

EVALUATION AND FITNESS CHECK (FC) ROADMAP				
TITLE OF THE EVALUATION/FC	Evaluation of legislation related to the irradiation of food and food ingredients			
LEAD DG – RESPONSIBLE UNIT	DG SANTE G4	DATE OF THIS ROADMAP	03/2017	
TYPE OF EVALUATION	Evaluation Mixed	PLANNED START DATE	Q4/2017	
		PLANNED COMPLETION DATE	Q4/2018	
		PLANNING CALENDAR	http://ec.europa.eu/smart-regulation/evaluation/index_en.htm	
This indicative roadmap is provided for information purposes only and is subject to change.				

A. Purpose
(A.1) Purpose
<p>Directives 1999/2/EC (framework Directive) and 1999/3/EC (implementing Directive) set out the legal framework to improve the free movement of irradiated foodstuffs within the single market. The purpose of this evaluation is to assess, in the light of the experience gained and technical progress made during their implementation, whether they are still fit for purpose. The evaluation will consider past and current performance and provide an assessment through five different criteria: relevance, effectiveness, efficiency, EU-added value and coherence. The evaluation is expected to provide a sound evidence base which will be used to identify the need for any changes to the legislation.</p>
(A.2) Justification
<p>Since its entry into force in 1999, no evaluation of the Directives has taken place, despite a considerable degree of scientific and technological development in the sector. An evaluation is therefore considered essential in the context of the Commission's better regulation policy to ensure that it is fit for purpose.</p> <p>Every year the Commission publishes a report to the European Parliament and the Council based on information provided by Member States. The reports contain the results of checks carried out by Member States in irradiation facilities, including, in particular, the categories and quantities of foodstuff treated with ionising radiation and the doses administered, and the results of checks carried out at product marketing stage. Currently only one category of foodstuffs, dried aromatic herbs, spices and vegetable seasoning, is authorised for irradiation at EU level and may circulate freely within the single market. While Member States could agree on that category of foodstuffs where irradiation allows to address their inherent high microbial load and to ensure their safety, they preferred to stay with their national approaches on other types of foodstuffs. National authorisations for other foodstuffs thus exist in seven Member States (BE, CZ, FR, IT, NL, PL, UK) while other Member States may restrict or ban irradiated foodstuffs because they are not on the EU list. As there is only one category of irradiated foodstuffs able to circulate in the internal market, this may explain the continuous decline in the use of irradiation within the EU over the past 20 years whilst its use is steadily growing outside the EU (the Americas and Asia). As a consequence, competent authorities in the EU and third countries, together with European industry, are calling on a regular basis for an extension to the very limited scope of the application of the irradiation legislation.</p>
B. Content and subject of the evaluation
(B.1) Subject area
<p>Technically, food irradiation is the treatment of foodstuffs by a certain type of radiant energy known as ionising radiation. Radiant energy has differing wavelengths and degrees of power and disappears when the energy source is removed.</p>

<p>Irradiation is used for sanitary and phytosanitary purposes. It is a safe and effective way to kill bacteria, such as salmonella, campylobacter and E. coli, that can cause food poisoning and it helps eliminating organisms harmful to plant or plant products such as insects and pests. In addition it delays fruit ripening, helps to stop vegetables such as onions and potatoes from sprouting or germination, and ultimately contributes to extending the shelf-life of foods. For example, irradiation of a food ingredient such as aromatic herbs, spices and vegetable seasonings, common in many dishes worldwide including ready-to-eat and processed food, enables bacteria that can affect these foodstuffs naturally through the soil despite the most hygienic harvesting and drying process to be destroyed. Without this treatment, the shelf-life of certain foodstuffs would be greatly reduced and the safe use of these ingredients could not be guaranteed. Irradiation of food does not replace proper food handling and irradiated food still requires appropriate refrigeration and to be cooked prior to consumption. Irradiation of food does not lead to radioactive food.</p> <p>The EU regulatory framework for irradiation of food is strict: treatment can only take place in approved treatment facilities, under stringent safety conditions and only for certain types of foodstuffs which have undergone a favourable scientific assessment thus guaranteeing the treated food is fit for human consumption. Irradiated food placed on the market in the EU must be labelled. All irradiated food imported from a third country into the EU must be treated in facilities approved by the EU and the food must meet EU requirements.</p> <p>Food irradiation is used worldwide. Agricultural and food products currently irradiated represent 700,000 tons per year, of which only 1% is treated in the EU. Since 2007, on average 6000 tons of foodstuffs are irradiated each year. This comprises mainly of frogs legs (55%) and dried aromatic herbs, spices and vegetable seasoning (16%).</p> <p>However, current use in the EU is limited because the EU positive list of foods authorised to be irradiated contains only dried aromatic herbs, spices and vegetable seasonings and thus it is only this category of irradiated foodstuff which may circulate freely within the EU. National authorisations existing prior to 1999 in seven Member States, containing other foodstuffs which may be irradiated, are still in force. This means that while seven Member States can authorise and carry out the irradiation of a number of foodstuffs, other Member States may still restrict or ban these irradiated foodstuffs because these foodstuffs have not yet been placed on the harmonised EU list.</p>
<p>(B.2) Original objectives of the intervention</p> <p>The overall objective of the irradiation Directives is to achieve the free movement of irradiated foodstuffs within the single market while at the same time ensuring safe food and a high degree of protection of human health and the environment.</p> <p>More specifically, Directive 1999/2/EC requires that a food item may be irradiated if the treatment poses no health hazard, it is of benefit to consumers, it is not used as a substitute for good hygiene, health and agricultural practices and if there is a technological need such as to limit the germination of some vegetables. Any food irradiated or containing irradiated ingredients must be authorised, labelled and have been treated only at approved facilities.</p> <p>The legislation aimed at achieving the following operational objectives:</p> <ol style="list-style-type: none"> 1. Defining general and technical requirements and conditions for the use of ionising radiation in foodstuffs; 2. Ensuring effective regulatory oversight of the irradiation of foodstuffs sector; 3. Achieving a degree of harmonisation of the treatment of foodstuffs with ionising radiation and the conditions of use at Union level and facilitate EU-wide exchanges; 4. Establishing a high level of legal certainty at Union level.
<p>(B.3) How the objectives were to be achieved</p> <ol style="list-style-type: none"> 1. Legally binding conditions to be fulfilled for authorising food irradiation were established. They address among others, approval of facilities by competent authorities, sources and doses of ionising radiation to be used, labelling of irradiated foodstuffs, listing of food and food ingredients authorised for irradiation, import requirements and reporting, control and monitoring systems in order that they meet common standards without compromising human health or food safety; 2. Provisions were included for the competent authorities to establish monitoring and control systems necessitating the collection of data by the food business operator available during inspection and the submission of data to the Commission concerning the results of checks carried out in the ionising facilities and at the product marketing stage which is published by the Commission annually. 3. A stepwise harmonised listing of food and food ingredients authorised for irradiation at EU level, using existing

national authorisations as a starting point (a Community (now EU) positive list) was set up and dried herbs, spices and vegetable seasonings were the first ingredients to be placed on the list. The intention was that by 31st December 2000, the Commission would, after examination of Member States national lists of foodstuffs authorised for irradiation and following scientific approval, complement this EU positive list by adding these nationally authorised foodstuffs. To enable the markets to continue to function, transitional measures allowed Member States to continue to apply their national lists. This also meant, however, that Member States not irradiating foodstuffs could restrict or ban foodstuffs irradiated in other Member States. Before preparing a proposal to the European Parliament and the Council for an EU positive list, the Commission launched an open discussion during 2000 with consumer organisations, industry organisations and other interested parties on the strategy for drawing up the positive list and published a Commission Communication¹ with the results. Due to the strong views received, both in favour and against, the Commission considered that a broader debate was appropriate before progressing further with the positive list. However, the debate has not yet taken place.

4. A clear legal scope was provided for the treatment of foodstuffs with ionising radiation to ensure that existing rules for labelling, official controls of foodstuffs, scientific consultation and basic safety standards were also applicable.

C. Scope of the evaluation/FC

(C.1) Topics covered

The evaluation will cover Directives 1999/2/EC and 1999/3/EC in all EU Member States from the date of their entry into force until the present day. For those Member States which joined the Union after the entry into force of the Directives, the evaluation will cover the period from their date of accession. The evaluation will focus on the main pillars of the legislation as outlined above, as well as looking at whether the intended objectives of the legislation have been achieved and whether the objectives are still relevant. Aspects which fall within the competence of the Commission, such as evaluation and inspection of third country facilities are also covered by this evaluation.

(C.2) Issues to be examined

Effectiveness

- To what extent do the irradiation Directives meet their objectives and in particular:
 - What is the impact of having only one category of irradiated foodstuff listed at EU level and different categories at the national level in several Member States?;
 - Which provisions or parts of the Directives have met their objectives (i) most effectively and (ii) less effectively or (iii) not at all and why?
 - To what extent are the Directives effectively implemented across Member States (e.g. enforcement or possible restrictions and bans)? What are the implementation and enforcement measures that have been put in place? Were they adequate?

Efficiency

- What are the quantitative and qualitative costs and benefits for industry/food business operators/consumers (eg. measurable improvement in food hygiene or reduction in foodborne outbreaks) and the environment associated with the implementation of the irradiation Directives?
 - What are the key drivers for those costs (facilities, equipment, different sources of ionising radiation)?
 - To what extent are costs involved in implementing the irradiation Directives justified, proportionate and affordable given the benefits which have been achieved (eg irradiation facilities used for other purposes, extended shelf life of foodstuffs, reduced loss of foodstuffs, reduced incidence of food-borne disease and of organisms harmful to plants or plant products) and what factors influence any particular discrepancies (eg. given that irradiation extends the shelf life of foods, would Food Business Operators (FBOs) like to see more foods on the EU list, or do they think that potential negative public opinion is more important than extended shelf life)?
- Is there a potential to simplify and obtain the objectives of the Directive more efficiently? How can this be

¹ [http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52001XC0829\(01\)&from=FR](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52001XC0829(01)&from=FR)

achieved?

- To what extent does the Directive allow for efficient policy monitoring (e.g. reporting mechanism)? How far do the reporting processes allow for efficient collection of all relevant information (eg should information on the quantity and type of imported irradiated foods into the EU be requested)?
- Given that the EU accepts the import of irradiated foods from Third Countries (provided that they are treated facilities approved by the EU) how successful is this practice in Member States?

Coherence

- To what extent are the irradiation Directives coherent with other EU legislation? Do provisions overlap or contradict, do they co-act as intended? What impacts do these overlaps have? (Legislation and policy activities to be considered include legislation concerning food hygiene of animal origin (best practices in agriculture, good hygiene and manufacturing practices, HACCP principles, chemical and bacteriological decontamination etc).
- What is the impact on trade of the current legislation on irradiated foodstuffs and what are the reasons for the impact (taking into account the level of coherence between EU and international rules)?

Relevance

- To what extent do the objectives of the irradiation Directives still correspond to the needs of the food safety policy area?
- To what extent are the objectives of the irradiation Directives still relevant considering the evolution of societal needs and technological developments?
- Have there been any new problems/issues related to irradiation, its use on foodstuffs and its impact on the human health and environment that are currently not addressed through the irradiation Directives?

EU added value

- To what extent has the legislative framework at EU level added value to the irradiation of foodstuffs in a manner that could not have been achieved by measures taken at national level?
- Have Member States' national rules on the irradiation of foodstuffs been more effective in the sector than EU rules? If yes, to what extent?
- To what extent is EU level intervention still warranted?

(C.3) Other tasks

An external study will be commissioned to support the evaluation. It will also perform an analysis of EU market covering the following topics:

- What is the current state of play of irradiated foodstuffs on the market (main product types and their share in the market; new technologies, products or sales practices, initial bacterial load of products marketed, quantity and product type of imported irradiated foodstuffs)?
- What are the main reasons for the continuous decline of irradiated foodstuffs on the EU market?

D. Evidence base

(D.1) Evidence from monitoring

Commission reports providing information from Member States on the results of checks carried out in ionising facilities, in particular regarding the categories and quantities treated and the doses administered, and checks at the product marketing stage are available on the Commission's [food safety website](#) at the following address:.

(D.2) Previous evaluations and other reports

In 2001, a Communication from the Commission on foods and food ingredients authorised for treatment with ionising radiation in the Community ([2001/C 241/03](#)) summarised the findings of an open discussion which was launched with consumer organisations, industry organisations and other interested parties in autumn 2000 on the strategy for drawing up the positive list.

There are a lot of recent or ongoing worldwide studies and coordinated research Programmes mainly coordinated

by IAEA and some scientific studies carried out at EU level. The most relevant ones related to Food Irradiation are the following:	
a)	Development of Electron Beam and X Ray Applications for Food Irradiation (DEXAFI)
b)	The Development of Generic Irradiation Doses for Quarantine Treatments
c)	EU/JRC research carried out in 2015 about the “Verification of the applicability of EN 1785:2003 for the detection of irradiation treatment of cashew nuts and nutmeg”
d)	Research and development programme in the field applied metrology and chemical analysis (Com Bureau of Reference) 1988-1992.

(D.3) Evidence from assessing the implementation and application of legislation (complaints, infringement procedures)

<p>1. RASFF notifications (follow-ups made by MS following unfavourable results of checks on the market).</p> <p>2. Directorate F audits on food irradiation facilities in Third Countries prior to approval.</p> <p>3. Due to the restrictive EU list, the Commission is unable to grant any request from food business operators or Competent authorities in the EU and in third countries for the irradiation of other foodstuffs.</p> <p>Two recent examples are the following:</p> <ul style="list-style-type: none"> • Canadian irradiated beef; • Export of irradiated cherries to the US from some EU MS (eg Greece/Spain/Italy)
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(D.4) Consultation

<p>Stakeholder consultation will consist of:</p> <ul style="list-style-type: none"> • A 12 week Open Public consultation will take place in the fourth quarter of 2017. The Open Public consultation will be carried out in English while replies can be made in any of the 24 official EU languages. The open public consultation can be accessed via the Commission's central public consultation page. • A targeted consultation of relevant stakeholders through either targeted surveys and/or bilateral and group meetings including Member State (Standing Committee representatives) and Third Country competent authorities, industry and civil society; • A synopsis report in English, summarising the results of all consultation activities will be published on the public consultation page once all consultation activities are closed. <p>Key stakeholder groups have been identified as follows:</p> <ul style="list-style-type: none"> • Member State and third country competent authorities for human health and food safety; • Member State and third country food business operators dealing with food irradiation including National and European food business federations, with a specific focus on SME; • Manufacturers of irradiation devices and upstream / downstream services; • Other EU and national authorities, including national and European food safety authorities (e.g. European Food Safety Authority, French Agency for Food, Environmental and Occupational Health & Safety, UK Food Standards Agency) • Civil society organisations from areas such as Consumer protection and public health; • European and international research centres and academia such as the Technology Resource Centre and Technical Institute for Food Industry in Strasbourg/France • Relevant international organisations such as the Council of Europe, World Health Organisation and the International Atomic Energy Agency;

(D.5) Further evidence to be gathered

The external contractor referred to in above will produce a study based on the documents and reports provided, the
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relevant published literature, documents developed by other bodies (such as the [International Atomic Energy Agency](#), reports and opinions delivered by European Food Safety Authority² and the [Scientific Committee for Food](#) scientific publications, research studies, Third Country case studies of the 5 highest exporters to the EU) and the results of the public and targeted consultation. Where information gaps remain, the contractor will be expected to find additional sources of information.

E. Other relevant information/ remarks

The findings of the evaluation will be presented for discussion to Member States representatives in the Standing Committee and other interested parties such as the Advisory Group of the Food Chain and EFSA.

² Statement summarising the Conclusions and Recommendations from the Opinions on the Safety of Irradiation of Food adopted by the BIOHAZ and CEF Panels (published 6 April 2011):
<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2107/epdf>
Scientific Opinion on the efficacy and microbiological safety of irradiation of food (published 6 April 2011):
<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2103/epdf>
Scientific Opinion on the Chemical Safety of Irradiation of Food (published 6 April 2011):
<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.1930/epdf>