yearly basis (Chiaravalle *et al.*, 2011; Directive 1999/2/EC).

Detection methods: international and European efforts towards a standardization system

There are currently no easy tools of detection methods available at international entry points to determine whether an imported item of food has received the foreseen irradiation doses. We can only rely on shipping documents and labelling obligations, if present. Consequently, such assurance, needs to be based on the dosimetry and process control records generated at the entry facility, which should be in accordance with international standards. This requires bilateral agreements to allow for such inspection and the application of mutually accepted standards. Formal accreditation of the standards of laboratories and quality control systems operating in an irradiation facility results in mutual equivalence and recognition of dose measurements, contributing to international trade in radiation processed products, whilst removing trade barriers. Several national regulations currently allow for the importation of irradiated foods provided that the requirements of the importing country have been met at the facility abroad (IAEA, 2002a, 2002b).

To validate the correctness of irradiated food labelling, analytical techniques were needed. Ideally, such techniques had to be simple, accurate, easy to perform, quick and not expensive, at the same time allowing the standard regulatory procedures and thereby helping assure consumers that processors and distributors are adhering to government control procedures. This sentiment was clearly expressed in the International Document adopted in 1988 by the FAO/IAEA/ITC/WHO *International Conference on Acceptance, Control of and Trade in Irradiated Food* (Geneva, Switzerland). The Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture took the initiative to propose an international Coordinated Research Project on "*Analytical Detection Methods for Irradiation Treatment of Food – ADMIT*" between 1989 and 1994, joined by the European Commission's Bureau of Chemical References (BCR), through the coordination of similar research programmes within the EU. The outcome of these two parallel research programmes as well as those from elsewhere was reported at an international symposium titled "*General Principles for the Development of Detection Methods*", held in Belfast, Northern Ireland, 20–24 June 1994 (McMurray, Stewart, Gray, & Pearce, 1996). The Belfast ADMIT Meeting decided that the measured test parameter should be able to clearly identify whether food has been irradiated throughout the entire storage life of the food product, without requiring a sample of the non-irradiated food for comparison from the particular batch tested. Moreover, it would be optimal if the test could also fulfil practical criteria, such as simplicity, low cost, high speed, applicability to a wide range of foodstuffs, and resistance to falsifying its results. Finally, the test should be capable of easy standardization and cross calibration (Delincée, 1998).

In 1993, the European Commission gave a mandate to the European Committee for Standardization (CEN) to standardize irradiated food detection methods. These EU methods were adopted by the Codex Alimentarius Commission as General Methods and referred to in the Codex General Standard for Irradiated Foods (Codex, 2003).

The list below shows EU detection methods (Table 1):

According to Table 1, it is important to highlight a first classification according to whether chemical, physical or

Table 1. List of the European standardized detection methods.

Method (classification):	Acronym	Method description:
CHEMICAL	EN 1784:2003	Detection of irradiated food containing fat – Gas chromatographic analysis of hydrocarbons
CHEMICAL	EN 1785:2003	Detection of irradiated food containing fat – Gas chromatographic/mass spectrometric analysis of 2-alkylcyclobutanones
PHYSICAL	EN 1786:1996	Detection of irradiated food containing bone – Method by ESR spectroscopy
PHYSICAL	EN 1787:2000	Detection of irradiated food containing cellulose by ESR spectroscopy
PHYSICAL	EN 1788:2001	Thermo-luminescent detection of irradiated food from which silicate minerals can be isolated
PHYSICAL	EN 13708:2001	Detection of irradiated food containing crystalline sugar by ESR spectroscopy
PHYSICAL	EN 13751:2002	Detection of irradiated food using photo-stimulated luminescence
BIOLOGICAL	EN 13783:2001	Detection of irradiated food using Direct Epifluorescent Filter Technique/Aerobic Plate Count (DEFT/APC) – Screening method
BIOLOGICAL	EN 13784:2001	DNA comet assay for the detection of irradiated foodstuffs – Screening method
BIOLOGICAL	EN 14569:2004	Microbiological screening for irradiated food using LAL/GNB procedures

Source: European Committee for Standardization.

biological methods were used, strictly linked to a second specification, namely: being "screening methods" or not (as EN 13783, EN 13784, EN 13751 and EN 14569). This last specification has particular relevance because "screening methods" should be supported by "confirmatory methods" European standards (EN 1784, EN 1785, EN 1786, EN 1787, EN 13708 and EN 1788). The existence of several analytical methods of post-irradiation verification causes some practical problems: the irradiation treatment produces physical and chemical changes to the extent that it differs significantly among foodstuff treated, and these differences are very small and difficult to detect.

By turning our attention to the Italian Decree, the EU Directives introduced the important obligation relating to the official controls to be implemented in the marketing stage, mainly for the purpose of consumer protection. According to the different detection methods shown previously, the Competent Italian Authority started its internal controls in 2005 (Graph 1):

As can be seen, Italy has never used the EN 1784 and EN 14569 methods, whereas, the most commonly used ones (either as number of samples tested or the number of times the method has been used) are the EN 1788, EN 13784 and EN 13783. Of these last, only the first one is a "confirmatory method", while the other two are "screening methods" that cannot be used alone. In general, the physical and biological methods are much more used than chemical ones in Italy. An increase in the use of "screening methods" (such as the EN 13751) has been noted in recent years because of their several advantages: simplicity of execution, low costs, speed of measurement; whereas "confirmatory methods" are more expensive, slower, require specialized equipment and qualified staff for the interpretation of results.

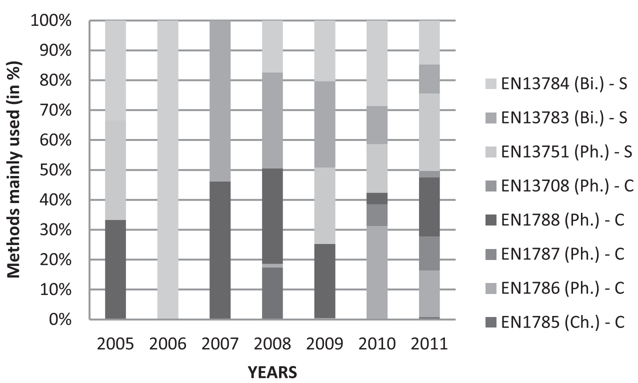
The Italian approved facility and checks at the market stage

The facts that happened after the application of Directive 1999/2/EC differ a lot from country to country, as described by the Reports that Member States must produce, on a yearly basis, containing information about the amount of food irradiated in their own approved facilities as well as the results of checks carried out at market stage (art. 7). During the first period (September 2000 to December 2001), only six Member States (Germany, The Netherlands, United Kingdom, France, Denmark and Belgium) had given an approval to facilities in their territory, and four of these had not yet implemented the Directive 1999/2/EC into national law (namely: Belgium, Germany, Denmark and France). The same for the controls at market stage, where only a few Member States were able to perform appropriate checks while other countries did not produce any information, asserting that there were no analytical equipments or skills available yet (2002/C 255/02).

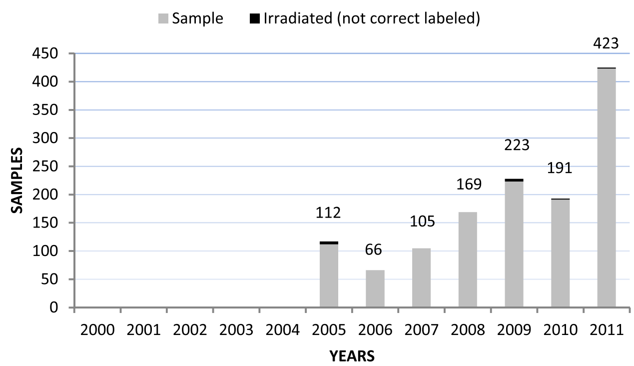
Italy did not perform analytical checks at the product marketing stage until 2005 because (like Spain and Luxembourg) it has no analytical capability to carry out these checks yet. In 2002 the country started a specific training course for public laboratory staff in order to equip them with the necessary skills, allowing in 2005 (2007/C 122/03) the implementation of analytical checks at the market stages. Below (Graph 2) a summary of the Italian checks:

In 2006, irradiation facilities had approval in 10 Member States, including Italy (2008/C 282/04), where the Competent Authority confirmed compliance to the Italian facility (Gammarad Italia SpA). In the same year, for the first and last time, the Italian facility irradiated foods. Apart from this isolated experience, no other clients asked for any new irradiation contracts.

In the meanwhile, a lot of EU countries started a series of national investigations aimed at testing and improving their detection methods with the aim to better contrast the importation of illegally irradiated food from abroad (FSA, 2006; FSAI, 2008). During 2005–2006, the ISS performed the first Italian survey on imported dried spices and herbs, including herbs used in food supplements, using photo-stimulated luminescence (PSL) and thermoluminescence



Graph 1. EN detection methods mainly used in Italy. Legend: Bi.: Biological method; Ph.: Physical method; Ch.: Chemical method; S: Screening methods; C: Confirmatory method.



Graph 2. Samples checked in Italy (2005–2011). Source: EU Reports (2002/C 255/02), (2003/C 230/12), (2004/C 230/28), (2006/C 230/07), (2006/C 230/08), (2006/C 242/02), (2006/C 282/03), (2007/C 122/03), (2008/C 282/04), (2009/C 242/02), (COM – 2011 – 359 final), (COM – 2012 – 16 final), (COM – 2012 – 17 final), (COM – 2012 – 659 final).

methods. About 10% of the examined products (imported from China, USA and Peru) were found irradiated and none of them were labelled or accompanied with the shipping documents certifying the foodstuffs irradiation and the name and the address of the facility which carried out the irradiation treatment. Moreover, herbal supplements and their ingredients that resulted irradiated, represented an infraction of EU law, due to the fact that the irradiation of dietary supplements or their ingredients is not allowed, raising a further problem about the unauthorized use of irradiation and the necessity to perform checks also on the imported raw materials (Aureli, Boniglia, Bortolin, & Onori, 2004; Boniglia, Aureli, Bortolin, & Onori, 2009).

The historical Italian nuclear fear undermines the diffusion of scientific knowledge

Talking about the situation in Italy could be incorrect, without considering the historical country aversion to the nuclear word and to all the issues related to it. Even if food irradiation techniques have nothing in common with nuclear energy and, above all, do not transform food into nuclear food, unfortunately people easily interpret the word "irradiation" with "nuclear irradiation", as discovered in a survey on Italian opinions about irradiated food (Cioce, 2009). So therefore, it is not strange that in the EU Member States that are today active in the field of food irradiation through the functioning of their facilities, there is at least one nuclear plant for energy production currently functioning[1] or Governments are about to build one (see Poland and Estonia).

After the Chernobyl disaster, Italy starts its closure of the nuclear option. A National popular referendum was held in Italy on 8 November 1987, with three questions about nuclear energy:

- abolishing the statutes by which the Inter-ministries Committee for the Economical Programming (CIPE) could decide about the locations for nuclear plants, when the regions did not do so within the deadline stipulated by National Law n. 8, 10/01/1983;
- abolishing rewards for municipalities in territories with nuclear or coal plants that were to be built;
- abolishing the statutes allowing ENEL2 to take part in international agreements to build and manage nuclear plants (as foreseen in the Law n. 856 of 1973).

In each referendum "Yes" won. Even if the three questions formally did not explicitly represent a concrete closure towards the nuclear option, the Italian population interpreted them in these terms. Between 2008 and 2011, a new hypothesis about a possible Italian Nuclear Programme was launched. Thus, a second popular referendum was organized (to be held on 12/13 June 2011). But a few days after the approval, the Fukushima seaquake and the related damages widely predicted the final result of the coming referendum (that was held only three months after). Indeed, as expected, the nuclear option was stopped again.

This brief view about the main facts affecting the nuclear opinion of the majority of Italian citizens is necessary to conclude that too often people do not really know the facts from a scientific point of view, but only from the media and from interest groups (too often piloted) and not well informed (Cioce, 2009).

Education and information campaigns as a tool to strengthen checks and to raise awareness among consumers

The Annex I of the Italian Decree foresees a series of conditions to authorize the treatment of foodstuff through ionizing radiations. The treatment can be authorized only if: (a) rationale technological reasons require such a kind of technology to already exist; (b) the treatment does not represent a risk to consumer health and it is implemented in conformity with the provisions of the law; (c) it is carried out for the benefit of the consumer; (d) the treatment does not represent an alternative/substitute of hygienic and sanitary procedures of the adequate production and agricultural procedures. Focussing on letter (b) and (c) the first question concerns the level of knowledge among the Italian population as regards to the existence of irradiation techniques and its benefit in terms of food safety and public health quality improvement. As far as we know, only one survey has been carried out in the last decade in Italy, confirming the lack of knowledge from the population. The same document confirmed, once again, how communication channels (media) pilot the final message, producing negative information about irradiated food (Cioce, 2009; Rosati & Saba, 2004).

The reason why consumers must be informed and educated about food irradiation technology, market shares, labelling and benefits is double. From one hand it is the citizens right to know about the existence of safer technology used for the storage aims of a particular foodstuff, and secondly, as in the Italian case, that ionizing irradiation is allowed for those foods, like potatoes widely consumed and, at the same time widely imported (with or without accurate controls), inside the country. So, consumers must also be informed about the fact that a lot of products enter our market today without any labels or have been illegally irradiated (in terms of doses).

As Kume, Furuta, Todoriki, Uenoyama, and Kobayashi (2009) underlines, in Europe, the diffusion of irradiated foodstuff was mainly hampered by the labelling duty. This fact, was confirmed by an American study (He, Fletcher, & Rimal, 2005a, 2005b), where the authors assessed the decision to not buy food reporting irradiation on the labelling, because they are not sure about its safety. People must be informed in order to make the final choice, considering that the diffusion or not of ionizing irradiation as a treatment for some foodstuff is not a matter of health

[1] It is the case for Germany, France, Spain, Czech Republic, Belgium, the Netherlands and Hungary.

Table 2. Review on studies related to consumer acceptance of irradiated food products across the world (from 1989 to 2011).

Authors	Field of study	Region or country	Food products	Technology	Data collection
Schutz *et al.* (1989)	Influence of label statements on the perception of quality, safety, and willingness to buy	USA	Food products (fruit, lamb)	Irradiation, chemical fumigants	Survey
Gallup (1993)	Attitude towards food irradiation	USA	Meat	Irradiation	Interview
Henson (1995)	Consumer acceptance of new food technologies	Different countries	Food products	Irradiation	Review
Resurreccion *et al.* (1995)	Consumer attitudes towards irradiation	USA	Meat	Irradiation	E-mail survey
Bruhn (1995)	Consumer attitudes and market response to irradiated food	USA	Meat	Irradiation	Survey
Bruhn (1998)	Consumer acceptance of food irradiation	USA	Meat	Irradiation	Review
Fox (2002)	Consumers purchasing irradiated foods	USA	Food products in general and pork	Irradiation	E-mail survey
Cardello (2003)	Consumer attitudes and concerns towards new food technologies	USA	Chocolate pudding	20 different food processing and preservation technologies	Tests of foods
Deliza *et al.* (2003)	Consumer attitude towards the information contained in the label	Brazil	Fruit juice	Pressure technology	Survey
Nayga *et al.* (2004)	Willingness to pay for irradiated food	USA	Meat of beef	Irradiation	Survey
Rimal *et al.* (2004)	Actual purchase and intention to buy irradiated beef products	Georgia	Beef products	Irradiation	Survey
Wilcock, Pun, Khanona, and Aung (2004)	Consumer attitudes towards the safety of food	USA, Belgium, United Kingdom, Japan,	Food products	Food biotechnology, food irradiation	Review
He *et al.* (2005a)	Consumer assessment of the desirability of beef irradiation	USA	Beef	Irradiation	Survey
He *et al.* (2005b)	Willingness to consume and to pay irradiated foods	USA	Beef	Irradiation	Survey
Gunes and Tekin (2006)	Consumer awareness and acceptance of irradiated foods	Turkey	Raw red meat and poultry products	Irradiation	Survey
Ornellas *et al.* (2006)	Consumer attitude to food irradiation and the Radura symbol	Brazil (Belo Horizonte – MG)	Food products in general	Irradiation	Survey
Bruhn (2007)	Consumer acceptance of new processing technologies	USA, Germany, France, United Kingdom	Food products in general	Irradiation, GM technology, Biotechnology.	Review
Cardello *et al.* (2007)	Factors contributing the consumers interest towards food processed by innovative and emerging food technologies	USA	Meat, milk, bakery, vegetable, fruit, sauce	Irradiation, pulsic electric fields, high pressure, heat pasteurization, ionizing energy genetic modification	Survey
Ronteltap *et al.* (2007)	Consumer acceptance of technology-based innovation	Different countries	Food products	Nutrigenomics	Review
Costa-Font, Gil, and Traill (2008)	Public acceptance of GM food and its underlying behavioural processes	Various countries	Food products	GMOs	Review
Kume *et al.* (2009)	World food irradiation scenario	60 Countries from: America, Europe, Asia and Oceania, Africa	Spices and dry vegetables, grains and fruits, meat and seafood, etc.	Irradiation	Published data, survey and direct visit

(*continued on next page*)

Table 2 (*continued*)

Authors	Field of study	Region or country	Food products	Technology	Data collection
Behrens *et al.* (2009)	Consumer attitude to food irradiation	Brazil	Lettuce salads, roast chicken and sliced mangos	Irradiation	Three focus groups
Byun *et al.* (2009)	Women attitude to purchase irradiated food	Korea	Food products in general	Irradiation	Survey
Teisl *et al.* (2009)	Consumers' attitudes towards emerging food technologies	USA	Food products in general	Organic production, biotechnology, and irradiation	Telephone survey
Rollin *et al.* (2011)	Consumers' attitudes towards emerging food technologies	Europe	Food products	Nanotechnology, GMOs, nutrigenomics, food irradiation, animal cloning	Review
Frewer *et al.* (2011)	Consumer response to novel agri-food technologies	Europe	Food products in general	GM technology, animal cloning technology, nutrigenomics, food irradiation, nanotechnology, high-pressure processing (HPP), pulsed electric field processing (PEF)	Review
Junqueira-Gonçalves *et al.* (2011)	Consumers attitude to food irradiation and the Radura symbol	Chile (Santiago)	Food products in general	Irradiation	Survey

security, but only a problem of misinformation. Therefore, the whole discussion could be linked to those concerning the necessity to restore public trust in science by developing an avowedly two-way public dialogue with science initiatives. Indeed, the disinformation about food irradiation and its benefits, too often rejected before any knowledge, represents a symptom of the continuing failure of scientific institutions to place their own science-policy and institutional culture into the frame of dialogue, as this is a possible contributory cause of the public mistrust problem. In Italy, as well as in Europe, if the labelling obligation can be seen as the main obstacle to the diffusion and progress of such technology, clearly it is necessary to take into account psychological and, consequently, political factors, promoting misinformation from various groups. The future of food irradiation mainly depends on an informed public and a better understanding of the public and media on the role the process can play in the control of foodborne pathogens.

The literature about methods and surveys addressed to consumers is rich enough and tested (Table 2). Since the end of 1980, above all in the USA, research about irradiated food technology and consumers acceptance has grown rapidly. Studies consistently demonstrate that when provided with scientific-based information, a high percentage of consumers prefer irradiated foods (Bruhn, 1995). In particular, recent works show how consumers want information on the effect of long-term consumption of irradiated food, the nutritional value, the use in other countries, and the impact of the facility on the community. Educational and informative messages should stress the benefits of food irradiation, while, on the other hand, the endorsement of Public Health Authorities should represent an important component of any food safety discussion (Bruhn, 1998). A common point of the several works carried out in this sector highlights how consumers are still unfamiliar with the concept of food irradiation, so it is easy to presume that when consumers are asked about their willingness to purchase irradiated foods, the information provided about irradiation will affect the outcome. On the other hand, the positive effect on consumer behaviour of additional information about the process has been widely demonstrated. A powerful anti-irradiation message can be effectively counteracted and consumer confidence in the safety of irradiation process can be restored by detailed scientific-based information on irradiation (Fox, 2002).

The scientific literature suggests different ways, according to which organize an efficient educational and informational campaign. All the information acquired about methods, sample involved and questions, should be taken into consideration when setting up the framework for an investigation strong enough to be tested in a country, like Italy, where the topic of food irradiation could be welcomed with expected difficulties. The interesting findings achieved by the literature in the last 20 years, allow us to think about a complete and exhaustive survey on consumers about irradiation foods (Gunes & Tekin, 2006; Teisl, Fein, & Levy, 2009). At first, a *two step survey* is strongly recommended. During the first stage, investigators should aim at assessing consumer awareness about food irradiation without providing any information about the technology, starting from the assertion that people opinions suffer from a lack of information about this technology. At this stage, it is necessary to know more about such kind of disinformation, with the specific aim to counteract negative information in the next steps. In the works considered, indeed, people interviewed are not informed about the subject, as confirmed by the high percentage of these kind of answers: "*I do not know that ionizing irradiation is a storage technique*" (Behrens, Barcellos, Frewer, Nunes, & Landgraf, 2009), or "*I have never heard of it*" (Byun *et al.*, 2009). Given the unfamiliarity with the concept of food irradiation, it is not currently recommendable to put forward any questions concerning, for example, the willingness to buy irradiated food, as the lack of awareness will totally influence the answer. Another aspect to be investigated during the first stage, concerns the related benefits deriving from eating irradiated food: questions usually included in a questionnaire that received the highest percentage of "*I dont know*" answers are: "*Do you know if food irradiation can cause damage to consumer health and/or to the environment?*" (Junqueira-Gonçalves *et al.*, 2011). Remaining at the first stage, some authors have gone even further, such as, Junqueira-Gonçalves *et al.* (2011) and Ornellas, Gonçalves Junqueira, Silva Rodrigues, and Martins Travassos (2006), including a question about the *Radura* symbol (the symbol indicating a food as irradiated). Also in this case, the highest percentage of the answers were negative: "*I do not know the symbol*". The introduction of the *Radura* symbol on the questionnaire allows for more exhaustive information of the subject on one hand, and on the other hand an analysis of the impact that such a kind of symbol could produce to people, as was detected through the inclusion of pertinent questions.

The second step of the survey should assess consumer behaviour against food irradiation but, this time, after the participation in a educational and informative campaign. As underlined by Resurreccion, Galvez, Fletcher, and Misra (1995), there is evidence that people could change their opinion about food irradiation, if they receive the correct information. This affirmation is verified by the fact that the authors, included replies in their questionnaire, such as "*Do you know if food irradiation can cause damage to consumer health and/or to the environment?* three possible answers with a very different meaning, namely: "*I do not know; true; false*". The majority of respondents tick the box "*I do not know*", and not on *true* or *false*, therefore leaving a space of curiosity, a sort of willingness to want more information about it, and not a closure *a priori*. The starting point is that generally people perceive the irradiation treatment as a high-risk technology, and this is mainly attributable to the lack of information about the subject, as confirmed by the Chilean survey where authors (Junqueira-Gonçalves *et al.*, 2011) received a percentage of 90.7% to the statement "People might become consumers of irradiated food if they know that irradiation increases food safety and does not cause short-term and/or long-term health problems".

At this point, it is necessary to specify how an effective educational and information campaign could be carried out. The main aspect relies on how to better counteract incorrect information that is currently dominant, above all in countries like Italy, where nuclear fear is ever present. People must know and must receive proof of what happens in foodstuff treated with ionizing irradiation (Bruhn & Mason, 1996). Generally, people say that irradiated food means the same as being radioactive (in a Chilean survey 45.9% of persons interviewed replied in this way). The success of a counteracting information campaign depends on the content of the campaign itself (Fox, 2002). It is widely suggested that in order to better counteract the negative information, the two stage survey thanks to the opinions collected before the information campaign, usually provides a lot of interesting suggestions, like fears and specific misinformation on the subject, allowing the researcher to better hypothesize the counteracting message content to be promoted; on the other hand, it is important to explain the negative effects of the techniques actually used to reach the same scope, making a comparison between these last ones mentioned and the ionizing irradiation technology.

As recommendable communication tools, researchers, around the world, have used different channels, and the selection partly depends on the density of the sample, apart from financial constraints (Pohlman, Wood, & Mason, 1994). We can cite: round tables, oral explanation of the technology functioning, visual presentations both through film or documentary, direct consumption of irradiated food, informative brochure/leaflets, questionnaires together with informative tools, etc.

European labelling obligations and the issue of the ISO 14470:2011

Even if a real acceptance of irradiation treatment, and its consequent market opening, could be achieved mainly thanks to an effective educational campaign, it is necessary to focus on the role that the endorsement of Public Authorities, like Public Health and/or Food Quality Authorities, could play. The market alone cannot do much more in this context (Fox, 2002; Ten Eyck & Deseran, 2001). Indeed, if one of the main obstacles could be the labelled description on the irradiated food, namely "*Treated with radiations*", or "*Treated by irradiation*", or "*Treated with ionizing energy*" (Codex Alimentarius Commission, 2007), it is important to remember that consumer's behavioural patterns change according to the perceived risk and the process-related benefits compared to any existing alternatives (Henson, 1995). For this reason, it is better to adequately inform people, avoiding opposite effects rather than changing the sentence with a softer one. Several studies (Cardello, Schutz, & Lesher, 2007; Farkas & Farkas, 2011; Fox, 2002; He *et al*., 2005a, 2005b; Nayga, Poghosyan, & Nichols, 2004; Schutz, 1994; Schutz, Bruhn, & Diaz-Knauf, 1989) point out that an irradiated food label is perceived as a warning sign for the consumer, who tends to exclude the product in question and fails to pay a premium price for its purchase. However, a few studies conclude that consumers have a greater awareness of the processing treatment, which the product undergoes *via* the presentation of clear information stated on the label, contributing to increase the intention to purchase, as in the case of irradiated meat (Gallup, 1993; Rimal, McWatters, Hashim, & Fletcher, 2004), therefore rising the safety-based perception of the actual consumer (Schutz *et al*., 1989).

The transfer of knowledge to the consumer *via* the information illustrated in food product labels is strategic in order to ensure a high degree of protection, but also to enhance the endorsement of innovations in terms of product and process alike. As regards process-oriented innovations and in relation particularly to the introduction of emerging food technologies, a plethora of studies have shown that the lack of innovation-based knowledge on behalf of consumers represents one of the key obstacles to their acceptance (Bruhn, 2007; Cardello *et al*., 2007). As a result, the impact from the introduction of emerging food technologies on the acceptance and inclination towards purchasing the products and the function of the information contained in the label, executed with a view to affect the choices of the consumers themselves, are arguments that received particular attention. The results indicate that the individual perception of personal control tends to increase, if consumers are aware of the treatment which the product undergoes (Deliza, Rosenthal, & Silva, 2003; Rollin, Kennedy, & Wills, 2011), thus underscoring the importance of the type and standard of information stated on the label, that becomes one of the main instruments able to exert a certain influence over the choices made by the consumers and the degree of innovation acceptance (Cardello, 2003; Ronteltap, van Trijp, Renes, & Frewer, 2007).

The actual legislative situation in Italy does not allow a clear identification of an irradiated foodstuff by consumer, contributing to the diffusion of an irradiation market that lacks transparency. The fact that irradiated unpackaged foodstuff is not required to be accompanied by the *Radura logo* or other types of labelling, *a priori* undermines an effective control at the market stage. Turning back to Directive 1999/2/EC, in art. 6 the legislator, also by referring to what is already laid out in art. 5, paragraph 3 of Directive 79/112/EEC – relating to the labelling, presentation and advertising of foodstuffs – determines that the food product labels intended for the end-user should bear the legend "*irradiated*" or "*treated with ionizing radiation*", even if it is only one ingredient of any given composite food to be processed. The same legend must appear on a leaflet or sign for any unpackaged foods. On the other hand, as pertains to the products not intended for the end-user or the community, the mandatory legend needs to be complemented by the registered name and address of the irradiation facility, or, its reference number. In any case, the indication of the processing treatment must appear in the document accompanying the irradiated products.

EU Regulation No. 1169/2011, representing the last step in relation to the EU labelling system, with reference to the labelling of food products processed *via* ionizing radiation, integrally refers to the Directive of 1979 and fails to bring any novelty, despite a negative effect on the diffusion of the treatment and the food processed within European boundaries. Concerning the labelling of the treated products, Legislative Decree 109/1992 – implementing Directives 89/395/EEC and 89/396/EEC – relating to labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer – is still in force. The Decree incorporates what is determined on a European level, thus resulting in the compulsory legend "*radiated*" or "*treated with ionizing radiation*" to be applied to all food products or ingredients subjected to the treatment (art. 4).

In terms of European as well as International Authorities involvement, it is interesting to report the conclusions produced by the EFSA Panel on Biological Hazards – BIOHAZ Panel – after a request from the EU Commission to deliver a scientific opinion on food irradiation (efficacy and microbiological safety). The document confirms that there are no microbiological risks for the consumer linked to the use of food irradiation and its consequences on the food micro-flora. The opinion, *inter alia*, recommends that food irradiation should be based on risk assessment and on desired risk reduction rather than on predefined food classes/commodities and doses as proposed in the past. In addition, with respect to efficacy and microbiological safety, it is recommended that upper dose limits for pathogen reduction should not be specified, since other constraints, such as undesirable chemical changes, will limit the doses applied. It finally, recommends that food irradiation should only be used in conjunction with an integrated food safety management program, concluding that when this includes Good Agricultural, Hygienic and Manufacturing Practices (GAP, GHP, GMP) and Hazard Analysis and Critical Control Points (HACCP), and depending on the dose applied, food irradiation can contribute to improved consumer safety by reducing food-borne pathogens (EFSA, 2011). It is therefore necessary to focus on modern food safety management systems widely accepted around the world that rely on a farm to fork approach, involving a range of actions at each step of the food chain. Following the quality approach, the EU scientific opinions underline once more the need that food irradiation has to be interpreted as a further tool, second to the integrated food safety management program before cited, able to guarantee safer foodstuff production and commercialization. A recommendation for recall was explicitly contained in the Directive 1999/2/EC, where indeed food irradiation can be used "*to reduce the incidence of food-borne disease by destroying pathogenic organisms*" and one of the preconditions to its authorization is that "***it is not used as a substitute*** *for hygiene and health practices or for good manufacturing or agricultural practice*".

From a practical point of view this means that both in the primary production level and in the transformation one, it is suggested that producers implement and respect the main procedures pertaining to HACCP principles (as mainly laid down by Regulation (EC) No 852/2004), as well as Good Hygiene Practice (GHP), Good Agricultural Practices (GAP), and Good Manufacturing Practices (GMP), according to the final product.

At International level the most important standardization effort is represented by the issuing of the **ISO 14470:2011** (International Standard Organization) titled Food Irradiation: Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food. Perfectly in line with what concluded by the EFSA (2011), namely "*the irradiation dose needed to inactivate food-borne pathogens depends on the targeted pathogen, on the reduction required and on the physical state of the food, regardless of the food classes as previously proposed*", the ISO norm takes into account the possible incorporation of food irradiation technologies as part of a food safety management system (ISO 22000) considering, therefore that the irradiation of food as a critical control point (CCP) of a HACCP programme, contributes to the minimization of risks from the transmission of pathogenic micro-organisms to consumers. According to its scope, the norm was prepared by the ISO/TC 34 *Food Products* Technical Committee, the same that prepared the ISO 22000. The norm specifies requirements of food production directly related to the irradiation process that may affect the safety or quality of the irradiated food, establishing, *inter alia*, a documentation system to support the controls of the food irradiation process. The final aim of the norm is to contribute to confidence and transparency among the different stakeholders operating in the food sector, trying to provide regulators and consumer representatives with improved information on products, enabling better choices. The necessity of such a standard to assist customers, irradiation operators and consumers derive from the diffusion that such technology has been experimenting over the last few decades. The standard does not specify requirements for the primary production and/or harvesting, post-harvest treatment, storage and shipment, and packaging for foods that are to be irradiated. Only those aspects of food production directly related to the irradiation process that may affect the safety or quality of the irradiated food are addressed (ISO 14470:2011, p. 1).

The ISO involvement in this field, as has already happened in the past, should be interpreted as the need felt by the international community to standardize something that is experimenting a worldwide diffusion that is motivated for the necessity of improved checks. At the same time, the impact that such norm could also play in terms of improved consumer acceptance, or trust, as has happened in the past with other ISO norms is important.

Having a look to the Italian actual context, there isn't any detailed information about the ISO 14470:2011 diffusion available. To discover something more about the next steps, it is interesting to have a look at the voluntary certification systems and related bodies in charge of this task: for this purpose, some information can be extracted from the ACCREDIA official web site, where it is possible to find updated information about all the international standards (ISO ones included) currently implemented and requested by the Italian market. The reason why putting the attention to ACCREDIA: it is the Italian Accreditation Body, whose task is to release accreditation according to the provisions included in the EU Regulation n. 765/2008,[2] valid since the first of January 2010 inside the EU internal market and compulsory for all the EU Member States. According to it, each EU Member State must identify each own Accreditation Body in charge of this task. If we have a look at the ACCREDIA database, the ISO 14470:2011 is not present, meaning that until now the Italian Accreditation Body has not started the procedures needed to enable ACCREDIA to accredit Certification Bodies for this norm. The reasons why this is lacking, might be because of different sources: from a scarce interest of the market (more probable giving the Italian historical nuclear fear) to a reasonable delay as the ISO 14470:2011 has been recently issued (almost 1 year).

Economic and business potential of irradiation: the role of stakeholders

The economic and business potential of food irradiation is an open matter yet. Compared to thermal or cold treatment, this technology has shown to be more efficient in terms of required treatment time (Moy & Wong, 2002). In spite of its economic usefulness for hygienization and quarantine treatment of agricultural commodities and food production has been amply demonstrated (Sharma & Madhusoodanan, 2012), the treatment facilities are poorly disseminated. This is due not only to the social acceptance of this technology among consumers, as it has been seen, that affects the demand for irradiated food but also to the cost of building, staffing and operating of the facilities. It was estimated that \$3–6 million is required for a single facility, depending mainly on the size of the plant and the type (Bustos-Griffin, Hallman, & Griffin, 2012). Furthermore, also the costs of irradiation treatment are relevant and vary with the application, total volume and mix of

[2] ENEL is the Italian electric utility company, the second-largest in Europe by market capitalization. Formerly a state-owned monopoly, it is today partially privatized with Italian government control.

throughput, source of irradiation and local factors (Hallman, 2012). Nowadays, the use of irradiation treatments is well below optimization, and economy of scale has yet to be reached by any commercial facility doing food irradiation. As its use increases, therefore the per-unit cost of treatment should fall. On one hand, it would be logical to locate big facilities near ports used for export of the commodities to avoid increasing transportation and handling costs. But, on the other hand, the high investment costs together with the low demand for irradiated food, oblige produce marketers who want to use irradiation on a specific food product to contract with an existing facility to perform the service. If in this way the problems linked to the initial investments costs could be overcome, the transport costs to and from the irradiation facility must be considered (Moy & Wong, 2002). The logistics involved in transporting food products from its point of origin to an irradiation plant, and then out to the markets can be particularly high, and able to negatively affect the final price. Nevertheless, such costs could often not prohibitive when a careful analysis of cost-benefit or risk-benefit is conducted. Whether and when the industry will build its own irradiation facility would be driven by the market, more probably over a period of years (Groth, 2007).

The general aspects just discussed have to be intended as broad conditions concerning the diffusion of irradiation technology in a large scale. With the final aim to better explain and understand the socio-economic and regulatory framework as well as the stakeholders roles necessary for an effective diffusion of the technology we cite the case of USA and India on mangoes commercialization. In these countries the irradiation treatment was considered as a basic technology for industry, as confirmed on March 2006, with the signature of an agreement between the two countries, for the entry of Indian mangoes to the United States market after 17 years of being prohibited for phytosanitary reasons. In this case, irradiation was chosen as a phytosanitary measure that could solve the issues involved. Today, irradiated Indian mangoes cost about 4 times the hot water treated Mexican mangoes, but the quality of the cultivars shipped is claimed to be better (Hallman, 2011). US represents an interesting example where the establishment of progressive irradiation treatment policies and regulations have facilitated the introduction of the technology, with the specific aim to provide an answer to the needs related to quarantine restrictions on the import of fresh fruits and vegetables due to concerns for exotic pests (Bustos-Griffin *et al.,* 2012). On the other side, ever in 2004, the Indian Ministry of Agriculture amended plant protection and quarantine regulations to include irradiation as a quarantine measure (Sharma & Madhusoodanan, 2012). Consequently, real implementation of the technology mainly, even if not exclusively, depends on the willingness of National Regulatory Agencies to move the technology forward (Hallman, 2011). In the US–India case, those obstacles linked to the high investments costs that generally stop new investments in this sector, were solved thanks to the market trust assured by the endorsement of Public Authorities and, on consequence, from all the stakeholders (industry, producers, consumers, etc.). In particular, the industry, usually reluctant towards this technology, resulted more mindful of the risks linked to rest outside the new market. In the long period, the rejection of irradiation technology use from the industry would have been associated with loss of trade opportunities and access to markets where current disinfestation methods are not accepted, causing a great delay in developing global competitiveness and new market opportunities. Witness to the successful operations of Indian irradiation demonstration programmes together with the diffusion of the treatment for commercial needs, a number of private entrepreneurs evinced interest in establishing radiation processing facilities in the country. As a private entrepreneur, it is noticeable in the case of MICROTROL, one of the early investors in the field. With its sustained efforts towards providing quality contract services, MICROTROL has obtained all Quality/System certifications such as ISO 9001, ISO 13485, ISO 14001, ISO 22000, including the accreditation of the European Commission (Sharma & Madhusoodanan, 2012).

Concluding, Governments should frankly show their interest in those technologies, as irradiation is, able to ensure safe, abundant food and to increase trade opportunities. The key stakeholders in food irradiation as a potential technology for the 21st century have been by now clearly identified in: consumers, food industry, irradiation processors, but also humanitarian organizations with an interest in food (e.g. FAO, WHO, IAEA), nuclear science institutions and relevant NGOs. Nevertheless, today the reality sees several National Authorities worldwide using a case-by-case approach to food irradiation, and for this reason it is impossible and useless producing uniform recommendations at this regards (IAEA, 2002a, 2002b). The case-by-case approach is caused both by different internal regulations and the market value of the food product that could be irradiated in each country. In other words, if US needed the implementation of a phytosanitary framework for a specific food product (mango) which domestic market demand was high, this situation could not be the same in other countries. Also for this reason, the future economic diffusion of the technology will probably continue to follow a case-by-case approach.

The conclusion also applies to the European Union context where the prevailing market conditions, the Public Authorities poor interest and the consumer attitudes will negatively affect an effective diffusion of the technology in the short period, despite of the two EU Directives on the matter as well as the last ISO issued.

Conclusions

This overview was aimed at presenting the actual situation at European level, with a specific focus on the Italian context. Two important issues emerge from our study. On one hand, a problem of food fraud, linked to the entry of agro-food products illegally irradiated or incorrectly labelled onto the EU market. On the other hand, the limited diffusion in EU member countries of ionizing radiations for the treatment of agri-food, although, as amply demonstrated, food irradiation is a treatment that significantly reduces the dangers of primary and cross-contamination without compromising nutritional or sensory attributes. This is mainly due to a problem of misinformation. Although it is still evident that the significant information gap existing in relation to consumers' knowledge about food irradiation causes a distortion in the effective diffusion of the technology, it is the same necessary to remember that where the general public is not opposed to food irradiation, the final decision not to use it for phytosanitary purposes often rests with key production and marketing personnel who are understandably concerned with negative publicity (Eustice & Bruhn, 2006). Just have a look to the UK case, where the first responsibility to the poor diffusion of the technology is from the structure of the food retail market. Indeed, in that country the seventy per cent of all grocery sales are concentrated in the hands of four key retailers (Tesco, Sainsbury, Safeway and Asda), resulting in an intense competition and critical market share. From a marketing standpoint irradiated foods constitute a cost and a risk without any concomitant benefit. The key concern is that the first retailer to be associated with irradiated foodstuff will suffer adverse publicity and as a result lose market share not just in the area associated with irradiated foods but across the whole business (Woolston, 2000).

In the European scenario, the Italian case was taken as an interesting case study, giving the historical nuclear fear characterizing its public opinion, with a particular reference to the necessity to widely counteract misinformation. Only an effective communication campaign aiming to relay the information relating to the benefits of adopting ionizing radiation for the elimination or reduction of the microbial load, the prevention of sprouting, the discussion on insect eggs and the development of larvae, may both create a greater awareness among consumers with respect to this technology and alter the current scenario in the course of the next few years (Junqueira-Gonçalves *et al.*, 2011). The risk perception on behalf of the consumers in relation to the processing of food products treated with ionized radiation, and the imperativeness of stating the processing treatment itself on the label, hinder the diffusion of this technology. A powerful anti-irradiation message can be effectively counteracted and consumer confidence in the safety of irradiation process can be restored by detailed science-based information on irradiation (Byun *et al.*, 2009; Fox, 2002).

On this basis and in order to achieve a higher level of awareness and confidence among consumers in respect to food irradiation, it is strategically important to have a joint effort of health organizations and agri-food industries in finding strategies for consumers to overcome their fear of irradiated food and begin to see the advantages of having this option available. In the last years consumer choice is moving towards food of better quality for which they agree to pay a premium price. For this reason, the higher final price of irradiated food could be accepted if intended as an added value of the product itself. Firstly, the role of the health authorities and other institutions is crucial to allow, *inter alia*, to the business community a correct understanding about the potential and advantages of irradiation for the necessary investment to occur (Bustos-Griffin *et al.*, 2012). Moreover, their commitment is essential for the implementation of the detection of irradiation methods in order to contrast the importation of products illegally irradiated and improperly labelled. Secondly, the food industry should conduct a thorough study of the consumers perception and its influence on purchase intentions, formulate effective marketing strategies. Labelling and the information contained therein play a key role in the perception of consumer safety, the EU commitments towards the irradiation check improvement together with the ISO **14470:2011**, should be interpreted as relevant international endorsements, that could improve the efficacy of a future educational and information campaign addressed to consumers, representing an important step towards effective diffusion of the technology in the medium-term. Moreover, the diffusion of the new ISO 14470:2011 could solve the possible trade limits caused by the need of the EU approval for irradiation facilities located in third countries, standardizing at International level the matter and avoiding possible commercial incompatibilities.

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