Food Irradiation: The EU Regulatory Framework, Risk Assessment and International Trade Considerations

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This article looks at the different regulatory approaches on food irradiation, starting with international standards on food irradiation, describing the approach in the US and other third countries, and finally in the EU, where there has been a regulatory standstill since 1999. The current EU approach on food irradiation, which authorises irradiation of certain predefined product categories and sets upper dose limits, does not appear to be in line with the approach used under the relevant internationally-recognised standards, such as the Codex Alimentarius and the International Plant Protection Convention. There are potential legal conflicts between the current regulatory framework on food irradiation in the EU and the international trade framework of the World Trade Organization. Ultimately, the EU must base its measures on scientific principles, on relevant international standards, and choose the least trade-distortive measures that are available (i.e., ensure that they are applied only to the extent necessary to protect human, animal or plant life or health). In 2011, the European Food Safety Authority published new risk assessments on food irradiation, which the European Commission has requested in view of drafting new EU legislation on food irradiation, and which appear to open the way for a fundamental altering of the regulatory parameters (such that food irradiation regulations must be scientifically-justified and in line with the relevant international standards), and seem to weaken the EU stance vis-à-vis the possible instances where the current rules on food irradiation prevent (de jure or de facto) access to the EU market by third countries' operators and products, particularly those of developing countries.

I. Introduction

In order to reduce the incidence of food-borne diseases, food irradiation is a processing technique that exposes food to radiation in order to destroy pathogenic organisms. Some argue that the deadly 2011 E. coli crisis that killed almost 50 people in Europe alone (mainly in Germany), and left thousands seriously ill, is likely to renew interest in the irradiation of food.[1] Certain lots of fenugreek seeds imported from Egypt were identified as the causative agent of an outbreak in the EU in May/June 2011 of Shigatoxin-producing E. coli bacteria (STEC), serotype O104:H4.[2] This outbreak could almost certainly have

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1 This is what, according to a food irradiation specialist at the International Atomic Energy Agency, happened in the US, where irradiation was approved as a treatment for killing pathogens on spinach and lettuce following an E. coli scare in 2006. See Helen Glaberson, "E. coli crisis could prompt interest in irradiation for salads", 28 June 2011, available on the Internet at <http://www.foodproductiondaily.com/Quality-Safety/E.coli-crisis-could-prompt-interest-in-irradiation-for-salads-IAEA> (last accessed on 28 August 2012).

2 For more details on the outbreak and its trade impact, see Commission Implementing Decision 2011/402/EU, OJ 2011 L 179/10, which introduced a ban on the release for free circulation in the EU of seeds and beans from Egypt.

been averted by irradiating the fenugreek seeds, as wider irradiation of (particularly organic) foodstuffs would seriously reduce the risk of foodborne illness. However, there are strong reservations against the use of this technology, which has not been widely adopted due to an asserted negative public perception, concerns expressed by some consumer groups, and also the unwillingness of many food operators.

This article looks at the regulation of food irradiation, at the international level and in particular in the EU and the US. The introduction describes what food irradiation is and how it works, giving a brief history of food irradiation and its international regulation. Part II addresses different regulatory approaches to food irradiation, starting with international standards on food irradiation, describing the approach in the US and other third countries, and finally in the EU, where there has been a regulatory standstill since 1999. The law and practice of food irradiation is not completely harmonised in the EU and its Member States. In 2011, the European Food Safety Authority (EFSA) published new risk assessments on food irradiation, which should pave the way to future amendments or even a radical change of the EU regulatory framework. Part III of the article concerns international trade aspects. There are potential legal conflicts between the current regulatory framework on food irradiation in the EU and the international trade framework of the World Trade Organization (WTO). The article also addresses concerns about scientific uncertainties with the irradiation of food and the possibility of applying provisional measures based on the precautionary principle. Finally, the article looks at the question of whether food irradiation can be an effective, viable and acceptable means of food hygiene for countries, especially developing, emerging and newly industrialised countries.

1. What is food irradiation?

Food irradiation is a processing technique that exposes food to radiation in the form of electron beams, X-rays or gamma rays.[3] Food irradiation may be used in order to reduce the incidence of foodborne disease by destroying pathogenic organisms; to reduce spoilage of foodstuffs by retarding or arresting decay processes and destroying spoilage organisms; to reduce the loss of foodstuffs by premature ripening, germination or sprouting; and to rid foodstuffs of organisms harmful to plant or plant products. Irradiation can be used to destroy microorganisms, viruses, insects or bacteria (such as salmonella, campylobacter and E. coli) that might be present in food and cause food poisoning, but it can also delay fruit ripening and help stop vegetables, such as potatoes and onions, from sprouting. Irradiation is also applied in the treatment non-food items such as cosmetics, pharmaceutical and medical instruments (e.g., for sterilisation).

2. How does food irradiation work?

Food absorbs energy when it is exposed to ionising radiation. The amount of energy absorbed is called "absorbed dose", which is measured in units of Gray (Gy). The energy absorbed by the food causes the formation of short-lived molecules known as free radicals, which destroy micro-organisms and also interact with other food molecules. Irradiation causes damage to the DNA and proteins of bacteria and causes them to die.[4]

The common features of all commercial irradiation facilities are the irradiation chamber and a system to transport the food into and out of the room (either a conveyor belt or a rail system). To ensure that ionising radiation does not escape, concrete shielding surrounds the chamber. In the case of a gamma irradiator, the radionuclide source continuously emits radiation and must be stored in a water pool when not being used to treat food (water absorbs the radiation energy and protects workers from exposure if they must enter the room). In contrast to gamma irradiators, machines producing high-energy electrons operate on electricity and can be switched off. In a gamma irradiator, the size of the containers in which the food is moved through the irradiation

3 Different technologies are currently available and used for the irradiation of food. As foreseen by the Codex General Standard for Irradiated Foods, such technologies are primarily based on the use of three different kinds of ionising radiation: gamma rays (-rays) from the radionuclides cobalt-60 (Co-60) or cesium-137 (Cs-137); X-rays generated from machine sources operated at or below an energy level of 5 MeV (i.e., 5 million electron volts); and electrons (e-beams) generated from machine sources operated at or below an energy level of 10 MeV. While the first type (-rays) are produced from a radioactive source, the other two (X-rays and ebeams) are produced by specific equipment converting other energy sources, such as electric current, without the involvement of any radioactive substance.

4 See information of the UK Food Standards Authority on Irradiated food, available on the Internet at: <http://www.food.gov.uk/safereating/rad_in_food/irradfoodqa/> (last accessed on 28 August 2012).

chamber can vary and pallets up to 1 cubic meter may be used.[5]

3. History of food irradiation and its international regulation

The idea of irradiating food appears to have been first developed in Germany, shortly after Henri Becquerel's discovery of radioactivity in 1896. During the 1950s and 1960s, experiments with both low dose and high dose irradiation were carried out in the US.[6] In 1981, based on the findings of the Joint Expert Committee on Food Irradiation (JECFI) composed of members of the FAO (Food and Agriculture Organization of the United Nations), IAEA (International Atomic Energy Agency) and WHO (World Health Organization), the WHO published a document titled "Wholesomeness of Irradiated Foods".[7] The document concluded that no further toxicological or nutritional research is needed on foods irradiated up to an overall dose of 10 kGy. The Codex General Standard for Irradiated Foods No. 106-1983 adopted by the Codex Alimentarius Commission (under the auspices of the FAO and the WHO) endorsed the JECFI's statement that: "The irradiation of foods up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems". The publication of this standard had a profound influence on further international developments and formed the basis of legislation in many countries.

In 1997, the FAO/WHO/IAEA Study Group on High-Dose Irradiation convened to assess the safety and nutritional adequacy of food irradiated with doses above 10 kGy. The Study Group was formed in response to the technological need for average doses higher than 10 kGy to ensure that certain food items, particularly meat and poultry, are rendered consistently free of pathogens. On the basis of the extensive scientific evidence reviewed, the Study Group concluded in 1999 that food irradiated to any dose appropriate to achieve the intended technological objective is both safe to consume and nutritionally adequate. The experts further concluded that no upper dose limit need be imposed, and that irradiated foods are deemed wholesome throughout the technologically-useful dose range below and above 10 kGy.[8] The guiding principles for determining the wholesomeness of irradiated foods were such that foods are deemed safe if they pose no toxicological or microbiological hazards and that they are deemed adequate for consumption if they pose no special nutritional problem.[9]

II. Different regulatory approaches on food irradiation

This section describes the different regulatory approaches towards food irradiation at the international level, in the US, and the EU. In relation to the EU, it focuses on the recent EFSA risk assessments on food irradiation, which will likely influence future EU legislation on food irradiation.

1. International standards on food irradiation

There are a number of international standards on food irradiation. This section looks at the Codex Standard for irradiated food and standards of the International Plant Protection Convention (IPPC). Organisations like the International Standardisation Organisation (ISO) have also developed standards on irradiation.[10]

a. Codex Standard for irradiated foods

In 2003, the Codex Committee on Food Additives and Contaminants noted the conclusions of the Joint

5 International Consultative Group on Food Irradiation (Food and Environmental Protection Section Joint FAO/IAEA (International Atomic Energy Agency) Division of Nuclear Techniques in Food and Agriculture), "Facts about food irradiation", 1999.

6 Institute of Food Science and Technology, *The Use of Irradiation for Food Quality and Safety* (February 2006); Nordion, The History of Food Irradiation, available on the Internet at <http://www.nordion.com/documents/The-History-of-Food-Irradiation.pdf> (last accessed on 28 August 2012).

7 Report of a Joint FAO/IAEA WHO Expert Committee, "Wholesomeness of Irradiated Food", in *Technical Report Series 659* (WHO: Geneva, 1981).

8 Report of a Joint FAO/IAEA/WHO Study Group, "High Dose Irradiation: Wholesomeness of Food Irradiated with Doses above 10 kGy", in *Technical Report Series 890* (WHO: Geneva, 1999).

9 *Ibid.*, at p. 3.

10 The recently-adopted ISO Standard 14470:2011 *Food irradiation – Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food* specifies requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food, and establishes guidelines for meeting the requirements.

FAO/WHO/IAEA Study Group on Food Irradiation that food irradiated with doses above 10 kGy was both safe and nutritionally adequate. On the basis of this conclusion, and in consideration that the previous Standard stated that "the overall average dose absorbed by a food subjected to radiation processing should not exceed 10 kGy", the Committee reached a compromise solution and agreed to remove the 10 kGy limitation by defining a more practically applicable statement on dose limitation, under point 2.2 of the Standard (Absorbed Dose): "For the irradiation of any food, the minimum absorbed dose should be sufficient to achieve the technological purpose and the maximum absorbed dose should be less than that which would compromise consumer safety, wholesomeness, or would adversely affect structural integrity, functional properties, or sensory attributes. The maximum absorbed dose delivered to a food should not exceed 10 kGy, except when necessary to achieve a legitimate technological purpose". The revised Standard was adopted during the 26th Session of the Codex Alimentarius Commission in July 2003 as a final Codex text.[11]

It should be noted that the European Union, at that stage, had expressed reservations in the 33rd session of CCFAC (i.e., Codex Committee on Food Additives) concerning the deletion of the specific maximum dose of 10 kGy.[12]

The Codex Alimentarius has also published a recommended international code of practice for radiation processing of food.[13] The purpose of this Code is to provide principles for the processing of food products with ionising radiation that are consistent with relevant Codex Standards and codes of hygienic practice. Food irradiation may be incorporated as part of a HACCP[14] plan where applicable; but a HACCP plan is not required for the use of radiation processing of food processed for purposes other than for food safety. The provisions of this Code will provide guidance to the radiation processor in applying the HACCP system, as recommended in the Recommended International Code of Practice General Principles of Food Hygiene,[15] where applicable for food safety purposes, to foods processed by ionising radiation: "Primary food products intended for radiation processing should comply with the Codex General Principles of Food Hygiene with reference to the hygienic requirements as well as other relevant Codex standards and codes of practice for primary production and/or harvesting, which ensure that food is safe and suitable for human consumption."

b. IPPC Standards

Certain irradiation treatments are also addressed by the International Plant Protection Convention (IPPC) for the control of specific pests on specific articles, like fruits and vegetables. The IPPC is an international agreement on plant health which aims at protecting cultivated and wild plants by preventing the introduction and spread of pests. International Standards for Phytosanitary Measures (ISPMs) are the standards, guidelines and recommendations recognised as the basis for phytosanitary measures applied by Members of the World Trade Organization (WTO) under the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). ISPMs are adopted by contracting parties to the IPPC through the Commission on Phytosanitary Measures (CPM).

The ISPM No. 28 *Phytosanitary Treatments for Regulated Pests*[16] presents in its Annexes phytosanitary irradiation treatments, evaluated and adopted by the CPM, which can be used as phytosanitary measures. The treatments are for the control of regulated pests on regulated articles, primarily those moving in international trade. The adopted treatments provide the minimum requirements necessary to control a regulated pest at a stated efficacy. For example, Annex 14 (established in 2011) regulates the irradiation treatment related to *Ceratitis capitata,* the Mediterranean fruit fly and states that "this treatment applies to the irradiation of fruits and vegetables at 100 Gy minimum absorbed dose to prevent the emergence of adults of Ceratitis capitata at the stated efficacy".

11 Codex General Standard for Irradiated Foods No. 106-1983, Rev 1-2003, available on the Internet at <http://www.codexalimentarius.net/web/more_info.jsp?id_sta=16> (last accessed on 28 August 2012).

12 Common European Community Position for the Codex Alimentarius Commission, 24th session, 2-7 July 2001, Geneva, Switzerland – Agenda Item 10 b) Consideration of Standards and related Texts at Step 5 – Proposed Draft Revision to the Codex General Standard for Irradiated Foods at step 5.

13 Codex Alimentarius, CAC/RCP 19-1979, Revision 2-2003.

14 "Hazard Analysis and Critical Control Points".

15 Codex Alimentarius, CAC/RCP 1-1969, Revision 3-1997, Amendment 1-1999.

16 This standard was endorsed by the Commission on Phytosanitary Measures in March 2007.

2. Approach in the US and other third countries

In the US, Part 179 of Title 21 (Food and drugs) of the Code of Federal Regulations (hereinafter, 21 CFR)[17] regulates irradiation in the production, processing and handling of food. Section 179.25 of 21 CFR establishes general provisions for food irradiation and provides in part (b) that "Food treated with ionizing radiation shall receive the minimum radiation dose reasonably required to accomplish its intended technical effect and not more than the maximum dose specified by the applicable regulation for that use".

Part (b) of Section 179.26 of 21 CFR establishes the intended purposes and food categories for which irradiation is permitted.[18] For each food/effect category, the provision also establishes maximum irradiation doses (e.g., "not to exceed 3 kGy" for the control of foodborne pathogens in fresh or frozen, uncooked poultry products). Section 179.26 (c) of 21 CFR requires that the label of retail packages of foods irradiated in conformance with the above provision shall bear the so-called Radura logo[19] along with either the statement "Treated with radiation" or the statement "Treated by irradiation".

The US regulation, which sets out that "[f]ood treated with ionizing radiation shall receive the minimum radiation dose reasonably required to accomplish its intended technical effect and not more than the maximum dose specified by the applicable regulation for that use", appears to follow the Codex Standard, which requires that for the irradiation of any food, the minimum absorbed dose should be sufficient to achieve the technological purpose and the maximum absorbed dose should be less than that which would compromise consumer safety, wholesomeness, or would adversely affect structural integrity, functional properties, or sensory attributes. Under the US regulation, the 10kGy maximum absorbed dose-threshold is exceeded for the microbial disinfection of herbs and spices (30kGy) and for the sterilisation of frozen, packaged meats used solely in the NASA space flight programs (44kGy), as it seems necessary to achieve the required technological purpose. Also this is in line with the Codex Standard. It should also be noted that current US fruits and vegetables regulations[20] allow the use of irradiation to treat fruit for importation into the US. Specific authorisations have to be granted by the Animal and Plant Health Inspection Service of the US Department of Agriculture (USDA).

Apart from the US, irradiation of certain food is authorised in more than 35 other countries both in Europe and world-wide, such as Brazil, Canada, China, India, Indonesia, Israel, Pakistan, Russia, South Africa, Thailand, and Ukraine.[21] Legislation in those countries is, for the most part, broadly based on the relevant Codex Standards on food irradiation.

A study published in 2009[22] outlined the state-of-play for food irradiation in the world in 2005 (based on published data, a questionnaire survey and direct visits carried out in several countries all over the world) and reported that the total volume of food irradiated worldwide in 2005 was 405,000 tonnes. Commercial food irradiation is significantly increasing in Asia, but decreasing in the EU. China

17 USA, Code of Federal Regulations, 21 CFR 179, as revised on 1 April 2010.

18 Irradiation is permitted for 1) for control of Trichinella spiralis in pork carcasses or fresh, non-heat-processed cuts of pork carcasses; 2) for growth and maturation inhibition of fresh foods; 3) for deinfestation of arthropod pests in food; 4) for microbial disinfection of dry or dehydrated enzyme preparations; 5) for microbial disinfection of certain dry or dehydrated aromatic vegetable substances (i.e., herbs and spices) when used as ingredients in small amounts solely for flavouring or aroma; 6) for control of foodborne pathogens in fresh or frozen, uncooked poultry products; 7) for the sterilisation of frozen, packaged meats used solely in the NASA space flight programs; 8) for control of foodborne pathogens in, and extension of the shelf-life of, certain refrigerated or frozen, uncooked meat products; 9) for control of Salmonella in fresh shell eggs; 10) for control of microbial pathogens on seeds for sprouting; 11) for the control of Vibrio bacteria and other foodborne microorganisms in or on fresh or frozen molluscan shellfish; and 12) for control of foodborne pathogens and extension of shelf-life in fresh iceberg lettuce and fresh spinach.

19 The "Radura" is the international symbol indicating that a food product has been irradiated. The Radura is usually green and resembles a plant in circle. The use of the logo for irradiated food is required under the Codex Alimentarius Standard on Labelling of Prepacked Food.

20 USA, Code of Federal Regulations, CFR, Title 7: Agriculture, Part 305-Phytosanitary treatments; § 305.9 Irradiation treatment requirements.

21 According to the German Max Rubner–Institut of the Federal Research Institute of Nutrition and Food (Bundesforschungsanstalt für Ernährung und Lebensmittel), available at <http://www.bfa-ernaehrung.de/bestrahlung/>, irradiation is authorised in the following European countries: Croatia, Montenegro, Norway, Russian Federation, Serbia, Turkey and Ukraine; in Asia: Bangladesh, China, India, Indonesia, Iran, Israel, Japan, Korea, Pakistan, Philippines, Saudi-Arabia, Syria, Thailand and Vietnam; in Central-, North-, and South America: Argentina, Brazil, Canada, Chile, Costa Rica, Cuba, Mexico, Paraguay, Peru, Uruguay and the US; in Africa: Algeria, Egypt, Ghana, Libya, South Africa, Tunisia and Zambia; and in Australia and New Zealand.

22 Kume T., Todoriki S., and Uenoyama N. *et al.*, "Status of food irradiation in the world", 78 *Radiation Physics and Chemistry* (2009), pp. 222 *et sqq*. As to the products irradiated, the 405,000 tonnes comprised 186,000 tonnes of spices and dry vegetables, 82,000 tonnes of grains and fruits, 32,000 tonnes of meat and fish, 88,000 tonnes of garlic and potatoes, and 17,000 tonnes of other food items including food supplements, mushroom and honey.

was the leading country in the use of food irradiation (146,000 tonnes) followed by the US (92,000 tonnes) and Ukraine (70,000 tonnes), making up three quarters of the total amount of food irradiated in the world in 2005.

3. Approach in the EU and its Member States

a. Regulatory framework in the EU

The irradiation of food in the EU is regulated by Directive 1999/2/EC,[23] which covers general and technical aspects for carrying out the process, labelling of irradiated foods and conditions for authorising food irradiation. In addition, Directive 1999/3/EC[24] establishes an EU list of food and food ingredients authorised for treatment with ionising radiation. So far, this list contains only a single food category: dried aromatic herbs, spices and vegetable seasonings.

Food irradiation may be authorised only if there is a reasonable technological need; if it presents no health hazard and is carried out under the conditions proposed; if it is of benefit to the consumer; and if it is not used as a substitute for hygiene and health practices or for good manufacturing or agricultural practices.[25] Only a very limited quantity of food consumed in the EU is irradiated today.

Since 1999, when the framework Directive and the provisional list of foodstuffs that may be subjected to irradiation were adopted, there have been no further regulatory developments at the EU level. Directive 1999/2/EC stated that the Commission should establish the list in stages and, after examining the national authorisations in force, forward a proposal by 31 December 2000 to complete this positive EU list of foodstuffs authorised for irradiation, to be adopted through the co-decision procedure.[26]

In 2000, before preparing a proposal for the European Parliament and the Council for a positive EU list, the Commission Services launched a consultation with consumer organisations, industry organisations, and other stakeholders on the strategy for drawing up the positive list. The comments revealed strong views, either in favour or against irradiation and, given the complexity of this issue, the Commission considered that a broader debate was opportune at that stage.[27] In the end, the list has not been established, although the European Commission's Scientific Committee on Food[28] (hereinafter, SCF) has indicated in its risk assessments several categories of food and safe dose limits for irradiation (see below).

b. EU Member States' legislation and practices regarding food irradiation

Up to the entry into force of the supplemented positive EU list, existing EU Member States' national authorisations on food irradiation can be maintained under Article 4(4) of Directive 1999/2/EC, provided that: 1) the treatment of the foodstuff concerned has been subject to a favourable opinion of the SCF; 2) the overall average absorbed radiation dose does not exceed the limit values recommended by the SCF; and 3) ionising radiation and placing on the market are effected in accordance with Directive 1999/2/EC (this concerns the permitted radiation sources and labelling requirements). On the other hand, according to Article 4(7) of Directive 1999/2/EC, EU Member States may, until the entry into force of the list, continue to apply existing national restrictions or bans on ionising radiation of foodstuffs and on trade in irradiated foodstuffs that are not included in the initial positive list.

Therefore, in principle, in addition to herbs and spices, all foodstuffs that have been subject to a favourable opinion of the SCF may be authorised for irradiation in EU Member States: this includes fruits, vegetables, cereals, starchy tubers, fish and shellfish, fresh meats, poultry, camembert cheeses manufac-

23 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, OJ 1999 L 66/16, last amended by Regulation (EC) No 1137/2008 of the European Parliament and of the Council, OJ 2008 L 311/1.

24 Directive 1999/3/EC of the European Parliament and of the Council on the establishment of a Community list of foods and food ingredients treated with ionising radiation, OJ 1999 L 66/24.

25 Annex I point 1 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, OJ 1999 L 66/16, last amended by Regulation (EC) No 1137/2008 of the European Parliament and of the Council, OJ 2008 L 311/1.

26 Article 4(3) of Directive 99/2/EC, *supra* note 23, refers to Article 100a of the Treaty (i.e. Article 114 of the TFEU).

27 See Communication from the Commission on foods and food ingredients authorised for treatment with ionising radiation in the Community, OJ 2001 C 241/06.

28 In May 2003, the five Scientific Committees providing the Commission with scientific advice on food safety were transferred to the EFSA.

tured from raw milk, frog legs, shrimp, gum Arabic, casein/caseinates, egg white, cereal flakes, rice flour and blood products. However, only seven EU Member States (i.e., Belgium, Czech Republic, France, Italy, the Netherlands, Poland and the UK) authorise additional products to be irradiated. According to Article 4(6) of Directive 1999/2/EC, the EU publishes a list of Member States' authorisations of food and food ingredients which may be treated with ionising radiation [see Table 1 below]:[29]

List of Member States' authorisations of food and food ingredients which may be treated with ionising radiation

	Authorised at the given maximum overall average absorbed radiation dose (kGy)						
Product / EU Member State	**B**	**CZ**	**F**	**I**	**NL**	**PL**	**UK**
Deep-frozen aromatic herbs	10	10	10				
Potatoes	0.15	0.2		0.15		0.1	0.2
Yams		0.2					0.2
Onions	0.15	0.2	0.075	0.15		0.06	0.2
Garlic	0.15	0.2	0.075	0.15		0.15	0.2
Shallots	0.15	0.2	0.075				0.2
Vegetables, including pulses	1	1					1
Pulses		1			1		
Fruit including fungi, tomato, rhubarb	2	2					2
Strawberries	2	2					
Dried vegetables and fruits	1	1	1		1		
Cereals	1	1					1
Dried fruit		1					
Cereal flakes and germs for milk products	10	10	10				
Flakes from cereals		1			1		
Rice flour	4	4	4				
Gum Arabic	3	3	3		3		
Chicken meat		7			7		
Poultry	5	5	5				
Poultry (domestic fowls, geese, ducks, guinea fowls, pigeons, quails, and turkeys)	7	7					7
Mechanically recovered poultry meat	5	5	5				
Offal of poultry	5	5	5				
Frozen frog legs	5	5	5		5		
Dehydrated blood, plasma, coagulates	10	10	10				
Fish and shellfish (including eels, crustaceans and molluscs)	3	3					3
Frozen peeled or decapitated shrimps	5	5	5				
Shrimps					3		
Egg white	3	3	3		3		
Casein, caseinates	6	6	6				

Irradiation practices vary considerably from country to country within the EU. There are 26 approved food irradiation facilities in 13 of the 27 EU Member States (i.e., Belgium, Bulgaria, Czech Republic, Estonia, France, Germany, Hungary, Italy, the Netherlands, Poland, Romania, Spain and the United Kingdom).[30] Approvals for new irradiation facilities are granted by the competent authorities in EU Member States, in accordance with the procedure established by Directive 1999/2/EC. Each year, EU Member States must inform the European Commission about the amount of food irradiated in facilities on their territory. In addition, they must report on the checks carried out

29 OJ 2009/C 283/5.

30 List of approved facilities for the treatment of foods and food ingredients with ionising radiation in the Member States, OJ 2011 C 336/14.

on food products placed for sale and the results of testing. The European Commission is supposed to publish this annual data.

According to the report for the year 2008, published in 2011,[31] a total of 8,718 tonnes of food were irradiated in approved irradiation facilities in eight EU Member States (i.e., Belgium, Czech Republic, France, Germany, Hungary, the Netherlands, Poland and Spain). This shows that not all approved facilities actually irradiate food. 87.65% of foodstuffs were irradiated in three EU Member States: Belgium (41.19%), the Netherlands (35.61%), and France (10.85%). 83.26% of the irradiated foodstuffs included the following products: frog legs and frog parts (28.16%), herbs and spices (19.95%), poultry meat (18.97%), and vegetables (16.18%). The rest accounts for products such as food samples, gum arabic, starch, fish and shellfish, egg white, and dehydrated blood. These quantities and food categories include both foodstuffs placed on the EU market and foodstuffs exported to third countries. In annual Commission reports from 2000 to 2006, a minimum of around 14,300 tonnes (in 2004) to a maximum of around 19,700 tonnes (in 2002) of irradiated food was reported in the EU.[32] These figures show that, within the EU, irradiation has been used in a limited number of countries (mainly Belgium, France, and the Netherlands), and in relation to a very limited number of products. Within this limited number of allowed foodstuffs, many are often not subject to actual irradiation. The UK, for example, permits irradiation on the following types of foodstuffs: fruit, vegetables, cereals, bulbs and tubers, dried aromatic herbs, spices and vegetable seasonings, fish and shellfish, and poultry. However, there is currently only one licensed irradiation facility in the UK, which is licensed to irradiate a variety of herbs and spices.

The reason why there is a difference between the number of EU Member States that authorise food and food ingredients for irradiation (seven: Belgium, Czech Republic, France, Italy, the Netherlands, Poland, and the UK) and the number of EU Member States in which food is actually irradiated in approved irradiation facilities (eight: Belgium, Czech Republic, Germany, Spain, France, Hungary, the Netherlands, and Poland) is that not all countries in which food is irradiated also authorise (in their legislation) the marketing of irradiated food on their territory (like in the case of Germany). It is also because irradiation does not actually take place in all countries where irradiation is authorised in national legislation.

One question is, therefore, whether irradiated foods can circulate freely within the EU. According to the principle of mutual recognition, a product lawfully marketed in one EU Member State and not subject to EU harmonisation (under the EU framework Directive on irradiation, EU Member States are permitted to keep national provisions dealing with the irradiation of food in force until the "list" is completed) must be allowed for marketing in any other EU Member State, even when the product does not fully comply with the technical rules of the EU Member State of destination. There is one exception to this principle: under the EU Treaty, the EU Member State of destination may refuse the marketing of a product only where it can show that this ban is strictly necessary for the protection of, for example, public safety, health or the environment. Therefore, EU Member States must allow irradiated foodstuffs on their national markets if they are legally irradiated and traded in another EU Member State. If those foodstuffs originated in a third country and are also irradiated there, they can be legally imported in any EU Member State once they have fulfilled the legal conditions of the irradiation directives and are legally on the market of one EU Member State.[33]

In EU Member States' practices, irradiation is dealt with in different ways. This is also the case in relation to the checks carried out at the product marketing stage, and the methods used to detect treatment with ionising radiation. Under Article 7(3) of Directive 99/3/EC, EU Member States shall forward to the Commission every year the results of checks carried out at the product marketing stage. In 2007, a total of 3,744 food samples were examined in Germany, 77 of which had been irradiated. Only two of these samples were found to be compliant with the EU Directives: one sample belonging to the category "Spices and herbs", and one sample belonging to the category "Soups, sauces, instant noodles". The remaining 75 irradiated samples were non-compliant (i.e., 21 samples belonged to categories for which ir-

31 COM(2011) 359 final, Report from the Commission on food irradiation for the year 2008 of 27 June 2011.

32 See data compiled in the following sources: Scientific Opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on the Chemical Safety of Irradiation of Food, adopted on 25 November 2010, and Published on 6 April 2011 in 9:4 *EFSA Journal* (2011), 1930 pp. 15 *et ssq.*

33 Timo Röcke, "The Law on Treatment of Food with Ionising Radiation – Legislative Silence", 4 European Food and Feed Law Review (2006), pp. 203 *et sqq*, at p. 208.

radiation is authorised, but showed non-compliant labelling, 34 samples belonged to categories for which irradiation is not authorised, and 20 samples, mostly noodles and dried soups, were irradiated but it was not possible to determine which of the ingredients in these compound foods were irradiated in order to find out if irradiation was authorised). Other EU Member States performed far fewer tests. It appears that no analytical checks regarding food irradiation were performed in 2007 (or no information was published) by Bulgaria, Cyprus, Denmark, Estonia, Portugal and Romania.[34]

c. Import of irradiated foods from non-EU countries

Irradiated foods imported into the EU from non-EU countries must first have been irradiated at facilities approved by the EU. There are currently ten approved facilities outside the EU (i.e., three in South Africa, one in Turkey, one in Switzerland, two in Thailand, and three in India). Decisions on the approval of food irradiation facilities in non-EU countries are based on the results of inspections performed by the European Commission's Food and Veterinary Office (FVO). In 2009, the FVO completed a mission evaluating Chinese irradiation facilities, and ultimately found that none of the visited facilities met all the requirements of Directive 1999/2/EC concerning the irradiation of foodstuffs.[35] Therefore, products irradiated in China cannot be legally imported into the EU.

As stated above, if a foodstuff originated in a given third country and was also irradiated there in an approved facility, it can be legally imported into any EU Member State. An example is the import of irradiated frozen frog legs onto the German market.[36] German legislation does not permit irradiation of frog legs which are, however, legally irradiated with up to 5 kGy in Belgium, France and the Netherlands. An importer was granted authorisation to import frozen frog legs onto the German market as the products, which originally came from Southeast Asia and were irradiated in a facility approved by the European Commission, were legal on the Dutch market. It should be noted that the products were not first imported into the Netherlands and then freely circulated to Germany, but went directly to Germany according to §54 of the German Food and Feed Code,[37] making use of the principle of mutual recognition. In the relevant part, §54(1) No.2 of the German Food and Feed Code provides that "food imported from a third country which is legal in an EU Member State may be placed on the market in Germany, even if it does not comply with the applicable regulations in Germany for food, cosmetics or consumer goods".

d. Future amendments to EU legislation and EU risk assessments

The European Commission is considering drawing up a proposal to complete the list of food and food ingredients legally authorised for treatment with ionising radiation (i.e., the positive list of Directive 1999/3/EC), and has expressed that any possible addition to this list will have to be considered in light of an update of the scientific opinions previously expressed by the SCF and the other criteria laid down in the legislation. Therefore, the European Commission mandated the EFSA in May 2006 to provide an "updated and general opinion on risks linked to food irradiation" after the SCF had expressed scientific opinions in 1986, 1992 and 1998 on the subject defining the classes of food irradiation and maximum safe doses to apply. In the 1986, 1992 and 1998 opinions on irradiated foods,[38] the SCF gave favourable opinions on irradiation of a number of foodstuffs for which the classes and radiation doses have been listed below in Table 2:

34 OJ 2009/C 242/02, Report from the Commission on food irradiation for the year 2007. For the latest available figures on the frequency of testing and number of incompliant samples in the EU Member States, see the last report available at *supra* note 31.

35 See: Final report of a mission carried out in China from 24 February to 2 March 2009 in order to evaluate food irradiation facilities, DG(SANCO)/2009-8144 – MR – FINAL.

36 Röcke, "The Law on Treatment of Food with Ionising Radiation", *supra* note 33 at p. 208.

37 Lebensmittel- und Futtermittelgesetzbuch of 01.09.2005 in der Fassung der Bekanntmachung vom 22. August 2011 (BGBl. I S. 1770).

38 In a further opinion, the *Revision of the opinion of the Scientific Committee on Food on the irradiation of food* of 4 April 2003 (SCF/CS/NF/IRR/24 Final), the SCF concluded that it is not possible to accept at present the suggested removal of the upper limit of 10 kGy for the production of safe and wholesome irradiated foods. On the basis of the information presently supplied to it, the Committee argued that it is appropriate to specify a maximum dose for the treatment of certain food products by ionising radiation and that irradiated foodstuffs should continue to be evaluated individually, taking into account the technological need and their safety.

General food classes and specific food commodities and radiation doses evaluated as acceptable by the SCF*

Food class/commodity assessed by the SCF	Overall average radiation dose (kGy)	Dose (kGy)
Fruits (a)	Up to 2	
Vegetables (a)	Up to 1	
Cereals (a)	Up to 1	
Starchy tubers (a)	Up to 0.2	
Spices & condiments (a)	Up to 10	
Fish & shellfish (a)	Up to 3	
Fresh meats (a)	Up to 2	
Poultry (a)	Up to 7	
Camembert cheeses manufactured from raw milk (b)		Up to 2.5
Frog's legs (c)	Up to 5	
Shrimps (c)		5
Gum arabic (c)		3
Casein / caseinates (c)		Up to 6
Egg white (c)		Up to 3
Cereal flakes (c)		10
Rice flour (c)		Up to 4
Blood products (c)		10

(a): Assessed by SCF (1986)
(b): Assessed by SCF (1992)
(c): Assessed by SCF (1998)
*: The EFSA states that where previous SCF opinions have considered dose limits for food irradiation, it is not always clear if the Opinion is expressed in terms of overall average dose or maximum dose.
Source: EFSA

The intention of the EFSA's new mandate was basically to evaluate whether, considering the evolving science, previous opinions of the SCF were still up-to-date, and also to get an updated and general opinion on risks linked to food irradiation. The EFSA and the Commission agreed in 2008 on two scientific opinions to be adopted not later than 31 December 2009 (this deadline was later extended to 31 December 2010): one on the efficacy and microbiological safety of irradiation of food; and one on the chemical safety of the process.

(i) EU risk assessments on food law matters

This section describes how risk assessments in food law matters function, and the relevant boundaries dictated by EU law and the WTO (inasmuch as the EU measures may have an impact on trade).

The general principles and procedures on how a risk assessment on food law matters should be carried out are established in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.[39] Article 6 thereof concerns risk analysis and states that:

> "1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.
> 2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.
> 3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the European Food Safety Authority, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5".

Risk management is defined in Article 3 thereof as the process, distinct from risk assessment (i.e., a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation), of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options. Specifications on how risk assessment and risk management are to be performed are given in the introduction to the Regulation: the EFSA should take on the role of an independent scientific point of reference in risk assessment;[40] where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis (i.e., risk assessment, risk management, and risk communication) provide a systematic methodology for the de-

39 OJ 2002 L 31/1–24, last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council, OJ 2009 L 188/14-92.

40 *Ibid.*, at para 34.

termination of effective, proportionate and targeted measures or other actions to protect health;[41] in order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data;[42] and it is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account, including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.[43]

As to the WTO boundaries of an appropriate risk assessment, the EU's approach on risk assessment in relation to food law matters appears to be in line with Article 5 of the SPS Agreement, whereby sanitary or phytosanitary measures have to be based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations (in the assessment of risks, account shall be taken of, e.g., the available scientific evidence).

(ii) New EFSA risk assessments (2010-2011)

According to Article 22(2) of Regulation (EC) No 178/2002, the EFSA shall provide scientific advice and scientific and technical support for the EU's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks. Under paragraph 6 of Article 22, the EFSA shall provide scientific opinions, which will serve as the scientific basis for the drafting and adoption of EU measures in the fields falling within its mission.

In response to the abovementioned request of the European Commission, EFSA's BIOHAZ Panel (on biological hazards) and the CEF Panel (on Food Contact Materials, Enzymes, Flavourings and Processing Aids) adopted in 2010 two distinct scientific opinions: 1) the scientific opinion of the BIOHAZ Panel on "the efficacy and microbiological safety of irradiation of food", adopted on 22 September 2010; and 2) the scientific opinion of the CEF Panel on "the chemical safety of irradiation of food", adopted on 25 November 2010. On 29 March 2011, the EFSA published both opinions and issued a Statement summarising the Conclusions and Recommendations from the Opinions on the Safety of Irradiation of Food adopted by the BIOHAZ and CEF Panels in order to have an overall appraisal of the safety of the irradiation of food.[44]

In its advice to the European Commission, EFSA's BIOHAZ Panel looked at the efficacy of irradiation (understood as the ability of irradiation to reduce foodborne pathogens in food) and microbiological safety of the process (understood as the contribution of irradiation to reduce the risk to human health from foodborne pathogens). The BIOHAZ Panel has also considered potential microbiological risks linked to food irradiation, such as the development of resistance, and the possibility that irradiation might be used to mask unhygienic food production practices, etc.

In general, it was stated that none of these kinds of ionising radiation, when used for food irradiation purposes at the doses established by the Codex Standard and EU legislation, have energy levels sufficient to induce radioactivity in the irradiated food.[45] The EFSA's CEF Panel considered the chemical safety aspects of irradiated food and looked at possible risks arising from the formation of several chemical substances as a result of food irradiation, taking into consideration new information published in the scientific literature since the most recent opinions of the SCF. The EFSA's Panels basically concluded that there are no microbiological risks for the consumer linked to the use of food irradiation. The only new evidence pointing to possible adverse health effects concerns some recent studies reporting neurological problems in cats fed exclusively with animal feed, which had been irradiated at extremely high doses, although further research would be required to assess the possible relevance of these studies for human health.

As to the question of which food categories can be irradiated (and at which doses), the EFSA's Panels did not simply update the SCF's previous opinion, but they also completely changed the criteria on how the assessment should be carried out. The EFSA Panels

41 *Ibid.*, at para 17.

42 *Ibid.*, at para 18.

43 *Ibid.*, at para 19.

44 9:4 *EFSA Journal* (2011), 2107 pp. 1 *et sqq.*

45 *Ibid.*, at p. 10.

recognised the shortcomings of the current classification,[46] and recommended that decisions on foods which can be irradiated and on the doses which may be used, should not be based only on predefined food categories, as is currently the case, but also on other factors. Such factors include the bacteria concerned, the level of bacterial reduction required, whether the food is fresh, frozen, or dried, or on the food's fat or protein content.

The EFSA Panels also indicated that decisions on the type of food which can be irradiated should also take into account the diversity of food products nowadays available to consumers, such as ready-to-eat foods, sliced meat or cheese. With regards to efficacy and microbiological safety, the BIOHAZ Panel recommended that the application of food irradiation should be based on risk assessment and on the desired degree of risk reduction, rather than on predefined food classes/commodities and doses. For the reduction of pathogens, upper dose limits should not be specified.

Therefore, it appears that the recent EFSA opinions no longer follow the systematic approach of previous SCF opinions on irradiation of a number of foodstuffs, with established classes and radiation doses. In view of the EFSA's scientific experts, a mere update and completion of the list of foods that may be irradiated and the respective maximum safe doses are not the appropriate methodology.

Nevertheless, the EFSA's position appears to be more in line with the Codex Alimentarius. In consideration that the previous Codex Standard stated that "the overall average dose absorbed by a food subjected to radiation processing should not exceed 10 kGy", the current Standard adopted in July 2003[47] removed the limitation by defining a more practically applicable statement on dose limitation, stating that the minimum absorbed dose should be sufficient to achieve the technological purpose and the maximum absorbed dose (which should not exceed 10 kGy, except when necessary to achieve a legitimate technological purpose) should be less than that which would compromise consumer safety, wholesomeness, or would adversely affect structural integrity, functional properties, or sensory attributes. The CEF Panel also agrees with the approach of the Codex Standard, which no longer uses the concept of overall average dose (still being used in EU law).[48]

In conclusion, it appears that EFSA's latest assessment seems to acknowledge that the current restrictive EU regulatory framework on food irradiation is not in compliance with the Codex Alimentarius.

(iii) Uncertainty of science and the application of the precautionary principle

There is certainly controversy around the question of the safety of irradiated food in the context of the '*uncertainty of science*'. In particular, some consumer advocacy groups maintain that the safety of irradiated food is not proven and that long-term studies on the effects of consuming irradiated food are still lacking.[49] Criticism is directed also towards the Codex Alimentarius.[50]

In its latest risk assessments, the EFSA describes as the only new evidence pointing to possible adverse health effects some recent studies reporting neurological problems in cats fed exclusively with animal feed, which had been irradiated at extremely high doses. According to EFSA, several hypotheses have been put forward in the scientific literature (e.g., specific sensitivity of cats to deficiency in vitamins, which may be caused by irradiation, peroxides generated by irradiation). However, EFSA finds that "a clear mechanistic explanation in terms of risk assessment has not been established" and concludes that further research would be required to assess the

46 9:4 *EFSA Journal* (2011), 1930 at p. 3.

47 Codex Alimentarius, Codex General Standard for Irradiated Foods No. 106-1983, Rev 1-2003, available on the Internet at <http://www.codexalimentarius.net/web/more_info.jsp?id_sta=16> (last accessed on 28 August 2012).

48 Various terms are used for defining radiation dose and the CEF Panel agrees with the approach of the Codex Standard which no longer uses the concept of overall average dose (which is still used in EU law). Therefore it is considered that the limits should be expressed in terms of a maximum dose. In order to convert the overall average dose into a maximum dose, the conversion factor should not exceed 1.5, which corresponds to the currently maximum allowed dose uniformity ratio of 3.0. 9:4 *EFSA Journal* (2011), at p. 7.

49 See, e.g., Open Letter of Food and Water Watch, French collective against food irradiation and other organisations of 11 October 2010 to EFSA, the European Commission and the European Parliament, and statement of the French collective against food irradiation of 8 April 2011 'Food Irradiation: let us ban it under the precautionary principle!.' Both documents are available on the internet at <http://www.foodandwaterwatch.org/europe/questionable-technologies/food-irradiation/> (last visited on 28 August 2012).

50 It is argued that the fact that the Codex Alimentarius allows food irradiation at virtually unlimited doses presents a risk to countries refusing imports of food because they are irradiated and that this could lead to a complaint before the Dispute Settlement Body of WTO, which could then lead to trade retaliation, as was the case concerning EU measures prohibiting imports of meat from animals treated with hormones in the late 90s. See, Open Letter of Food and Water Watch, French collective against food irradiation and other organisations of 11 October 2010 to EFSA, the European Commission and the European Parliament, available on the internet at <http://www.foodandwaterwatch.org/europe/questionable-technologies/food-irradiation /> (last accessed on 28 August 2012).

possible relevance of these studies for human health. Therefore, the EU risk assessment body deems that there is basically no scientific uncertainty in relation to the safety of food irradiation. The European Commission as risk manager is ultimately not bound by its risk assessment body[51] and may not follows the latest risk assessments by EFSA and may not modify its current approach accordingly. In addition, it should be noted that in other contexts, such as in biotechnology, even the scientific independence of EFSA's scientists has been questioned.[52]

Provided the EU regulator were to conclude that, for some reason, there is scientific uncertainty in relation to the irradiation of food, the question of the application of measures based on the precautionary principle would arise.

Article 7 of Regulation (EC) No. 178/2002[53] concerns the precautionary principle:

"In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment."

According to the relevant EU jurisprudence, in case of scientific uncertainty as to the existence of a risk to human health, the EU institutions may invoke the precautionary principle in order to adopt protective measures, in spite of the fact that a proper risk assessment showing conclusive scientific evidence cannot be conducted. Such measures cannot, however, be based on a purely hypothetical approach founded on mere hypotheses and may be adopted only if the risk appears to be properly backed up by the scientific studies available at the time when the measure is taken.[54]

In this context, further insights may be taken from the Gowan Judgment of the European Court of Justice of 22 December 2010[55], which deals with the question of whether and under which conditions European authorities can depart from the outcome of risk assessment while adopting risk management measures. It has been argued that "by failing to surround the invocation of the precautionary principle with a set of procedural guarantees, the Court allowed the policy-makers to dress up a public concern, (in the case at stake in Gowan, the risk of endocrine disruption) in the clothing of a science-based concern, although this time it was not emerging as such from the risk assessment."[56] Furthermore, while it is not the first time that the ECJ enables the EU institutions to accommodate public concern within its risk decision-making, this time the Court seems to accept that this might occur in a hidden way, after having concealed it under '*scientific uncertainty*' clothes, and with science made out to be the real justification.[57]

It remains to be seen whether scientific uncertainty and the possibility of harmful effects on health might be addressed by the European Commission in it policy decision in relation to food irradiation.

(iv) Public opinion on food irradiation and its possible influence on regulators

In the context of food irradiation, public opinion plays a special role. Irradiation has not been widely

51 On the relation of EFS with the European Commission, see: Alberto Alemanno, The European Food Safety Authority at Five, 1 European Food and Feed Law Review (2008), pp. 2 *et sqq*

52 EFSA's scientific independence has been questioned over the last years, arguing that too often it is not independent science that underlies EFSA opinions. See, e.g., Conflicts on the menu. A decade of industry influence at the European Food Safety Authority (EFSA), report by Corporate Europe Observatory (CEO) and Earth Open Source (EOS), February 2012. Available on the internet at <www.corporateeurope.org> (last accessed on 28 August 2012).

53 *Ibid*. Article 14(4)a) of Regulation (EC) No 178/2002 even establishes that "In determining whether any food is injurious to health, regard shall be had: (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations."

54 See Case T-13/99, Pfizer v. Council [2002] ECR p. II-3305, paras 143-144. For a review of the jurisprudence of the EU and EFTA courts on the precautionary principle, see Alberto Alemanno, The Shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Certainty, Valori Costituzionali E Nuove Politiche Del Diritto, L. Cuocolo, L. Luparia, eds., Cahiers Europèens, Halley, 2007.

55 'Case C-79/09, Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute, Judgment of the Court of Justice (Second Chamber) of 22 December 2010.' In the case at stake, following a favourable assessment of a pesticide and a favourable draft proposal by the European Commission, the authorisation procedure for fenarimol, a fungicide, ended with a Directive restricting its use, relying on the precautionary principle. The Court concluded that since there was still "some scientific uncertainty regarding the assessment of the effects on the endocrine system" at the time the draft decision was drawn up, the Commission cannot be considered to have erroneously applied the precautionary principle.

56 For a detailed analysis of the Gowan judgment, see: Alberto Alemanno, 'Case C-79/09, Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute, Judgment of the Court of Justice (Second Chamber) of 22 December 2010' (2011), 48 Common Market Law Review pp. 1329–1348.

57 Alberto Alemanno, "Case C-79/09, Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute, Judgment of the Court of Justice (Second Chamber) of 22 December 2010", 48 *Common Market Law Review* (2011), pp. 1329–1348.

adopted in the EU due to an asserted negative public perception, the concerns expressed by some consumer groups, and the reluctance of many food producers. In simple terms, there is scepticism regarding whether irradiation of food can be safe when radiation itself is considered to be dangerous.[58] The question is whether public opinion considerations have to be considered in risk management decisions.

As stated above, it is recognised in EU law that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account, including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.[59]

Therefore, it seems that objections in relation to food irradiation have to be taken seriously both in the process of risk management and the legislative work. The debate in the EU is not only scientific about the possible risks and benefits of irradiation; it is also about the usefulness and effectiveness of irradiation and consumer concerns. Consumer advocacy groups strongly oppose the use of the technology and maintain that the safety of irradiated food is not proven and that, in particular, it is argued that long-term studies are still lacking. Certain retailers prefer not to sell irradiated products for reasons of consumer perception. It is also argued that large-scale irradiation would increase processing, transportation, and handling times for fruits and vegetables, thus contributing to a negative ecological balance compared to locally grown foods. Nutritional effects, for instance the reduction of vitamin levels, are also debated in relation to food irradiation. In conclusion, there seems to be numerous aspects, including societal concerns, which the EU takes into consideration in relation to risk management decisions regarding irradiation.

III. International trade aspects

This section concerns potential trade conflicts with the current regulatory framework on food irradiation in the EU, and addresses the question of whether irradiation is an effective, viable and acceptable means of food hygiene, in particular for developing, emerging and newly industrialised countries. Finally, potential violations of WTO rules by the EU system on food irradiation are framed.

1. Potential trade conflicts with the current regulatory framework on food irradiation in the EU

The current EU approach on food irradiation, which authorises irradiation of certain product categories and sets upper dose limits, is not in line with the approach used in internationally-recognised standards, such as the Codex Alimentarius and the IPPC (both described above), which focus on the technological purpose of the treatment (and the minimum absorbed dose to achieve it) and a maximum absorbed dose which should be less than that which would compromise consumer safety and wholesomeness of the food (i.e., only exceeding 10 kGy when necessary to achieve a legitimate technological purpose).

The question is whether this current restrictive regulatory framework on food irradiation in the EU has an impact on international trade. To elaborate statistics on the amount of fruit (for example) that is not entering the EU because of it having been irradiated or because of it not having a market (due to distance, pest presence, etc.) if not irradiated, is not a simple task. Foodstuffs treated with ionising radiation may not be imported from a third country unless they are accompanied by documents showing the name and address of the EU-approved irradiation facility which carried out the irradiation treatment and providing information such as the nature and quantity of foodstuffs irradiated.

The rapid alerts under the EU Rapid Alert System for Food and Feed (RASFF) indicate that there is trade in unauthorised irradiated products coming, in particular, from Southeast Asia. There are numerous notifications and border rejections related to unauthorised irradiation of products imported into the EU. For example, since 1 January 2010, different EU Member State Authorities have detected unauthorised irradiation in a number of Chinese products (i.e., flavoured linseed covered soybeans, food supplements, herbal tea, red rice yeast powder extract, dried shredded squid, ginseng, cactus extract, pigweed

58 Röcke, "The Law on Treatment of Food with Ionising Radiation", *supra* note 33 at p. 204.

59 In relation to the issue that, apart from science, decision makers should take into account other legitimate factors, such as societal, ethical or traditional concerns, see: Anna Szajkowska, "Different Actors, Different Factors – Science and Other Legitimate Factors in the EU and National Food Safety Regulation", 4 *European Journal of Risk Regulation* (2011), pp. 523 *et sqq*.

powder extract, red yeast rice, sauce for noodles, dried and salted blue whiting fish, spicy tofu), but also in frozen frog legs from Indonesia and Vietnam, spices from the US, food supplements from Russia, the US and Israel, vegetable dishes from Taiwan, tea from Russia, and various cases of irradiated seafood from Vietnam. The recently published RASFF annual report for the year 2010[60] states that, in 2010, thirty notifications reported to RASFF concerned irradiation of food, that the number of notifications on irradiation doubled compared to 2009, and that most reported products were originating from China and from the United States, where there are no EU-approved facilities. The reasons for the rejections may be an unauthorised product category, an overly high dose, and/or irradiation in a non-approved facility. In any event, it is clear that irradiated products are being exported to the EU.

As described above, EU Member States have used the clause in Directive 99/2/EC allowing the retention of authorisations prior to 1999 for irradiation of a wide range of foods, in particular in Belgium, the Czech Republic, France, the Netherlands, and the UK. Even if the quantities irradiated on EU territory do not appear to increase, worldwide they do, and the EU market is interesting and commercially attractive for products that are susceptible of being irradiated, such as frog legs, fruit and vegetables, poultry meat, and shrimps. China, India and Southeast Asian countries have become significant exporters to the EU. The irradiation of all these commodities has been authorised by some EU Member States (frog legs in Belgium, the Czech Republic, France and the Netherlands; fruit and vegetables in Belgium, the Czech Republic and the UK; poultry meat in Belgium, France, the Czech Republic and the UK; and shrimps in the Netherlands), and these products may be imported into the EU if they have been irradiated in an EU-approved irradiation facility. But the approval of third country irradiation facilities does not seem to be straightforward, as exemplified by the rejection of the request from the Chinese Authorities for the approval of four irradiation facilities for the purposes of exporting irradiated foodstuffs. Furthermore, a number of products which seem to be irradiated in practice, like prepared meals and food supplements, are currently not authorised in any Member State.

2. Is irradiation an effective, viable and acceptable means of food hygiene, in particular for developing, emerging and newly industrialised countries?

Restrictions on food irradiation in developed countries appear to arise more due to the fact that irradiation is not accepted in public opinion, rather than because irradiation is not considered an effective, viable and acceptable means of food hygiene. The question is whether food irradiation is an effective, viable and acceptable means of food hygiene, especially for developing emerging and newly industrialised countries. In developing countries in Asia and Africa, foodborne diseases and post-harvest losses due to insect infestation are frequent, and the use of chemicals has created problems related to health, environment and workers' safety. In terms of food trade, developing countries have to comply with the increasingly strict standards of quality and hygiene in major importing markets.

In September 1993, the IAEA General Conference endorsed a detailed project proposal for the introduction of commercial-scaled food irradiation in developing countries through appropriate technical cooperation channels, and in collaboration with other United Nations organisations, including the FAO, WHO, and the International Trade Centre. Already in 1994, an IAEA publication concluded that food irradiation can provide developing countries with an additional instrument to combat high food losses and foodborne diseases, and to broaden trade markets for various food commodities. The IAEA argued that, as the world's population is growing and there are rising pressures on agricultural resources, all available technologies to safely process and preserve food will have vital roles, both in health and economic terms.[61]

Work conducted by the FAO and the IAEA has stimulated interest in applying the irradiation process commercially and for purposes of developing international standards to regulate and promote its use. Argentina, Brazil, China, Colombia, India, Ghana, Guatemala, Mexico, Nigeria, Sri Lanka, Thailand and the Philippines have plans for new or additional ir-

60 See European Commission, Directorate General for Health & Consumers, Rapid Alert System for Food and Feed, available on the Internet at <http://ec.europa.eu/food/food/rapidalert/index_en.htm> (last accessed on 28 August 2012).

61 Paisan Loaharanu, "Food irradiation in developing countries: A practical alternative", *IAEA Bulletin*, 1/1994, pp. 30 *et sqq*..

radiation facilities for the phytosanitary treatment of foodstuffs, especially fruits, which are being increasingly traded on the international market. According to the IAEA, such facilities require investments ranging between $15–20 million (US)and $50–70 million (US), depending on the technology used.[62]

The cost of irradiation facilities seems to be within the range of plant costs for other technologies, for example, a moderately-sized, ultra-high temperature plant for sterilising milk, fruit juices, and other liquids or a small vapour-heat treatment plant for de-infestation of fruits. The FAO argues that often the capital costs of irradiation equipment are seen as prohibitive, even though low operating costs for most commodities make per-unit costs very competitive vis-à-vis other treatments. Most of these facilities combine irradiation of various food products and treatment of other non-food items such as cosmetics, pharmaceutical and disposable medical products. It is argued that irradiation provides the added economic benefit of prolonged fresh market life to many foods, decreased waste, and increased market potential of the food.[63]

These alleged advantages should be considered in any cost-benefit analysis. The effectiveness and viability of food irradiation as a measure of food hygiene can be best addressed by means of an example. Mangoes have a short "shelf life", and bruise very easily. The high rate of respiration, moisture loss and susceptibility to infestation with pests, especially when ripe, limit the shelf life of mangoes to a couple of days. This short shelf life aggravates post-harvest losses and does not allow for efficient distribution and marketing. Because of being highly perishable, mangoes from regions like India or Pakistan can be difficult to export to the EU or US markets by sea. Exporting by air adds substantial freight costs to the price of the produce and makes it uncompetitive in export markets. As attempts to extend the shelf life by other means (i.e., refrigeration) have apparently not been very successful, irradiation of mangoes is considered to be an alternative.

On 25 August 2010, the Animal and Plant Health Inspection Service of the US Department of Agriculture (USDA) issued a *Notice of Decision to Issue Permits for the Importation of Fresh Mango Fruit from Pakistan into the Continental United States*,[64] based on the findings of a pest risk analysis.[65] Based on this evaluation, the USDA believes that the application of irradiation with a minimum absorbed dose of 400 Gy[66] will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh mango fruit from Pakistan. The decision is based on the abovementioned US fruits and vegetables regulations[67] that allow the use of irradiation to treat fruit for importation into the US. In addition to mangoes from Pakistan, since April 2007, India is shipping mangoes irradiated with a minimum absorbed dose of 400 Gy to the US. This practice was later followed by Thailand, which started shipping mangoes and longans to the US as of 1 November 2007. Other fruits that may be imported into the US from Thailand after having been irradiated are litchi, lotus root, mangosteen, pineapple, rambutan and dragon fruit.[68] Irradiated commodities are also permitted from Vietnam (dragon fruit), Malaysia (rambutan), and Mexico (guava and sweet lime).[69] Imports of irradiated eggplant, okra, and pepper are permitted from Ghana, although trade in these products is currently not taking place as there are no preclearance programs in force.

Irradiation also seems to be attractive for imports from other developed countries. On 25 October 2011, the USDA Animal and Plant Health Inspection Service published a proposed rule according to which mangoes may be imported into the continental US from Australia if they have been treated by irradia-

62 Contributions to Global Food Security by the Joint Division of the Food and Agriculture Organization and the International Atomic Energy Agency, *Atoms for Food – a global partnership* (IAEA and FAO, October 2008), at p. 11, available on the Internet at <http://www-naweb.iaea.org/nafa/fao1008.pdf> (last accessed on 28 August 2012).

63 International Consultative Group on Food Irradiation – Food and Environmental Protection Section, *Facts about food irradiation* (Joint FAO/IAEA Programme, Division of Nuclear Techniques in Food and Agriculture, 1999).

64 USA, Federal Register/Vol. 75, No. 166/27 August 2010/Notices, at p. 52712.

65 USA, Department of Agriculture, Animal and Plant Health Inspection Service, Importation of Fresh Mango Fruit (*Mangifera indica L.*) from Pakistan into the Continental United States, Risk Management Document, 2 March 2010, available on the Internet at <http://www.regulations.gov/#!docketDetail;rpp=10;po=0;D=APHIS-2010-0065> (last accessed on 28 August 2012).

66 400 Gy = 0.4 kGy.

67 USA, Code of Federal Regulations-CFR, Title 7: Agriculture, Part 305-Phytosanitary treatments; § 305.9 Irradiation treatment requirements).

68 The importation of irradiated dragon fruit from Thailand is permitted according to a recent decision of 4 October 2011.

69 USA, Department of Agriculture Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Fresh Fruits and Vegetables Import Manual, May 2011, available at <http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/fv.pdf> (last accessed on 28 August 2012).

tion for plant pests of the class Insecta, except pupae and adults of the order Lepidoptera.[70]

3. Relevance of the WTO and applicable WTO rules

The irradiation of food is a tool to ensure food safety. The SPS Agreement disciplines the application of food safety and animal and plant health regulations. "Sanitary or phytosanitary measure" is defined in Annex A of the SPS Agreement as a measure applied, e.g., to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs. The aim of the EU framework on food irradiation regulations (Directive 1999/2/EC,[71] which covers general and technical aspects for carrying out the process, labelling of irradiated foods, and conditions for authorising food irradiation, and Directive 1999/3/EC[72] establishing the EU list of food and food ingredients authorised for treatment with ionising radiation) can be broadly described as designed to protect human health from risks arising from food irradiation. Therefore, the EU regulatory framework on food irradiation appears to fall within the scope of the SPS Agreement, and EU Directive 1999/2/EC can be considered an SPS measure.

The SPS Agreement requires that SPS measures be enacted and maintained on the basis of scientific evidence and a risk assessment, or on the basis of a relevant international standard. The SPS Agreement allows countries to set their own standards, but it also states that regulations must be based on science. Regulations should be applied only to the extent necessary to protect human, animal or plant life or health, and they should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail. In particular, Article 2.2 of the SPS Agreement provides that Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles, and is not maintained without sufficient scientific evidence, except for precautionary measures as provided for in Article 5.7 of the SPS Agreement.

Articles 2.2 and 5.1 of the SPS Agreement (read together) require that all SPS measures be based on scientific evidence and a risk assessment, respectively. The current EU regulatory framework on food irradiation, which authorises irradiation of certain predefined product categories and sets upper dose limits, appears to violate Articles 2.2, 5.1, and 5.2 of the SPS Agreement (which requires that, in their assessments of risks, WTO Members must take into account a series of enumerated factors, such as available scientific evidence), because this approach does not seem to be based on a risk assessment or is maintained without sufficient scientific evidence. As shown above, it is not backed by the SCF and EFSA assessments, in particular the latest EFSA assessments. Without a scientific risk assessment that identifies the adverse effects on human health arising from irradiated food, regulations restricting food irradiation would most likely be found to be inconsistent with Articles 5.1 and 5.2 of the SPS Agreement if these were to result in restrictions on trade in irradiated food products.

Under Article 3.1 of the SPS Agreement, WTO Members are encouraged to use international standards, guidelines and recommendations of the Codex Alimentarius Commission (food safety), the IPPC (plant protection and quarantine), and the International Office of Epizootics (animal health and quarantine), where they exist. However, according to Article 3.3, WTO Members may use measures that result in higher (i.e., stricter) standards if there is scientific justification. They can also set higher standards based on an appropriate assessment of risks, so long as the approach is consistent and not arbitrary. Countries' SPS measures must be based on an appropriate assessment of the actual risks involved (Article 5).

The current EU regulatory framework on food irradiation does not appear to be in line with the approach used in internationally-recognised standards, such as the Codex Alimentarius and the IPPC, which focus on the technological purpose of the treatment, the minimum absorbed dose to achieve it and a maximum absorbed dose, which should be less than that which would compromise consumer safety and the

70 USA, Federal Register, Vol. 76, No. 206 of 25 October 2011, at p. 65988.

71 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, OJ 1999 L 66/16, last amended by Regulation (EC) No 1137/2008 of the European Parliament and of the Council, OJ 2008 L 311/1.

72 Directive 1999/3/EC of the European Parliament and of the Council on the establishment of a Community list of foods and food ingredients treated with ionising radiation, OJ 1999 L 66/24.

wholesomeness of the food (i.e., only exceeding 10 kGy when necessary to achieve a legitimate technological purpose). It is also not backed with science, as the latest EFSA assessments demonstrate. Therefore, a violation of Article 3.3 of the SPS Agreement may be argued, because the regulations exceed the level of sanitary or phytosanitary protection achieved by the relevant international guidelines without a scientific justification or risk assessment.

With the existence of the Codex General Standard for Irradiated Foods, which recognises the safety and effectiveness of food irradiation, and the endorsement of irradiation as a quarantine treatment within IPPC, there are international standards which should be used by WTO Members. WTO Members may use measures that result in higher (i.e., stricter) standards if there is scientific justification. They can also set higher standards based on appropriate assessment of risks, so long as the approach is consistent and not arbitrary. There do not seem to be scientific grounds for a different approach other than a need for a technological purpose of the irradiation treatment without compromising consumer safety and wholesomeness of the food, as established by the Codex Standard on food irradiation.

4. The question of scientific uncertainty and the precautionary principle under WTO law

To some extent, WTO Members can apply the precautionary principle to deal with cases where relevant scientific evidence is insufficient.[73] Article 5.7 of the SPS Agreement allows provisionally precautionary measures, on the basis of available pertinent information, including from the relevant international organisations, as well as from sanitary or phytosanitary measures applied by other WTO Members.

The application of Article 5.7 requires cumulative satisfaction of the following requirements: (i) insufficiency of scientific data, (ii) that the measure is based on available pertinent information, (iii) that the Member seeks to obtain additional scientific information, (iv) that the provisional measure is the subject of review within a reasonable time.[74] Insufficiency of scientific data exists if "a body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment or risks as required under Article 5.1".[75] The Appellate Body added in the same case that the concept of insufficiency should not exclude "cases where the available evidence is more than minimal in quantity but has not led to reliable or conclusive results".[76] In EC-Hormones, the Appellate Body held that a panel charged with determining, for instance, whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible (e.g., life terminating) damage to human health are concerned.[77]

Is the irradiation of food a case of scientific uncertainty and are there potential threats to human health? Further to the argument put forward by consumer advocacy groups that the safety of irradiated food is not proven and that long-term studies on the effects of consuming irradiated food are still lacking, in its latest risk assessments, the EFSA describes as the only new evidence pointing to possible adverse health effects some recent studies reporting neurological problems in cats and that further research would be required to assess the possible relevance of these studies for human health.

As a comparison, in *EC-Biotech Products*, the European Communities argued that GMOs are characterised by scientific complexity and uncertainty and contended that during recent years scientific understanding of, and knowledge about, risks potentially arising from GMOs and GMO-derived products have evolved, but remain incomplete. In addition, the European Communities noted that many questions

73 In general in relation to uncertainty of science and the application of the precautionary principle, see: Lukasz Gruszczynski, "The Role of Science in Risk Regulation under the SPS Agreement, European University Institute", EUI Working Paper Law No. 2006/03; Lukasz Gruszczynski, "SPS Measures Adopted in Case of Insufficiency of Scientific Evidence", in Julien Chaisse and Tiziano Balmelli (eds) *Essays on the Future of the World Trade Organization Volume II, The WTO Judicial System: Contributions and Challenges* (Editions interuniversitaires suisses – Edis 2008), p. 91 *et sqq*.

74 See Appellate Body Report, Japan–Measures Affecting Agriculture Products, WT/DS76/AB/R, adopted on March 19, 1999, para. 89; Appellate Body Report, Japan – Measures Affecting the Importation of Apples, WT/DS245/AB/R, adopted December 10, 2003 [hereinafter Japan-Apples] para. 176; Panel Report, European Communities – Measures Affecting The Approval And Marketing Of Biotech Products, AWT/DS291/R, WT/DS292/R, WT/DS293/R, adopted on of 29 September 2006, at para, 7.2973.

75 Japan-Apples para. 179.

76 Japan-Apples para. 185.

77 Appellate Body Report, EC Measures Concerning Meat And Meat Products (Hormones), WT/DS26/AB/R, WT/DS48/AB/R, adopted on 16 January 1998, para. 124.

remain unanswered, and that there is limited experience with GMOs in terms of time and quality, and pointed out in this regard that only very few systematic studies have so far been conducted on indirect and long-term effects of large-scale cultivation of GMOs.[78]

A similar argumentation could be made in the case of irradiation, but there should be some sort of monitoring programme to assess the long-term effects of food irradiation on human health. Therefore, whether in its policy decision the EU could meet the test provided in the SPS Agreement is debatable.

5. Discussions taking place within the relevant international fora (primarily FAO-Codex and WTO)?

Discussions within the relevant international fora (primarily FAO-Codex and WTO) do not seem to be currently taking place, but there have been issues concerning the EU regulatory framework in the past which have not yet been resolved. In a document submitted in July 2001 to the WTO Committee on Sanitary and Phytosanitary Measures,[79] the US stated that following the adoption of two EU directives on food irradiation in 1999 (including only dried aromatic herbs, spices and vegetable seasonings in the positive list), in January 2001, it had sent comments on an EU consultation paper (which describes possible strategies for expanding the positive list). The US requested that all foods which received a favourable opinion from the SCF be included in the positive list and also requested information on how additional foods could be added to this list.

Already in 1998, in a meeting of the WTO SPS Committee,[80] when discussing the notification by the EU of measures on food treated with ionising irradiation,[81] the US considered that the Directive was a positive step toward recognising the role that this technology could play in ensuring the wholesomeness and safety of food. However, the US emphasised that the list of products which may be irradiated in the EU should be expanded to cover other food products such as pork, beef, poultry, fruits and vegetables, and also requested an explanation of how the EU approval process for treatment facilities worked. According to the document of 1 March 2011 of the Committee on Sanitary and Phytosanitary Measures on "Specific Trade Concerns", a solution to the issue of the EU Measures on food treated with ionising radiation raised by the US in 1998 and 2001 has not been reported.[82]

V. Conclusions

The current EU approach on food irradiation, which authorises irradiation of certain predefined product categories and sets upper dose limits, does not appear to be in line with the approach used under the relevant internationally-recognised standards, such as the Codex Alimentarius and the IPPC, which focus on the technological purpose of the treatment, the minimum absorbed dose to achieve it, and a maximum absorbed dose, which should be less than a dose which would compromise consumer safety and the wholesomeness of the food (i.e., only exceeding 10 kGy when necessary to achieve a legitimate technological purpose). It is also not backed by scientific justification, as the latest EFSA assessments demonstrate.

This currently restrictive regulatory framework on food irradiation in the EU appears to have a negative impact on international trade. Irradiated products are being imported into the EU, but in relatively small numbers, and pursuant to complicated and restrictive procedures. The EU's regulatory framework on food irradiation has a particularly negative effect on the trading opportunities of food from developing, emerging and newly industrialised countries, which could often only have a market in the EU if exported as irradiated products, due to their highly perishable nature. This stance by the EU appears to be some-

78 Panel Report, European Communities – Measures Affecting The Approval And Marketing Of Biotech Products, AWT/DS291/R, WT/DS292/R, WT/DS293/R, adopted on of 29 September 2006, at para, 7.1520.

79 WTO, Committee on Sanitary and Phytosanitary Measures – Specific Trade Concerns – Submission by the United States Regarding G/SPS/GEN/204/Rev.1, document number G/SPS/GEN/265.

80 WTO, Committee on Sanitary and Phytosanitary Measures – Summary of the Meeting Held on 15-16 September 1998 – Note by the Secretariat, document number G/SPS/R/12, at paras. 37-38. See also WTO, Committee on Sanitary and Phytosanitary Measures – Summary of the Meeting Held on 10 – 11 July 2001 – Note by the Secretariat, document number G/SPS/R/22, at para. 127.

81 WTO, Committee on Sanitary and Phytosanitary Measures – Notification of Two Common Positions for: (a) A Framework Directive (FD) and (b) An Implementation Directive (ID), document number G/SPS/N/EEC/61.

82 WTO, Committee on Sanitary and Phytosanitary Measures – Specific trade concerns – Note by the Secretariat – Issues not considered in 2010 – Addendum, document number G/SPS/GEN/204/Rev.11/Add.2, at paras. 216 and 217.

what disproportionate and not adequately supported by science.

Ultimately, a convincing argument could be made that the EU regulatory framework on food irradiation is inconsistent with WTO law. With the existence of the Codex General Standard for Irradiated Foods, which recognises the safety and effectiveness of food irradiation, and the endorsement of irradiation as a quarantine treatment within the IPPC, there are clear and agreed international standards that should be used by WTO Members when regulating this sector and its impact on trade. WTO Members may use measures that result in higher (i.e., stricter) standards if there are scientific justifications. WTO Members can also set higher standards based on an appropriate assessment of the risks involved, so long as the approach is consistent and not arbitrary.

The recent EFSA assessments, which the European Commission has requested in view of drafting new EU legislation on food irradiation, basically concluded that there are no microbiological risks for the consumer linked to the use of food irradiation. The EFSA's approach appears to be in line with the Codex Alimentarius, inasmuch as it recommended that the application of food irradiation should be based on risk assessments and on the desired degree of risk reduction (e.g., bacterial reduction required), rather than on the application to predefined food classes/commodities and doses.

Furthermore, for purposes of reducing pathogens, upper dose limits should not be specified. According to the EFSA, decisions on the food that may be irradiated and on the doses to be used in irradiation should also be based on 'scientific' factors such as whether the food is fresh, frozen, or dried, or on the food's fat or protein content, taking into account the diversity of food products nowadays available to consumers such as ready-to-eat foods, sliced meat or cheese. This does not appear to inform the current approach by the EU and essentially results in negative trade impacts.

Provided the EU regulator were to conclude that, for some reason, there is scientific uncertainty in relation to the irradiation of food, the question of the application of measures based on the precautionary principle would arise. It should be recalled that under WTO law the precautionary principle can be used with a number of clear safeguards and that relevant dispute settlement precedents exist as to how far the precautionary principle can go to temporarily allow for the adoption of policies that may have negative effects onto trade.

Ultimately, the EU must base its measures on scientific principles, on relevant international standards, and choose the least trade-distortive measures that are available (i.e., ensure that they are applied only to the extent necessary to protect human, animal or plant life or health). The latest EFSA assessments appear, at the same time, to open the way for a fundamental regulatory change of parameters (such that food irradiation regulations need to be scientifically-justified and in line with relevant international standards), and to weaken the EU stance vis-à-vis the possible instances where the current rules on food irradiation prevent (de jure or de facto) access to the EU market by third countries' operators and products.