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EVALUATION

of the

EU legal framework on food irradiation (Directives 1999/2/EC and 1999/3/EC)

{SWD(2021) 226 final}

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Glossary

Term or acronym	*Meaning or definition*
2-ACBs	2-Alkylcyclobutanones
EFSA	European Food Safety Authority
FAO	The Food and Agriculture Organization of the United Nations
HACCP	Hazard analysis and critical control points
MEP	Member of the EU Parliament
NGO	Non-governmental organisation
RASFF	Rapid Alert System for Food and Feed
UV	Ultra Violet

1 INTRODUCTION

1.1. Definition of food irradiation

According to the Codex Alimentarius[1], food irradiation is the processing of food products by ionizing radiation, specifically gamma rays, X-rays or accelerated electrons in order to, among other things, control foodborne pathogens, reduce microbial load and insect infestation, inhibit the germination of root crops, and extend the durable life of perishable produce.

1.2. Purpose and scope of the evaluation

The present evaluation is carried out on the EU legislative framework for the treatment of food with ionising radiation (hereafter "food irradiation"), which consists of Directives 1999/2/EC[2] and 1999/3/EC[3] (hereafter "the Directives").

The evaluation was deemed necessary since the Directives had not been evaluated since their entry in force, despite significant scientific and technological developments, and despite the adoption of the General Food Law in 2002 (Regulation (EC) No 178/2002[4]), which provided a new legal framework for EU interventions on food safety.

The purpose of this evaluation is to assess whether the Directives are still fit for purpose, considering five different criteria: relevance, effectiveness, efficiency, EU-added value and coherence.

The evaluation covers the implementation of the Directives from the date of their entry into force until the present day, in all EU Member States.

In addition to assessing whether the intended objectives of the legislation have been achieved and whether the objectives are still relevant, the evaluation assesses the main provisions of the Directives: requirements on sources of irradiation and limits for absorbed doses, listing of foodstuffs authorised for irradiation, labelling of irradiated foodstuffs, approval of irradiation facilities by competent authorities, rules for import and intra EU trade of irradiated foodstuffs, enforcement of official controls and reporting obligations.

The evaluation is expected to provide evidence that will be used to identify any need for changes in the EU legislation on food irradiation.

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1 CAC/RCP 19-1979, Code of practice for radiation processing of food

2 Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation, OJ L 066 13.3.1999, p. 16.

3 Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation, OJ L 66, 13.3.1999, p. 24–25.

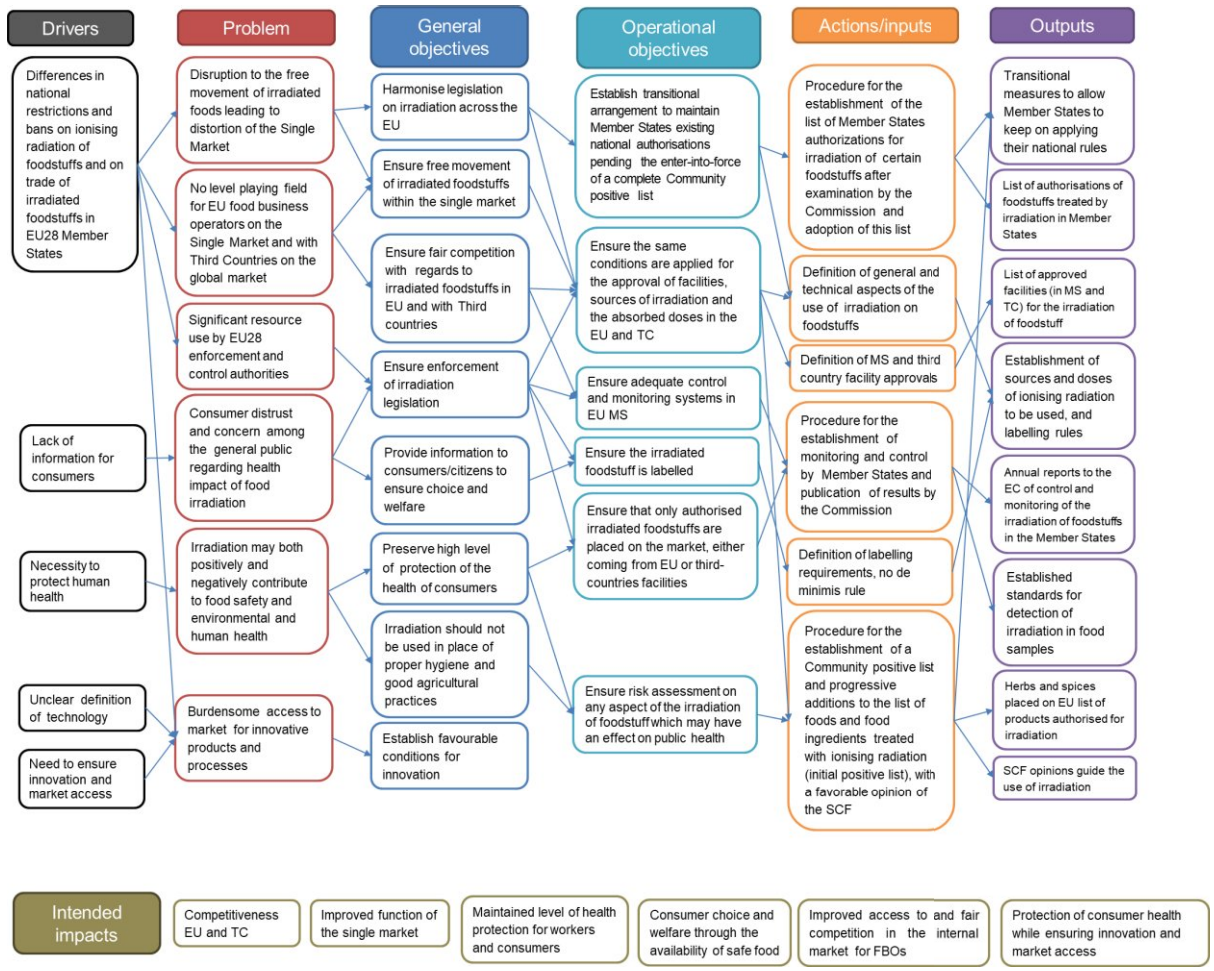
4 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 031 1.2.2002, p. 1.

2 BACKGROUND TO THE INTERVENTION

2.1 Description of the intervention and its objectives

The intervention logic, presented in Figure 1, indicates the drivers, objectives, intended actions and outputs of the intervention. However, part of what is captured in the intervention logic has not occurred because some processes defined by the Directives have not progressed as intended. Namely, the "progressive additions to the list of foods and food ingredients treated with ionising radiation" mentioned in "Actions/inputs" did not occur, and the measures meant to be transitional, as stated in "Outputs" have remained in place.

Figure 1 : Intervention logic



One of the **initial drivers** of the development of EU food irradiation legislation was the differences in national approaches to regulate the technology. These were perceived to disrupt the free movement of goods and meant that EU food businesses were not on an equal footing with each other or with food businesses in third countries importing into the EU. The variation may also have had significant resource impacts on enforcement and control authorities and hampered access to markets for innovative products and processes. A lack of information for consumers contributed to consumer distrust and concern regarding the potential health impact of food irradiation. The need to protect human health led to the need to consider the various positive and negative impacts irradiation may have on food safety and human health.

The **general objectives** of the Directives were set to address these problems. The disruption to free movement and the lack of a level playing field for EU food businesses was addressed through the harmonisation of legislation on irradiation, ensuring free movement and fair competition. Ensuring the enforcement of the Directives and a harmonised approach was meant to help address concerns surrounding the resource use by Member State enforcement and control authorities. Ensuring enforcement, alongside providing information to consumers, would also help to address consumer distrust. Preserving high levels of protection for the health of consumers and requiring that irradiation is not used in place of proper hygiene or good agricultural practices addressed the potential impacts of irradiation to human and environmental health. Through establishing favourable conditions for innovation, the Directives also aimed to reduce the burdens associated with market access for innovative products and processes.

To attain these general objectives, several **operational objectives** needed to be met. Harmonisation required the establishment of transitional measures to maintain existing Member States authorisations until a single EU-level list of products authorised for irradiation came into force. It also required the establishment of conditions for the approval of facilities, sources of irradiation and limits for absorbed doses. Ensuring fair competition and enforcement requires the same rules to be applied on imported foodstuffs and to products irradiated in the EU, and adequate control and monitoring systems. Ensuring that irradiated foodstuffs are labelled as such helps to provide information to consumers and to ensure that only authorised foodstuffs are placed on the market. Ensuring that risk assessments are undertaken contributes to preserving a high level of protection of consumer health, and helps to ensure that irradiation is not used to mask poor hygiene or agricultural practices. Which operational objectives were intended to establish favourable conditions for innovation, and how they have translated into actions and outputs, is unclear.

The Directives include a number of **actions and inputs** to address these objectives. A procedure for the establishment of lists of products authorised by Member States was included as a transitional measure in Directive 1999/2/EC. This Directive includes the definition of general and technical aspects, along with a definition of EU and non-EU facility approvals, to ensure that the same conditions are applied to all irradiated foodstuffs marketed within the EU market, whether from EU or non-EU countries. Definition of the labelling requirements in Directive 1999/2/EC was intended to ensure that products are consistently and appropriately labelled. Establishing procedures for the monitoring and control by Member States was intended to ensure that only authorised food enters the market and that an adequate control and monitoring system is in place. No EU-level monitoring or control procedures were specifically established for imports, however. The inclusion of a procedure for the establishment of an EU list and progressive additions to the list was intended to ensure that the same conditions are applied across Member States and to third country imports. The procedure for adding foods to the positive list also stipulated that this only happens with a favourable opinion of the Scientific Committee on food, so risk assessment is part of the approval process.

These actions and inputs lead to the key **outputs** that are meant to meet the Directives' objectives. Transitional measures have been established and these, along with the list of authorisations of foodstuffs in Member States and the establishment of the sources, doses and labelling rules are meant to contribute to the transparent use of irradiation within Member States, and to provide legal certainty for food

business operators on the use of irradiation. The list of approved facilities, the annual reports and the standards for the detection of irradiation in food samples have been established to contribute to the transparent management of food irradiation. Requiring a favourable opinion of the Scientific Committee on Food (which has now been replaced by the European food authority agency, EFSA) before the addition of foodstuffs to the initial positive list means that Scientific Committee on Food opinions guide the use of irradiation and that there is consequently a better alignment of the approval of irradiation for certain foodstuffs with scientific opinion and that relevant information is available for stakeholders.

The intervention logic mentions how the outputs of the Directives were expected to lead to **impacts**, namely: improving the competitiveness of Member States with third countries, improving the function of the single market, maintaining the level of health protection for workers and consumers, improving consumer choice and welfare through the availability of safe food, fair competition and access within the internal market and the protection of consumer health while ensuring innovation and market access.

2.2 Legislation before the adoption of the Directives

Before the Directives entered into force in 1999, EU Member State policies toward irradiation differed greatly. France, the Netherlands and Belgium were at the forefront of using food irradiation, while Germany was making extensive efforts to prevent irradiated foods from entering the market. These differences were the subject of discussions at the EU level in the 1980s and 1990s. Some countries, including Belgium, France, the Netherlands and the UK, promoted the development of a directive that would have authorised the irradiation of several product categories, while others and the European Parliament supported the development of a directive that would have limited the authorisation of food irradiation to herbs and spices. The first positive list proposed at EU level included nine different foods. Over the course of ten years of debate, this was reduced to just dried aromatic herbs, spices and vegetable seasonings. The broader regulatory context in the EU was characterised by the rejection of irradiation for imported fresh meat, as per Directive 72/462/EEC[5].

Labelling of irradiated foods was already required on foodstuffs intended for sale to the ultimate consumer by Council Directive 89/395/EEC [6] amending Directive 79/112/EEC[7]. Before then, various rules applied in the Member States. Belgium and the Netherlands had no labelling requirements in place, while France did. It was suggested in the late 1980s and early 1990s that the differences in labelling regulations within the single market led unlabelled irradiated products to be sold in countries that required labelling, although it is not clear whether this was actually the case. News reports indicate also that there was an issue with the import of herbs, spices and soft fruit that had been irradiated without being labelled as such. Studies

[5] Council Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine andfresh meat from third countries (OJ L 302, 31.12.1972, p. 28).

[6] Council Directive 89/395/EEC 89/395/EEC amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (OJ L 186, 30.6.1989, p. 17).

[7] Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (OJ L 33, 8.2.1979, p. 1).

by the Trading Standards Office in the UK[8] determined that around 1 in 10 samples may have been irradiated without stating as such. There was also an instance where regulators in the UK and Germany uncovered the illegal irradiation of liquid whole eggs. In some Member States, such as Poland and the Czech Republic, pre-existing legislation was in force until their EU accession, at a time where EU legislation on food irradiation was already in force. In the Czech Republic, national legislation required the labelling (with both the Radura symbol and specific words) of irradiated foods, but only for ingredients that made up more than 2% of a product by weight. This meant that processed products containing irradiated herbs and spices would generally not need to be labelled as such.

[8] Kilcast, D. (1995) Food Irradiation: Current Problems and Future Potential. International Biodeterioration & Biodegradation: 279-296.

3 IMPLEMENTATION / STATE OF PLAY

3.1 Main legal provisions

With the exception of the provisions regarding the exercise of implementing powers conferred on the Commission, the provisions of the Directives have not been amended since their entry into force.

Requirements on sources of irradiation

Directive 1999/2/EC provides that only gamma rays, X-rays and electron beams may be used as sources of ionising radiation, but does not include definitions for "ionising radiation" or "irradiation" (a term also used several times in the act). As a result, Member States have interpreted the scope of the Directive and implemented it in different ways (See Section 5.3.2 "Requirements for the sources of irradiation ").

Directive 1999/2/EC does not provide specific requirements regarding recently developed irradiation technologies for surface treatment (the traditional technologies affect the food "through and through"), such as low energy electron beam[9].

Listing of foodstuffs authorised for irradiation

The EU list of foodstuffs authorised for irradiation to the exclusion of all others ("the EU positive list") to be established before 31 December 2000 in accordance with the second subparagraph of Article 4(3) of Directive 1999/2/EC has not been established. This has two consequences.

First, the initial EU list established by the Directive 1999/3/EC is still in force. This list only contains one product category: "dried aromatic herbs, spices and vegetable seasoning", which is therefore the only irradiated food whose marketing cannot be prohibited, restricted or hindered by the Member States.

Second, the provisions of Article 4 (5) to (7) of Directive 1999/2/EC, which were meant to be transitional, still apply. They provide that Member States may:

- maintain existing national authorisations (a Member State may add to its national list of authorised products those the authorisation of which has been maintained in another Member State) ;
- continue to apply existing national restrictions or bans on ionising radiation of foodstuffs and on trade in irradiated foodstuffs which are not included in the initial EU list established by Directive 1999/3/EC.

So far, six Member States (BE, CZ, FR, IT, NL, PL) maintained a national list of authorisations concerning the treatment of foodstuffs with ionising radiation[10].

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[9] Contrary to high energy electrons, which can effectively penetrate food products up to several centimeters, the penetration depth of low energy electron beam (i.e. with energies of 300 keV or lower) is limited to the micrometer scale, resulting in an high efficiency for surface decontamination. https://www.sciencedirect.com/science/article/pii/S092422441730657X?via%3Dihub

An advantage of this technology, in addition to lower effect on food ingredients, is that low energy e-beam machines do not require thick shields and can be applied for in-line irradiation. This can eliminate the necessity of transportation of a large amount of spices to irradiation facility.

[10] List of Member States' authorisations of food and food ingredients which may be treated with ionising radiation (According to Article 4(6) of Directive 1999/2/EC of the European Parliament and of the

Labelling of irradiated foodstuffs

Directive 1999/2/EC provides that the words 'irradiated' or 'treated with ionising radiation' must appear on the label of irradiated foodstuffs, or, in case irradiated products are used as ingredients, the same words must accompany their designation in the list of ingredients. This provision is implemented by Member States, which regularly identify through their official controls a small proportion of non-compliances relating to non-labelling or labelling issues (See Section 3.4 "Results of official controls").

Approval of irradiation facilities

All approved facilities as well as facilities wishing to engage in food irradiation in the European Union are subject to controls carried out by the relevant Member State competent authorities. A list of EU-approved facilities is maintained up to date by the Commission[11].

Between 2003 and 2019, seven facilities have been added to the list due to the accession of new Member States (in Bulgaria (2), Cyprus (1), Estonia (1), Croatia (1), Hungary (1), and Romania (1)), three facilities have been added in Member States already present (in Germany (1), Spain (1) and France (1)), and three facilities were removed (in Denmark (1) and France (2)). The list was last updated in 2019 with the removal of two entries.

Non-EU facilities are subject to the same requirements as EU facilities. The Commission instructs experts to carry out, under its authority, evaluations and inspections of irradiation facilities in third countries for their inclusion on the list of approved non-EU facilities[12]. The last audit carried out by the Commission in a non-EU country took place in China in 2009. Prior to this audit, audits for the approval of irradiation facilities took place in 2008 (India), 2005 (Thailand), 2003 (Switzerland and Turkey) and 2001 (South Africa). Reports of these audits are published online[13].

Rules for intra EU trade of irradiated foodstuffs

Since the provisions of Article 4(7) of Directive 1999/2/EC still apply (see above), Member States may restrict or ban irradiated foodstuffs, which are not included in the initial EU list established by the Directive 1999/3/EC, from entering their market, whether these products come from other Member States or from third countries. The Directive does not require Member States to notify to the Commission the national restrictions or bans on trade that they apply (see Section 5.3.7 "Provisions on intra EU trade of irradiated foodstuffs").

Rules for import of irradiated foodstuffs in the EU

Council on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation) OJ C 283, 24.11.2009, p. 5.

11 List of approved facilities for the treatment of foods and food ingredients with ionising radiation in the Member States (According to Article 7(4) 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 C 37, 30.1.2019, p. 6).

12 Commission Decision 2002/840/EC of 23 October 2002 adopting the list of approved facilities in third countries for the irradiation of foods (OJ L 287, 25.10.2002, p.40).

13 https://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

Directive 1999/2/EC provides that a foodstuff treated with ionising radiation may not be imported from a third country unless it complies with the conditions which apply to that foodstuff, and was treated in a facility approved and listed by the Commission. The Commission carries out audits in non-EU countries and Member States carry out controls at point of entry into the EU to check the implementation of these rules.

Official controls and reporting obligations

The Directive 1999/2/EC provides that national competent authorities must forward every year to the Commission the results of checks carried out in the ionising irradiation facilities, in particular regarding the categories and quantities of products treated and the doses administered, and the results of checks carried out at the product marketing stage.

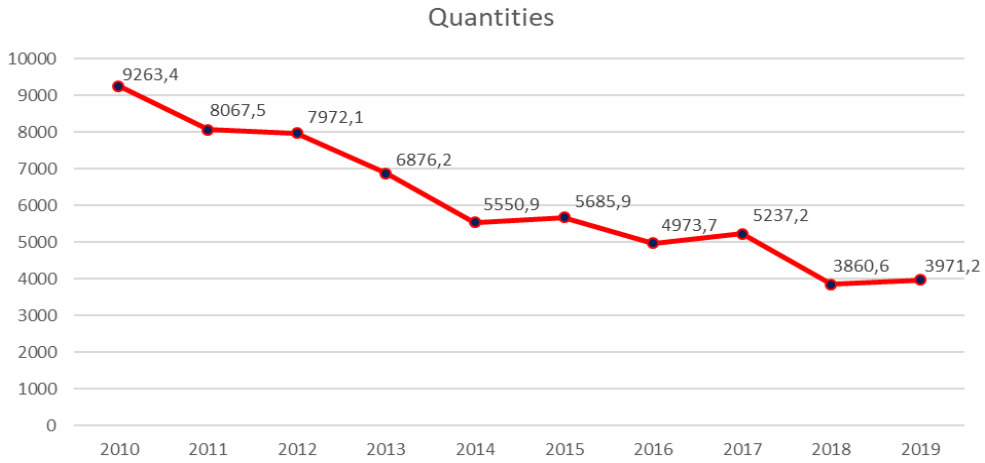
The Directive 1999/2/EC does not provide for specific requirements on the checks to be carried out, only that Member States must ensure that the methods used to detect treatment with ionising radiation comply with the Directive 85/591/EEC[14] and are standardised or validated.

In accordance with Article 7(4) of Directive 1999/2/EC, the Commission publishes a report to the European Parliament and the Council based on information provided by Member States[15], which contains the results of checks carried out by Member States in irradiation facilities and at marketing stage. The report was annual until 2015 and is biennial since then.

3.2 Use of irradiation by the EU food industry

The EU irradiated on average 6,100 tonnes of food annually in the last ten years, which is less than 1% of the volume irradiated worldwide. In contrast to the quickly growing world trend (especially due to USA and China), food irradiation in the EU decreased by more than 50% since 2010 (see Figure 2).

Figure 2 Quantities of foodstuffs treated by ionising radiation in approved irradiation establishments within the European Union since 2010 (in tons)



14 Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption (OJ L 372, 31.12.1985, p. 50–52)

15 https://ec.europa.eu/food/safety/biosafety/irradiation/reports_en

Among the three authorised sources of ionising radiation, the most common in EU is the high energy gamma rays emitted by a radioactive substance, usually cobalt 60. Streams of high energy electrons generated by an electron gun are also used, whereas EU facilities or approved importers do not currently use X-ray technology.

The radiation dose used varies depending on the product in question, the maximum doses stipulated by Member State regulations, and the intended outcome – the effects of irradiation change as the dose is modified. Lower dosages (e.g. below 1 kGy[16]) are used for treatments with plant health purposes, higher doses (e.g. up to 10 kGy, the legal maximum in the EU) are used for microbial decontamination of food.

On 31 December 2019, there were 24 approved irradiation facilities in the EU, which were located in 14 Member States: France (5), Germany (4), Bulgaria (2), the Netherlands (2), Spain (2), Belgium (1), Czech Republic (1), Croatia (1), Estonia (1), Italy (1), Hungary (1), Poland (1), Romania (1), and United Kingdom (1). Of those 14 Member States equipped with irradiation facilities, four did not irradiate any foodstuffs in 2018-2019: Bulgaria, Italy, Romania and the United Kingdom.

A total quantity of 7,832 tonnes of products were treated with ionising irradiation in Member States during the years 2018 and 2019. Most food irradiation in the EU occurred in a single facility in Belgium, which treated 81.4% of the irradiated food of the EU. The Netherlands also accounts for a substantial percentage, and there is some activity in France, Spain and Germany. Together, these five countries account for 96% of the food irradiation that occurs in the EU.

Irradiation is also concentrated on a few select products. The three main commodities irradiated in the EU are frog legs (65.1%), poultry (20.6%) and dried aromatic herbs, spices and vegetables seasoning (14.0%).

3.3 Import of irradiated foodstuffs in the EU

Currently, ten irradiation facilities are approved in non-EU countries to process products for export to the EU[17]: three in South Africa, three in India, two in Thailand, one in Switzerland and one in Turkey. The application of one non-EU country (China) was rejected in 2009 after the on-the-spot audit yielded an unfavourable result.

Since these facilities are not subject to reporting obligations, there is no data on the quantities of irradiated foodstuffs which enters the EU from third countries.

3.4 Results of official controls

3.4.1 Notifications through the EU report on food irradiation

For the period 2018-2019, 25 Member States notified having carried out analyses for the detection of irradiated foodstuffs at marketing stage. 9 808 samples were analysed, i.e. overall 12.1% less in average than in 2016-2017.

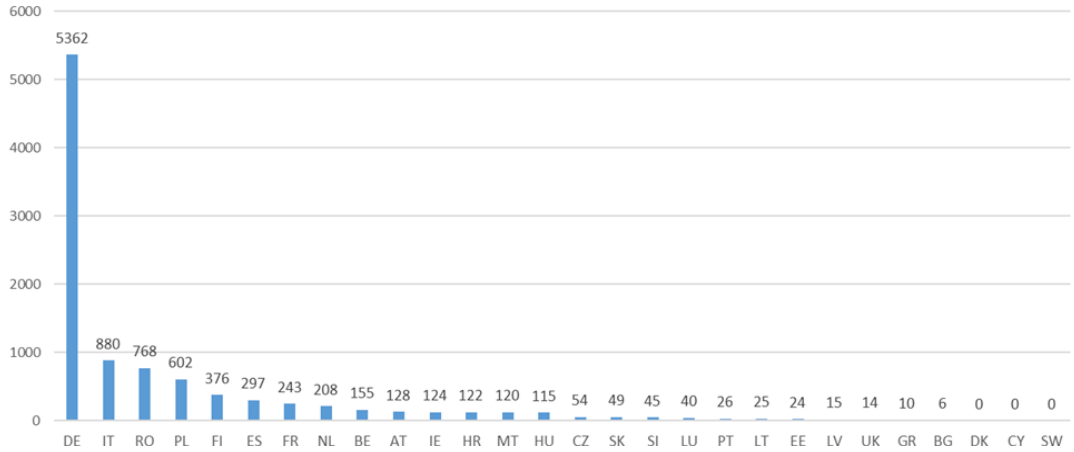
Germany accounted for more than 50% of the samples analysed (Figure 3). Three Member States and Norway did not perform any analytical checks at product

16 A gray is defined as the absorption of one joule of radiation energy per kilogram of matter

17 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002D0840-20120524&qid=1607098954360

marketing stage in 2018-2019 due to budgetary restrictions (Denmark and Norway), lack of laboratory capacity (Cyprus) or other control priorities (Sweden).

Figure 3 Samples analysed at product marketing stage within each Member State in 2018-2019



The majority of the products analysed were 'herbs and spices' (39%) and 'cereals, seed, vegetables, fruit and their products' (24%). Under category 'other' (foods supplements and soup and sauces) the percentage was 20%.

From the total of 9,808 samples, 83 gave not compliant results (1%) and 88 (1%) gave inconclusive results. The types of non-compliance observed were mainly incorrect labelling and forbidden irradiation. The percentage of non compliance (1%) was slightly higher than in the previous report (0.8%).

Over the past several years, the regular sampling carried out by Member States and reported to the European Commission indicate a consistent and small percentage of non-compliant foodstuffs (between 0.8%-2.4%) among those tested.

3.4.2 Notifications to the rapid alert system for food and feed (RASFF)

Created in 1979, the Rapid Alert System for Food and Feed (RASFF) enables information to be shared rapidly between EU Member State national food safety authorities, the Commission and EFSA when risks to public health are detected. Information exchanged through RASFF on the non-compliances detected can lead national competent authorities to apply control measures, e.g. products being recalled from the market. Between 1999 and 2019, out of about 50,000 notifications recorded in the RASFF database, 358 notifications related to irradiation. As shown in Figure 4, the most frequent countries of origin for products subject to RASFF notifications were China, the United States, Russia and Vietnam, none of them having EU approved irradiation facilities.

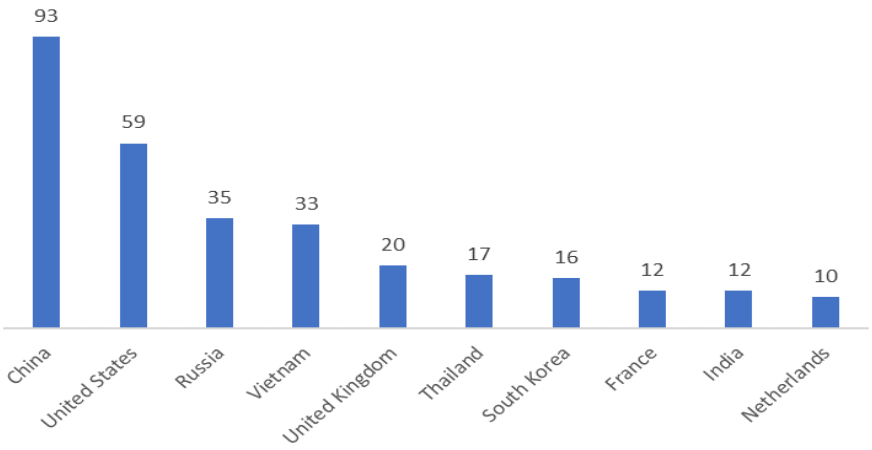


Figure 4: RASFF notifications related to irradiation by country of origin (top 10)

Of these 358 notifications, 87 (approximately 24%) related to unlabelled irradiation. A further 270 (approximately 75%) relate to "unauthorised irradiation". It is not clear whether this refers to the irradiation of unauthorised foodstuffs, irradiation in a not approved facility or unlabelled irradiation, or some combination of the three. Non-compliances were not identified in relation to the maximum permitted dose.

Of these 358 notifications, risk assessments had been made for 108 and these risk assessments indicated that serious non-compliance incidents were rare, with 98% labelled 'not serious'.

In 2020, 6 RASFF notifications related to irradiation were registered: 2 from China, and 1 each from USA, India, Vietnam and Belgium. The six notifications related to "unauthorised irradiation", the risk assessment for all of them led to "non-serious risk" classifications.

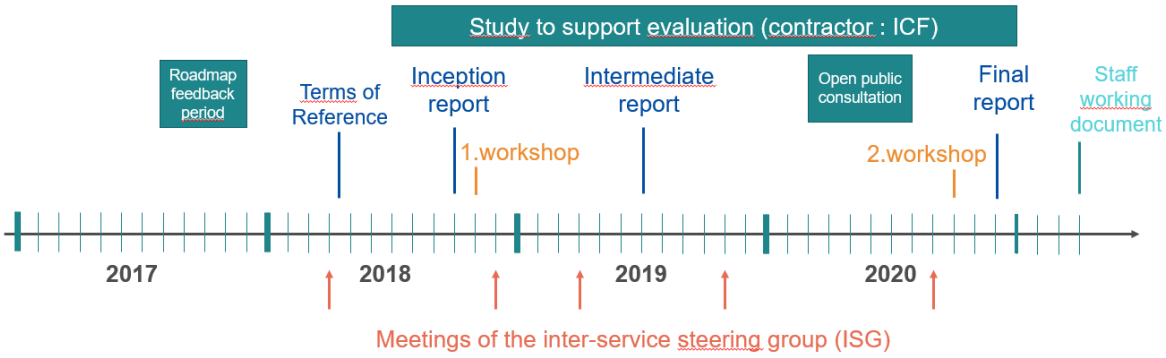
4 METHOD

4.1 Evaluation process

The Commission has set up an inter-service steering group (ISG) to supervise this evaluation, which includes representatives from SG, GROW, TRADE, RTD, SANTE, AGRI and JRC.

After validation of the roadmap in September 2017, the company ICF won the call for tenders for carrying out a support study[18], on which the evaluation is mainly based (hereafter, "the support study"). The support study was launched in 2018 and ended in 2020 (see timeline Figure 5).

Figure 5 Time of the evaluation process



4.2 Methodology of the study supporting the evaluation

The study supporting the evaluation applied a mixed-methods approach to address the evaluation questions, and consisted in five phases: Inception, Desk research, Implementation of the consultation strategy for the study, Analysis of the data collected, and Conclusions and recommendations. During these phases, the following analytical methods were employed: desk research, interviews and surveys, case studies.

Phase 1: Inception

The inception phase involved preliminary desk research on the legal situation in Member States and key trends in production and trade of irradiated foods, as well as seven exploratory interviews intended to provide an overview of stakeholder perspectives, assess potential data gaps, and identify sources of evidence and key contacts. Various actors were consulted, including national competent authorities, federations of food business operators, the International Atomic Energy Agency (IAEA). NGOs were solicited but declined the requests for interview. ICF also liaised with DG SANTE officials and ICF's external experts to further develop the intervention logic, and identify scientific, academic and legal sources of information.

[18] Final report of the study to support the retrospective evaluation of legislation related to the irradiation of food and food ingredients, 2021, ICF, Luxembourg: Publications Office of the European Union, DOI 10.2875/460710, ISBN 978-92-76-37808-2

Phase 2: Desk research

The purpose of the desk research phase was to extract qualitative and quantitative information relevant to the evaluation questions from published sources. The scope of the desk research includes relevant legislation, statistics, complaints, case law and infringements (including notifications from the RASFF, and audits on third country irradiation facilities), studies, reports, research and materials issued or endorsed by the EU institutions, European or national stakeholders' associations, individual stakeholders, as well as Member States' authorities.

A data collection template was used to structure the research and directly compare information collected on the same questions from different sources. Literature and data were retrieved online. The research covered international and EU documentation, and included both academic studies and grey literature.

Phase 3: Implementation of the consultation strategy for the study

Five **case studies** have been completed, on the following topics: labelling requirements in herbs and spices in France (1) and in Poland (2), advantages and disadvantages of irradiation and other available treatments for herbs and spices in the EU (3), use of irradiation to address plant health risks (4) and use of irradiation to prevent sprouting, extend shelf life and reduce food waste (5). The case studies involved interviews with industry, national competent authorities and experts from various EU countries and the United States, as well as desk research.

Three **online surveys**, respectively addressed to national competent authorities, the irradiation industry and food business operators, were conducted to validate the findings of the desk research and the case studies. A total of 56 responses were received, corresponding to 31 national competent authorities in 22 Member States, 20 irradiation industry representatives from seven Member States and six non-EU countries, and five food business operators' representatives. Since they refused to participate at the inception phase of the project, consumer organisations were not included in the surveys. A follow-up survey was issued to national competent authorities to address some remaining gaps in the data collection. This survey received 17 responses from national competent authorities in 14 Member States.

In addition, 16 **interviews** have been conducted with representatives from the national competent authorities (2), the irradiation industry (5), an expert from DG SANTE (1), and food industry representatives (8).

The survey for the **Web-based Public Consultation** was launched from 3 March 2020 to 6 July 2020, and received a total of 72 responses from academics/research institutions (5), business and business associations (16), national competent authorities of Member States (2) and third countries (2), NGOs (3), international organisation (1), EU citizens (39) and non EU citizens (4). Of the academics, business associations and businesses who responded, the majority appeared to be associated with the irradiation industry. Contributions were made from ten different Member States and six third countries.

Phases 4 & 5: Analysis of the data collected & Conclusions and recommendations

Data collected were brought together in consideration of judgment criteria agreed between the contractor and DG SANTE. The results of this analysis were presented in the interim report. Gaps in the data were identified based on this analysis and further targeted interviews, desk research and a survey were undertaken to address

them. The results of the additional research and the public consultation were then further triangulated with the analysis from the interim report.

Conclusions were developed based on a consideration of the analyses presented for each judgment criterion. The 'coherence' criterion was not included in the terms of reference of the support study, which only cover the four other criteria. SANTE assessed the 'coherence' criteria itself, based on the outputs of the public consultation, and feedbacks collected from other Units in SANTE and from other DGs (through the ISG).

4.3 Limitations and robustness of findings

The main issue encountered was the lack of information and knowledge regarding irradiation in the EU food industry. This reflects the marginal nature of the practice and its absence from the agenda of stakeholder groups - consumer organisations, NGOs, and in much of the EU food industry. Based on discussions with various stakeholders, it appears that many non-responses or refusals to take part were linked to the nature of food irradiation itself, which is perceived as controversial. In other words, the risk of seeing one's name associated with the term 'food irradiation' could discourage participation in consultations of this nature.

This has meant that securing participation and gathering meaningful feedback from several stakeholder groups, including food business operators, has been particularly difficult. This is reflected in the responses received to the surveys: only six of the 68 food business operators invitees responded. The study team tried to contact food business operators using food irradiation, since those may have more opinions and knowledge than the sector's representatives. But this initiative had only limited success since information on which companies are using irradiation is not publicly available. This means that the majority of the data collected through consultations for this project came directly from the irradiation industry or from national competent authorities.

Securing the participation of relevant persons exporting or importing irradiated food to or from the EU was a further challenge. While there was some success with the United States, no feedback was received from experts contacted in China and Turkey. Responses to the public consultation from other non-EU countries (including Australia and Israel) have helped to address this gap.

Another major data gap related to consumer views on food irradiation. Despite a strong belief among food business operators' organisations and others that food irradiation would not be accepted by EU consumers, few recent studies have sampled the EU consumer population and are relevant to this aspect of the evaluation. The methodology undertaken for this study was not able to fill in this gap. Further attempts were made to contact consumer organisations, in particular those who had previously written about the topic, but none agreed to participate in an interview. There were a small number of responses to the public consultation from the general public, but these did not provide any generalisable evidence.

This has meant that gaps remain in the evidence base and that there is a bias to the responses received. This has been addressed as much as possible in the text by acknowledging this bias wherever conclusions rely heavily on the consultations and by avoiding making strong conclusions based on the evidence provided by the irradiation and food industry alone.

5 ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS

The list of evaluation questions is available in Annex 4. All these questions are answered in the following sections, which have been revised in comparison to those of the study report, for the sake of clarity and to avoid repetitions.

5.1 Relevance

This section assesses the relevance of the food irradiation technology for food safety, plant health and environmental health, as well as the relevance of the Directives' objectives and requirements considering the evolution of societal needs, and scientific and technological developments.

Main findings

Although its use has decreased in the EU, **food irradiation is a technology that remains relevant to addressing food safety concerns in certain products**. Irradiation is an established food decontamination technique, and an EFSA scientific opinion published in 2011 has confirmed that it is effective and safe in ensuring the microbiological safety of foods.

Food irradiation has the potential to contribute to protecting the EU from certain **plant health risks**, although there has been no use of irradiation for this purpose in the EU thus far and stakeholders have not expressed interest in this application of the technology.

Food irradiation is not likely to significantly reduce consumer **exposure to pesticides**. Indeed, irradiation is not used commercially as fungicide or herbicide, and therefore cannot serve as alternative for pesticides used on fruits and vegetables for these purposes. Moreover, EU stakeholders prefer other strategies than irradiation for controlling insect infestations (such as choice of low-risk sourcing locations, inspections and other physical treatments e.g. hot or cold treatments).

All of the stated objectives of the directives are still relevant considering the evolution of societal needs and scientific and technological developments. However the directives do not address the strong drive at consumer, policy and, more recently, industry level, to reduce and manage the environmental impacts of food production.

While most of the requirements of the Directives are still relevant, **some requirements are no longer relevant given the progress of science and technology.** The Directives requirements are notably not relevant for the so called "low energy electron beam technology", which has been recently developed to enable surface treatment of dry food products.

Considering the low public awareness of the technology and consumer wariness when presented with labelling, it is difficult to characterise the current state of **public opinion on the relevance of food irradiation**. Consumer groups that opposed the technology in the early 2000s no longer have this topic on their agenda. But it is unclear whether this means that opposition to the technology has dissipated or whether it is simply no longer considered a topic of concern given the very marginal use of irradiation in the food industry in the EU.

5.1.1 Relevance of food irradiation for public health

Biological safety of irradiated foodstuffs

Irradiation is an established food decontamination technique and the 2011 EFSA scientific opinion on the efficacy and microbiological safety of irradiation of food[19] has confirmed that it is effective and safe in ensuring the microbiological safety of certain foods:

"*When integrated into an overall food safety management program that includes Good Agricultural, Manufacturing and Hygienic Practices and HACCP, and depending on the dose applied, food irradiation can contribute to improved consumer safety by reducing food-borne pathogens in all the food categories and food commodities addressed by the present Opinion*."

Where irradiation is used in the EU, it is generally well-integrated in the supply chain. There are certain cases and supply chains where irradiation is the preferred option for decontamination in the EU, notably frog legs. It is also the preferred option for certain herbs and spices in certain supply chains.

Consumer associations and the European Parliament have raised concerns that food irradiation may be misused by food business operators to mask poor hygiene in production processes, see Section 5.3.4 "Listing of foodstuffs authorised for irradiation". Such practice would be in contradiction with the Food Hygiene Regulations (EC) No 852/2004[20] and (EC) No 853/2004[21].

Toxicological safety of irradiated foodstuffs

The 2011 EFSA scientific opinion on the toxicological safety of irradiated foods concluded that most of the substances formed in food by irradiation are also formed during other types of food processing, with levels comparable to those arising, for instance, from the heat treatment of foods.

However it also indicates some outstanding concerns relating to the formation of 2-Alkylcyclobutanones (2-ACBs) in irradiated foods that contain fat and to the development of leukoencephalomyelopathy in cats fed highly irradiated feed.

On 2-ACBs, the 2011 EFSA opinion concluded that :

"*the available data indicate that at least some 2-ACBs may be genotoxic in vitro. The toxicological relevance of these findings, i.e. whether 2-ACBs may represent a genotoxic hazard for humans, is not elucidated due to the absence of proper in vivo studies. However, several arguments support the hypothesis that the genotoxic hazard associated with 2-ACBs intake is minimal, if any."*

Since 2011, new studies[22] were carried out, which confirmed that the ingestion of 2-ACBs through irradiated foods is unlikely to affect the human health, but suggesting

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19 Scientific Opinion on the efficacy and microbiological safety of irradiation of food, EFSA Journal 2011;9(4):2103, DOI: https://doi.org/10.2903/j.efsa.2011.2103

20 Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139 30.4.2004, p. 55)

21 Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139 30.4.2004, p. 55)

22 Song, B.S. (2014) A critical review on toxicological safety of 2-alkylcyclobutanones. Radiation Physics and Chemistry: 188-193

that the determination of chronic toxicity by long-term exposure to low concentrations of 2-ACBs has to be evaluated more clearly to determine if these compounds are safe to human.

On leukoencephalomyelopathy in cats, the 2011 EFSA's opinion suggests that "*information on the cause and pathogenesis in cats should be collected, including data on the relationship between irradiation dose, composition of feed, the amount of consumed irradiated feed and the elicitation of the leukoencephalomyelopathy. In absence of this understanding, the relevance for humans cannot be ruled out. Considering that only a very limited quantity of food is irradiated in Europe currently, the Panel is of the view that there is not an immediate cause for concern. However, the relevance of the cats studies for human health should be clarified*."

A concern was also raised by one national competent authority about possible migration of elements from packaging and into food in the context of food irradiation. It is described in the scientific literature that for pre-packaged foods undergoing irradiation, packaging made from polymers are susceptible to radiation effects. The extent of these effects differs depending on the polymer. This is not a new issue, and under the EU Directives, packaging materials used for foods undergoing irradiation "must be suitable for the purpose". However, as new packaging materials are developed, they should be tested before use in the irradiation process.

In a resolution of the 17 December 2002 against the establishment of an extended EU positive list of foodstuffs approved for irradiation[23], the European Parliament expressed concerns considering the lack of evidence regarding the long-term safety of eating a diet based largely on irradiated foods (See Section 5.3.4 "Listing of foodstuffs authorised for irradiation").

Nutritional quality of irradiated foodstuffs

The irradiation-induced changes in food components are generally small and not significantly different from those reported in other conventional preservation processes, especially those based on thermal treatment. The changes in some components that are sensitive to irradiation, like some vitamins, may be minimised by using proper treatment conditions. Moreover, this impact is generally minimal, as most foods that are irradiated are not significant enough to dietary requirements to play a nutritional substantial role.

5.1.2 Relevance of food irradiation for plant health

The increased globalisation of trade has increased the likelihood of invasive species being introduced to new countries and climate change has increased the likelihood that invasive species will survive in these new environments. Irradiation can prevent the reproduction of adult insects and their larvae, and can as such be an effective tool to address plant health risks. Irradiation is however not suitable for on the spot treatments when infestations are discovered, due to the specific infrastructure and packaging required to carry out irradiation.

[23] European Parliament resolution on Commission communication on foods and food ingredients authorised for treatment with ionising radiation in the Community (COM(2001) 472 – C5-0010/2002 – 2002/2008(COS))

There is a number of fruit irradiation treatments approved as international standards for phytosanitary measures (ISPM) under the International Plant Protection Convention (ISPM 28, ISPM 18). Irradiation has been approved for plant health purposes in some third countries, including the US, Australia and New Zealand. There, it can be used on a variety of fruit and vegetables, to address almost all pests. It is most frequently used for tropical fruit imported in the US from Asia, Mexico and Southern America and for trade between Australia and New Zealand.

According to DG SANTE, several non-EU countries (India, Australia, the US, Uganda, Jamaica and Israel) have expressed interest in using irradiation as a post-harvest treatment for products exported to the EU. However, the EU stakeholders consulted (one industry organisation and one food business) indicated that the current industry preference is to use strategic sourcing, systems approaches and inspections to address plant health risk.

Irradiation for plant health purpose can be allowed under Plant Health Regulation 2016/2031[24] as post-harvest treatment for certain products, but industry stakeholders indicated that they would be wary of using irradiation for this purpose due to the labelling requirements and expected consumer concerns associated with the use of irradiation.

Therefore, while irradiation could, from a technical perspective, be used as a tool for plant health protection, commercial interest in using the technique is low due largely to perceived consumer concerns.

5.1.3 Relevance of food irradiation for reducing pesticide use

Despite its potential for addressing certain plant health risks, food irradiation is unlikely to have a significant effect on pesticide use whether in the EU or in third countries exporting food in the EU.

Indeed, irradiation cannot serve as alternative for pesticides used on fruits and vegetables as fungicide or herbicide (such as imazalil and prochloraz), since it would be effective at higher doses than what would be suitable for fruit and vegetables (fruit and vegetables tend to lose firmness and quality when subjected to higher doses of irradiation).

Thanks to its effects on insects, post-harvest irradiation could theoretically serve as an alternative to certain insecticides. However, insecticides treatments, whether by fumigation or other means, are currently either prohibited or not the preferred post-harvest treatment methods for fruits and vegetables produced or imported in the EU.

In particular, food irradiation is unlikely to have an effect on the use of methyl bromide, a substance which has a detrimental effects for the environment and contributes to the deletion of the ozone layer, and for which irradiation is often cited as alternative. Indeed, the use of methyl bromide is already prohibited in the EU, and while the import of food treated in non-EU countries with methyl bromide is theoretically possible (as long as residue levels are kept below the maximum authorised by the EU legislation), the import of food treated with methyl bromide is

[24] Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

believed to be marginal: interviews with EU fruit importers showed that they prefer other strategies, such as choice of low-risk sourcing locations, inspections, systems approaches and physical treatments (e.g. hot or cold treatments) to control risks related to insects, see support study, Section 5.2.1.

5.1.4 Relevance of the Directives' objectives

All of the stated objectives of the Directives are still relevant considering the evolution of societal needs and scientific and technological developments.

These are:

- Harmonise legislation on irradiation across the EU;
- Ensure free movement of irradiated foodstuffs within the single market;
- Ensure fair competition with regards to irradiated foodstuffs in EU and with non-EU countries;
- Ensure enforcement of irradiation legislation;
- Provide information to consumers/citizens to ensure choice and welfare;
- Preserve high level of protection of the health of consumers;
- Irradiation should not be used in place of proper hygiene and good agricultural practices; and
- Establish favourable conditions for innovation.

The Directives do not address the strong drive at consumer, policy and, more recently, industry level, to reduce and manage the environmental impacts of food production. Concerns about climate change and other environmental issues have led to calls from various stakeholders, policy-makers, and elected officials to produce food in a more sustainable way, including reduction of the sector's carbon and water footprint. There was not the same emphasis on sustainable food production at the time the directives were passed. Consideration of the environmental impacts of irradiation and alternative technologies is not reflected in the Directives.

5.1.5 Relevance of the Directives' requirements

Most of the requirements of the Directives are still relevant.

The main three sources of irradiation in use at the time the Directives were adopted (Cobalt-60, electron beam and x-ray) are still in use. There have been some developments in detection techniques since the introduction of the Directives, which have helped to improve the accuracy of detection for certain foods. But since detection methods are not stipulated by the Directives, these developments do not have any implications for the relevance of the Directives.

Some of the requirements associated with the directives are no longer relevant given the progress of science and technology, notably:

- Assigning maximum doses to food classes, which does not take into account differences in processing or preparation (e.g. if a food is frozen or not); and
- The use of overall average absorbed dose, rather than minimum and maximum dose.

The use of overall average absorbed dose, and the setting of a maximal value for the "maximum/minimum dose" ratio is not relevant for the so called "low energy

electron beam technology", which has been recently developed to enable surface treatment of dry food products. However this technology is not yet used in the EU or in third countries in commercial conditions, based on information provided by the manufacturer of that technology.

5.1.6 Consumer opinion on the relevance of food irradiation

A survey[25] of British consumers conducted by a non-governmental organisation (NGO) in 1987, when irradiation was still banned in the UK, indicated that 85% of consumers would not buy irradiated food even if the government removed the ban. No further information was identified regarding consumer acceptance of irradiated foods in Europe prior to the Directives. In a consultation undertaken immediately after the implementation of the Directives[26], consumer organisations were highly critical towards the technology and cited the following concerns, which they summarised with the slogan 'good food does not need irradiation':

- Irradiation could be used to mask poor hygiene in production processes;

- Irradiated foods could be subject to re-contamination if not handled properly and re-introduced pathogens may multiply faster in a sterile environment;

- Irradiation may significantly reduce the nutritional quality of certain foods, and

- Prolonging the shelf life of foods may not always be desirable, as nutritional quality degrades over time.

The Food and You Survey[27] conducted by the UK Food Standards Agency in 2012 found that 34% of respondents were aware of food irradiation and that of those aware, 51% reported feeling uneasy about the technology. Awareness differed significantly by age: 19% and 54 % among people aged 16-24 and 55-64 respectively, were aware of the technology. Studies conducted beyond Europe[28], in countries where irradiation is used more widely, gave similar results: research has indicated that awareness in Australia and New Zealand is low and that consumers would generally pay a premium for foods that have not been irradiated.

A recent study involving German, Finnish and Spanish consumers[29] explored the effect of the labelling of low-energy electron beams on consumer acceptance, considering the impact of labelling products both as "treated with irradiation" and "surface treated with electrons" with differing amounts of additional information. Results showed that the lack of understanding of irradiation contributed to reduced

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25 Webb, T. and Lang, T. (1990) Food Irradiation: the myth and the reality. Thorsons: London.

26 Communication from the Commission to the European Parliament and the Council on foods and food ingredients authorised for treatment with ionising radiation in the community, COM(2001) 472, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52001DC0472&from=lv

27 Prior et al. (2013) Exploring food attitudes and behaviours in the UK: Findings from the Food and You Survey 2012. Food Standards Agency UK. Available at: https://www.food.gov.uk/sites/default/files/media/document/food-and-you-2012-main-report.pdf

28 Food Standards Australia New Zealand (FSANZ) (2017) Labelling Review Recommendation 34: Review of mandatory labelling of irradiated food. Supporting Document 5. Available at: http://www.foodstandards.gov.au/consumer/labelling/review/Pages/Labelling-review-recommendation-34irradiation-labelling.aspx

29 Balatsas-Lekkas, A., Arvola, A., Kotilainen H.M., Meneses N. & Pennanen, K.(2020). Effect of labelling fresh cultivated blueberry products with information about irradiation technologies and related benefits on Finnish, German, and Spanish consumers' product acceptance. Food Control, 107387.

willingness to purchase irradiated products. Although using labelling with no reference to irradiation had the highest level of consumer acceptance, consumer acceptance was greater where labelling indicating "surface treated with electrons" included additional information on its potential benefits and purpose.

Possible influencing factors on consumer acceptance include personal preference and consumer knowledge of irradiation, with those that are more informed about irradiation being more likely to purchase irradiated products. Part of consumers' concerns relates to nuclear technologies. For example, a 2014 study[30] showed that Italian consumers had a low acceptance to food irradiation because they associated radiation with the accident at the Chernobyl Nuclear Power Plant in 1986.

Considering the low public awareness of the technology and consumer wariness when presented with labelling, it is difficult to characterise the current state of public opinion on this subject. Within Europe, many of the consumer groups that opposed the technology in the early 2000s no longer have this topic on their agenda. But it is unclear whether this means that opposition to the technology has dissipated or whether it is simply no longer considered a topic of concern given the very marginal use of irradiation in the food industry in the EU.

[30] Parlato, A., Giacomarra, M., Galati, A., Crescimanno, M., 2014. ISO 14470:2011 and EU legislative background on food irradiation technology: The Italian attitude. Trends in Food Science and Technology 38, 60–74. https://doi.org/10.1016/j.tifs.2014.04.001

5.2 Coherence

This Section assesses the internal coherence of the Directives, their coherence with the EU food legislation, with other EU legislation and with international standards.

Main findings

Internal coherence

The provisions of the Directives co-act as intended. However, because the establishment of a EU list of foodstuffs authorised for irradiation to the exclusion of all others, as planned by the Directives, did not take place, some transitional measures are still in force more than 20 years after their adoption.

Coherence with EU food legislation

The Directives were adopted before the entry in force of the so-called "general food law" and "hygiene package", a set of legislative acts which form the basis of current EU legislation on food hygiene. However, no major inconsistencies between the Directives and these acts have been identified.

Coherence with other EU legislation

There are very few other pieces of EU legislation interacting with the Directives.

Directive 2013/59/EURATOM[31] lays down a clear definition of "ionising radiation", which excludes some technologies, such as UV radiation with wavelength above 100 nanometres. This definition would help clarify the scope of the Directives, if applied to food irradiation.

Regulation (EU) 2018/848[32] provides that food irradiation is incompatible with organic production, whose main objective is to protect the environment and the climate. The irradiation industry is on the contrary of the opinion that food irradiation could help protect the environment by reducing the use of pesticides as post-harvest treatment and food waste. Available information is insufficient to assess this aspect.

The EU legislation on plant heath protection includes irradiation as a potential treatment to address plant health risks. This legislation and the Directives both apply when food of non-animal origin are subject to irradiation for plant health purpose.

Coherence with international standards

The Directives do not take into account the latest updates of the standards of the Codex Alimentarius, notably as regards the concept of absorbed doses. Experts from the irradiation industry called for the EU legislation to be updated and aligned with the current Codex Alimentarius recommendations, considering that this could help to resolve conflicts or grey areas in relation to international trade.

[31] Directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (OJ L 13, 17.1.2014, p. 1–73)

[32] Regulation (EU) 2018/848 on organic production and labelling of organic products (OJ L 150, 14.6.2018, p. 1–92)

5.2.1 Internal coherence

The review by DG SANTE of the provisions of the Directives as regards the requirements for the sources of irradiation and limits for absorbed doses, the labelling of irradiated foodstuffs, the listing of foodstuffs authorised for irradiation, the import and intra EU trade of irradiated foodstuffs, and the official controls and reporting obligations, has not led to identify contradictions between them.

During the interviews and workshops carried out within the frame of the evaluation, stakeholders did not raised any issue regarding potential contradictions between the provisions of the Directives. The feedbacks gathered through the public consultation also did not mention any issue regarding the internal coherence of the Directives.

5.2.2 Coherence with the EU food legislation

Coherence of the Directives' objectives with EU Food Safety objectives

The desk research and the consultations carried out within DG SANTE showed that the objectives of the Directives are largely aligned with the EU food safety objectives, as shown in the **Error! Reference source not found.**.

Table 1 : Alignment of the EU food safety objectives and the Directives' objectives

Objectives of the Directives	EU food safety objectives
- ensure enforcement of irradiation legislation; - preserve high level of protection of the health of consumers; - provide information to consumers/citizens to ensure choice and welfare.	- guarantee a high level of protection of human life and health and the protection of consumers' interests. - guarantee fair practices in food trade, taking into account animal health and welfare, plant health and the environment.
- Harmonise irradiation legislation in the EU; - ensure free movement of irradiated foodstuffs within the single market;	- ensure free movement of food and feed manufactured and marketed in the Union, in accordance with the General Food Law Regulation.
- irradiation should not be used in place of proper hygiene and good agricultural practices;	- ensure that relevant hygiene requirements are applied at all stages of production, processing and distribution of food
- ensure enforcement of irradiation legislation	- ensure the application of food law through on official controls and other official activities (Official controls regulation)
- ensure fair competition with regards to irradiated foodstuffs in EU and with third countries	- facilitate global trade of safe feed and safe, wholesome food by taking into account international standards and agreements when developing Union legislation, except where this might undermine the high level of consumer protection pursued by the Union.

However, the Directives currently do not take into account the potential environmental impacts of food irradiation technology as compared to alternative technologies used for the same purpose, nor do they incorporate a provision to measure or regulate them. As such, their contribution to the objectives of the EU Farm to Fork strategy[33], which seeks to ensure that the EU food system is 'fair, healthy, and environmentally friendly' and that all food produced and consumed is economically and environmentally sustainable, could not be evaluated due to lack of information on this aspect.

[33] https://ec.europa.eu/food/farm2fork_en

General principles of the food law and hygiene package

The Directives were adopted in 1999, before the adoption of the general food law (Regulation (EC) No 178/2002) and the so called "hygiene package" (Regulations (EC) 852/2004, 853/2004, and 882/2004[34], the latter repealed and replaced by Regulation (EU) 2017/625[35]), which together constitute the foundation of current EU food legislation.

These acts apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene, such as the ones provided by the Directives.

As the following analysis of the legislation shows, there is no major inconsistencies between the Directives and the general principles of the food law and hygiene package (hereafter, "the EU food legislation"). In the EU food legislation, food decontamination techniques are one of the tools available to food business operators to ensure the safety of their products and is, as such, allowed under the EU food legislation. Food business operators who include food decontamination in their food safety management programmes have the responsibility to ensure that the techniques they use comply with the general and specific provisions laid down by the EU food legislation.

In most cases, the EU food legislation do not set specific requirements or restrictions on the use of food decontamination techniques, but rather targets or conditions to be met. Since decontamination is a critical control point under the principles of hazard analysis and critical control points (HACCP), the competent authority responsible for a food establishment using decontamination techniques must check whether the food business operator has carried out proper validation of the process, and whether this validation has given favourable results.

But in certain cases, the EU food legislation does set specific requirements (e.g. pasteurisation and ultra-high temperature treatment of dairy products) or subject the decontamination process to authorisation (e.g. the substances used to remove surface contamination from products of animal origin are to be authorised under Article 3(2) of Regulation (EC) 853/2004).

Thus, the approach provided by the Directives, which lay down specific requirements for food irradiation, and subject the process to authorisation, is coherent with the general approach towards food decontamination provided by the EU food legislation.

Some stakeholders questioned the coherence of the initiative with EU food legislation, as the latter prompts food business operators to ensure food safety by applying good hygiene practices at each stage of the production process, rather than relying on a final decontamination step. The risk that irradiation could be used to mask poor hygiene in production processes was notably mentioned as a concern by the consumer associations consulted before the adoption of the Directives (see

[34] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165 30.4.2004, p. 1)

[35] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (OJ L 095 7.4.2017, p. 1)

section 3.5), and by the European Parliament in its 2002 a resolution, which stopped the process for adding new categories to the EU list of foodstuffs authorised for irradiation (see section 5.3.4, Listing of foodstuffs authorised for irradiation). One stakeholder interviewed during the evaluation has suggested that irradiation may sometimes be used to compensate poor hygiene or agricultural practice elsewhere in the supply chain, but there was no evidence available to either substantiate or disprove this.

The Directives explicitly provide that irradiation should not be used in place of proper hygiene and good agricultural practices, but do not provide specific provisions on how to achieve this objective.

Approval of irradiation facilities

The desk research and the consultations carried out within DG SANTE did not lead to identify incoherence as regards the approval of irradiation facilities in the EU and in third countries, in comparison to the general framework for registration and approval of food establishments under the EU food legislation.

The registration and approval regimes provided by Regulation (EC) 852/2004 and Regulation (EC) 853/2004 apply to irradiation facilities when appropriate, in addition to their specific approval procedure laid down by the Directives.

The approach applied so far for the approval of food irradiation establishments in third countries is based on on-the-spot inspections carried out by the Commission in each facility applying for EU-approval. This approach differs from the one that the Commission applies to most other types of food-processing establishments in third countries, the so called 'pre-listing' approach.

The pre-listing approach means that the Commission relies on the competent authorities of exporting countries to draw up and keep up to date the list of approved establishments. To be eligible for pre-listing, a non-EU country must provide adequate guarantees with regard to the application and enforcement of the legislation of the third country applicable to the sector concerned, and the reliability of the official certification procedures. It must notably demonstrate that the listed establishments are under the official oversight of a competent authority, which carried out regular official controls and other activities to ensure that the establishments and their operations comply with applicable EU requirements.

The Directive 1999/2/EC does not lay down specific provisions on the approach to be applied for the approval of irradiation facilities in third countries, but only retains the right of the Commission to carry out on-the-spot inspections to verify that the facilities to be approved meet the applicable EU requirements. Therefore, the Directive 1999/2/EC does not prevent the application of the "pre-listing" approach to the approval of irradiation facilities in third countries.

Specific hygiene rules for food of animal origin

The audits carried out by the Commission have shown that the control of the temperature of refrigerate or frozen food in irradiation facilities is challenging during the food irradiation process, especially in irradiation facilities that predominately irradiate products other than foodstuffs.

Two stakeholders (from France and the Netherlands) interviewed within the framework of the support study mentioned notably that the maximum storage temperature set by Regulation (EC) 853/2004 for frozen mechanically separated

chicken (-18 degrees Celsius throughout the process) contributed to the decline of the irradiation of this product. Both explained that they stopped the irradiation of mechanically separated chicken, because maintaining that temperature throughout the irradiation process proved challenging.

Therefore, there is a certain incoherence in authorising certain foods to be irradiated, when these foods cannot (or only hardly can) be irradiated under conditions that would meet the specific hygiene rules under Regulation (EC) No 853/2004.

Microbiological criteria

The desk research and the consultations carried out within DG SANTE showed that the Directives are coherent with Regulation (EC) 2073/2005[36] on microbiological criteria for foodstuffs, which takes into account the possible use of decontamination to eliminate the microorganisms of concern from food.

Indeed, the criteria laid down by Regulation (EC) No 2073/2005 apply to irradiated foodstuffs, except where a derogation is granted for food which has undergone a treatment effective to eliminate the microorganisms of concern. Conversely, the Regulation lays down certain criteria that specifically apply to food that have undergone a treatment, in order to check on the efficiency of the treatment and prevent recontamination.

Novel food legislation

The desk research and the consultations carried out within DG SANTE did not identify incoherence between Regulation (EU) 2015/2283[37] ('the novel food regulation') and the Directives.

According to Regulation (EU) 2015/2283[38] ('the novel food regulation'), food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food affecting its nutritional value, metabolism or level of undesirable substances is considered a novel food.

According to Article 4 of the same regulation, food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation. If after considering all the information available food business operators are still unsure about a food as novel, they should consult the competent authorities of the Member State where they first intend to

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36 Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338 22.12.2005, p. 1)

37 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. OJ L 327, 11.12.2015, p. 1

38 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. OJ L 327, 11.12.2015, p. 1

place the food on the market, according to the procedure described in Commission Implementing Regulation (EU) 2018/456[39].

Although significant technological progresses have been achieved in the area of ionising radiation in the recent years (e.g. development of low energy electron beam), it is unlikely, but cannot be *a priori* excluded, that foodstuffs resulting from that technology might be considered as novel food as changes in composition or structure of food induced by such irradiation techniques are minor. However, as indicated above, it is responsibility of food business operators to verify whether or not the food which they intend to place on the market within the Union falls within the scope of the novel food regulation and a case by case analysis is necessary.

If foodstuffs resulting from a new irradiation technology would be considered as novel food, their irradiation would be possible once they are authorised under the Directives and under the novel food Regulation.

Labelling requirements

The desk research and the consultations carried out within DG SANTE did not identify incoherence between the labelling requirements laid down by the Directives, and those laid down by Regulation (EU) No 1169/2011 [40] on the provision of the food information to consumers.

Directive 1999/2/EC refers in its Article 6 to Directive 79/112/EEC, which has been repealed by Directive 2000/13/EC [41], itself repealed by Regulation (EU) No 1169/2011.

Regulation (EU) No 1169/2011 applies without prejudice to labelling requirements provided for in specific Union provisions applicable to particular foods (see Article 1(4) of Regulation (EU) No 1169/2011), i.e. without prejudice to Article 6 of Directive 1999/2/EC.

Regulation (EU) No 1169/2011 echoes the labelling requirements for irradiated foodstuffs laid down by the Directive 1999/2/EC, by providing in its article 17 paragraph 5 and Annex VI, Part A, point 3, that the particulars *'irradiated'* or *'treated with ionising radiation'* shall accompany the name of the food and by specifying in article 18(2) that "*ingredients shall be designated by their specific name, where applicable, in accordance with the rules laid down in article 17 and in Annex VI*". The same rules apply therefore for foods and ingredients: the particulars '*irradiated'* or '*treated with ionising irradiation*' shall accompany the name.

In addition to labelling rules in Regulation (EU) No 1169/2011, Directive 1999/2/EC provides that the irradiation facility's identity or reference number should be indicated in the case of products not intended for the ultimate consumer and mass caterers (Article 6.2.b of Directive 1999/2/EC), and provides that the

[39] Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 77, 20.3.2018, p. 6

[40] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (OJ L 304, 22.11.2011, p. 18).

[41] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29).

indication of the treatment shall in all cases be given on the documents which accompany or refer to irradiated foodstuffs (Article 6.3 of Directive 1999/2/EC).

Official controls and reporting obligations

Regulation (EU) 2017/625 (the Official Controls Regulation) establishes common rules for EU official controls carried out by national competent authorities to verify compliance with agri-food chain rules, including on food and feed safety, integrity and wholesomeness throughout production, processing and distribution and labelling. The regulation also covers imports of certain animals and goods from outside the EU which are subject to checks at EU border control posts.

Official controls concerning irradiated foodstuffs and irradiation facilities are not specifically addressed in this Regulation, but they are mentioned in Commission Implementing Regulation (EU) 2019/627[42], Article 45 of which lays down the measures in cases of non-compliance with requirements for fresh meat, and provides that the official veterinarian shall declare fresh meat unfit for human consumption if the meat "(*l) has been treated illegally with ionising radiation, including UV-radiation"*. The inclusion of UV-radiation under the term "ionising radiation" in this Article differs from the definition of ionising radiation under Council Directive 2013/59/EURATOM (see below).

Even if they are not specifically addressed in the Official Controls Regulation, official controls of irradiated foodstuffs and irradiation facilities falls within the scope of this Regulation and should therefore be carried out in accordance with its provisions. The data collected through the evaluation suggest that the controls carried out by Member States are not harmonised, neither by their frequency (Germany represents more than 50% of the samples taken in the EU) nor by the approach adopted. In particular, some Member States appear to carry out random sampling, while the Regulation sets out a risk-based control system, so that national enforcement authorities carry out official controls where they are most needed. This suggests that the organisation of the controls to check compliance with the Directives may not be carried out in line with the general provisions laid down by the Official Controls Regulation.

Directive 1999/2/EC provides that the methods used during official controls to detect treatment with ionising radiation shall comply with paragraphs 1 and 2 of the Annex to Directive 85/591/EEC. This Directive has been repealed by Regulation (EC) No 882/2004, itself repealed by Regulation (EU) 2017/625. However, paragraphs 1 and 2 of the Annex to Directive 85/591/EEC laid down general requirements for analysis methods, which all methods currently used under Regulation (EU) 2017/625 for official controls fulfil.

As the Directives do not set specific provisions regarding the monitoring of imports, no incoherence with the legal provisions applying to the control of imported foodstuffs in the EU have been identified.

[42] Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 (OJ L 131, 17.5.2019, p. 51).

5.2.3 Coherence with other EU acts

Plant health legislation

No incoherence has been identified between the Directives and the EU legislation on plant health.

Irradiation can be an effective tool to address plant health risks (see Section 5.1.2 "Relevance of food irradiation for plant health"), and is therefore addressed in the EU legislation on plant health.

Regulation (EU) 2019/2072[43] provides notably requirements for the import of plants (whether edible plant or non-edible plant) and plant products in the EU, which can include the use of post-harvest treatment by fumigation with plant protection products or irradiation (Annex VII and Annex IX). Regulation (EU) 2019/2072 provides that, in certain cases, third countries have to communicate in advance to the Commission if they plan to make use of post-harvest treatments on plants or plant products to be exported in the EU[44]. Exporting countries must declare in the certificate accompanying consignments of plant if a post-harvest treatment (whether chemical or physical) has been applied.

To date, the use of irradiation to fulfil phytosanitary import requirement is explicitly recognized as an available option in only two cases, namely for import of certain wood species and of wood packaging material. However, these are not commercially used, and they do not concern consumable plant products.

The scope of the Directives is not limited to the use of the technique for hygiene purpose, but also includes its uses for plant health purposes. Indeed Annex I of Directive 1999/2/EC provides that food irradiation may be used "*to rid foodstuffs of organisms harmful to plant or plant products*". Therefore, when irradiation is used on food of non-animal origin for plant health purposes, both the Directives and the EU legislation on plant health apply.

This means for example that import of food of non-animal origin irradiated for plant health purpose can only occur:

- from facilities authorised under the Directives, and
- if the efficacy of the treatment for plant health purpose has been demonstrated under the EU legislation on plant health (based on international standards or on a dossier submitted to the Commission).

Member States that do not authorise irradiation of certain food products on their territory may forbid the import of food of non-animal origin irradiated for plant health purpose, based on the provisions of the Directive 1999/2/EC.

Council Directive 2013/59/EURATOM

The Directives regulate use of ionising radiation for treatment of foods but do not define this expression, nor "food irradiation", which created uncertainty among stakeholders (see following Sections).

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[43] Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants (OJ L 319, 10.12.2019, p. 1).

[44] https://ec.europa.eu/food/plant/plant_health_biosecurity/non_eu_trade/declarations_en

'Ionising radiation' is on the other hand defined in Council Directive 2013/59/EURATOM as '*energy transferred in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of 3 x 1015 hertz or more) capable of producing ions directly or indirectly'*.

Applying this definition also for the purposes of the Directives would help clarify the scope of the Directives, since this definition clearly excludes certain technologies such as cold plasma and UV treatment with wavelength above 100 nanometres. Such technologies have begun to be used in commercial conditions in the years after the Directives came into force, but only in limited ways and for particular products (e.g. UV for water treatment). The definition would however not exclude the 'low energy electron beam' technology, which has been recently developed to enable surface treatment of dry food products but is not yet used in the EU or in third countries in commercial conditions (based on information provided by the manufacturer of that technology, see support study, Section 3.5.1.1.).

Regulation (EU) 2018/848 on organic production

Regulation (EU) 2018/848 on organic production and labelling of organic products prohibits the use of ionising radiation (i.e. irradiation) in the treatment of organic food or feed, and in the treatment of raw materials used in organic food or feed, considering that the use of ionising radiation is incompatible with the concept of organic production and consumers' perception of organic products.

Regulation (EU) 2016/425 on personal protective equipment

The desk research and the consultations carried out within the Commission did not identify any incoherence between the provisions of the Directives and the Regulation (EU) 2016/425[45] as regards occupational safety in food irradiation facilities.

5.2.4 Coherence with international standards

There is potential to revise the Directives to better align with the most recent update to the Codex Alimentarius General standards.

The Codex Alimentarius has developed a code of practice for radiation processing of food[46] and a general standard for irradiated foods[47], and has published a list of methods for the detection of irradiated foods[48]. These documents provide guidelines for governments to effectively apply the irradiation technology to improve food safety, together with guidance on the labelling of irradiated foods. However, it is left to governments to determine their own approach to the use of food irradiation.

Currently, there is a single reference to the Codex Alimentarius in Directive 1999/2/EC, article 7(2) of which provides that irradiation facilities must meet the "*Codex Alimentarius Commission Recommended International Code of Practice for the operation of irradiation facilities used for the treatment of foods (reference FAO/WHO/CAC, Vol. XV, edition 1)"* in order to be granted approval. Since the

[45] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51–98)

[46] CAC/RCP 19-1979, Code of practice for radiation processing of food

[47] CXS 106-1983, Rev.1-2003, General standard for Irradiated Foods

[48] CXS 231-2001, General methods for the detection of irradiated foods

code of practice referred to has now been replaced by the code of practice for radiation processing of food, CAC/RCP 19-1979, there is some ambiguity as to whether the Directives require compliance with this latest code of practice.

Further, the general standard for irradiated foods, updated in 2003, uses a concept of "maximum absorbed dose" which is considered a more appropriate than the one used in the Directives, i.e. the concept of "maximum overall average absorbed dose".

Experts from the irradiation industry called for the EU legislation to be updated and aligned with the current Codex Alimentarius recommendations, in particular as regards the concept of absorbed doses, considering that this could help to resolve conflicts or grey areas in relation to international trade, see Section 5.4.5 "Competition between EU and non EU businesses".

In addition to the recommendations provided by the Codex Alimentarius, Member States can rely on other international standard when enforcing the Directiveson. A standard ISO 14470:2011 on "food irradiation: requirements for the development, validation and routine control of the ionizing radiation process used for the treatment of food", was notably developed and published for the first time in 2011.

5.3 Effectiveness

Main findings

The Directives have not fully met their objectives.

The **harmonisation of the legislation** on irradiation across the EU has been only achieved to a limited extent. Requirements on sources of irradiation, absorbed doses, labelling of irradiated foodstuffs and irradiated ingredients, approval of irradiation facilities, and on reporting have been fully harmonised. However, national lists of foodstuffs authorised for irradiation remained, as well as national bans or restrictions on the trade of irradiated foodstuffs.

As a consequence, **free movement of irradiated foodstuffs** within the single market has been ensured only for the sole food category included in the current EU list of foodstuffs authorised for irradiation: "Dried aromatic herbs, spices and vegetable seasonings".

The Directives did not achieve their objective to establish a **fair competition in the EU and with third countries**, especially for products other than herbs and spices, since the harmonisation of the legislation has only be been limited. Moreover, while the Directives provide that irradiated foodstuffs entering the EU should comply with the EU requirements applicable to those foods, representatives of the EU food industry expressed concerns that irradiated products were being imported without meeting EU requirements, thus undermining competition with third countries.

The **enforcement of irradiation legislation** has been partially achieved. The controls applied by Member States are considered mostly effective, but the level of enforcement differs greatly between Member States, one Member State being responsible for more than 50% of the official controls in the EU. Almost all non-compliances identified relate to foodstuffs imported from third countries, which fuels the hypothesis that there may be gaps in the enforcement of EU requirements on import of irradiated foodstuffs, although the extent of this issue is difficult to evaluate.

It is difficult to conclude on the effectiveness of the Directives to **provide information to consumers/citizens** to ensure choice and welfare, in absence of direct data on consumer perceptions and understanding of the labels. Labelling requirements are harmonised and enforced, but available evidence suggest that consumers' awareness of irradiation has decreased since the implementation of the Directives, and that they frequently misunderstand irradiation labelling, interpreting them as a warning.

Finally, since they do not include specific provisions to **establish favourable conditions for innovation**, the Directives as such did not play a significant role for the achievement of these objectives. The requirements on sources of irradiation created confusion on the scope of the Directives, which may even have hampered innovation.

5.3.1 Overview of the provisions' effectiveness

The degree of achievement of the objectives were assessed for the following main provisions: requirements on sources of irradiation and limits for absorbed doses, listing of foodstuffs authorised for irradiation, labelling of irradiated foodstuffs, approval of irradiation facilities by competent authorities, rules for import and intra

EU trade of irradiated foodstuffs, enforcement of official controls and reporting obligations. A summary of the conclusions drawn from the answers provided during the support study, and detailed hereafter, is given in Table 2.

Table 2 : Summarized conclusions for the main provisions of the Directives

Provisions of the Directives	**Objectives have been met most effectively / less effectively / not at all**
Requirements on sources of irradiation and limits for absorbed doses	**Less effectively** The requirements for the use of food irradiation are harmonised but there are different national interpretation as regards the use of recently developed technologies
Listing of foodstuffs authorised for irradiation	**Not at all** The planned replacement of the initial EU list, which includes only one food, and of the national lists by an extended EU list has not taken place. As a consequence, Member States may maintain national lists of foodstuffs authorised for irradiation, and national bans or restrictions on the trade in irradiated foodstuffs.
Labelling of irradiated foodstuffs	**Less effectively** Where labelling requirement is followed and consumers understand the labelling, the Directives enables consumer's choice and welfare. However, consumers' awareness of irradiation is low and they may frequently misunderstand irradiation labelling.
Approval of irradiation facilities by competent authorities	**Most effectively** The process for approval is harmonized and applies to both EU and non EU facilities. Lists of approved facilities are published by the Commission
Rules for intra EU trade of irradiated foodstuffs	**Not at all** The provisions on intra EU trade of irradiated foodstuffs did not meet their objective of harmonising legislation on irradiation across the EU and ensuring free movement of irradiated foodstuffs within the single market.
Rules for import of irradiated foodstuffs into the EU	**Less effectively / Most effectively** Requirements applying to imported irradiated foodstuffs are considered adequate but stakeholders have concerns regarding compliance of imported products with EU requirements.
Enforcement of official controls	**Less effectively** Official controls applied by Member States are mostly effective, but their frequency differs among Member States and controls of food irradiated with low level doses are not possible with current standardised methods.
Reporting obligations	**Most effectively** The Commission published every two years a report presenting the quantities of foodstuffs irradiated in the EU and the results of checks carried out by Member States.

5.3.2 Requirements for the sources of irradiation

The technical provisions of the Directives have only partially met their objective of providing a unified legal status for irradiated food products in the EU.

In particular, the absence of definition of "ionising radiation" in the Directives (see Section 3.1) created uncertainty about the scope of the Directives as regards some

novel decontamination technologies such as low energy electron beam, cold plasma or ultraviolet (UV) treatment. This uncertainty led to some discrepancies in the implementation of Directive 1999/2/EC in the EU: some Member States considered that these new technologies are not listed in the Directive because their use is forbidden, while others considered that these technologies are authorised but not listed because they do not fall under the definition of ionising radiation, and therefore within the scope of the Directive. These differences between Member States' legal approaches towards novel technologies may have contributed to confusion in businesses.

Moreover, this issue may have posed problems for the development of innovative products and processes. Very few patents related to food irradiation have been filed in the EU since the Directives entered into force (none of which were granted). This suggests that the Directives have not been effective in allowing for the entry in the EU market of innovative products or processes. However, no evidence has been identified on the types of innovation that were prevented and in what ways. Moreover, no evidence showed that the lack of innovation has been caused by the confusion on the scope of the Directives, rather by the low interest of EU operators in such technologies because of the possible negative perception of consumers (See Section 5.4.6 "Main reasons for the decline of food irradiation in the EU").

5.3.3 Limits of absorbed doses

The requirements concerning the limits of absorbed doses are harmonised within the EU, but some issues in their implementation have been reported.

First, the Directives base dose requirements on a measurement of "overall average absorbed dose", a concept that is not directly measurable and must be estimated. This approach is not the one used in many non-EU countries and recommended by the Codex Alimentarius since 2003, which relies on minimum and maximum dose (See Section 5.2.4 "Coherence with international standards"). Stakeholders involved with the irradiation industry mentioned that the legislation's focus on "overall average absorbed doses" obscures the importance of ensuring a minimum dose is applied – particularly when irradiation is used to ensure food safety, a concept which is also reflected in the Codex Alimentarius General Standard for Irradiated Foods. However, the purpose of the Directive is in the first place to ensure food safety, not the efficiency of a treatment. It is primary to the irradiation establishment to demonstrate that the cost of such treatment has a benefit.

Second, the 2011 EFSA's opinion on the efficacy and microbiological safety of irradiation of food also noted that the way doses are currently assigned (to general food classes) does not consider other important factors (such as whether food is fresh or frozen, differentiations in composition between products within the same class and new and diverse types of products now available to consumers).

Finally, the requirements of the Directives for the limits for absorbed doses are not relevant for the recently developed 'low energy electron beam' technology, which enables surface treatment of dry food products, but this does not affect the effectiveness of the Directive, since this technology has not yet entered the market.

5.3.4 Listing of foodstuffs authorised for irradiation

The objective to replace the initial EU list and national lists of foodstuffs which may be treated with ionising radiation by an EU list of foodstuffs which may be treated with ionising radiation to the exclusion of all others has not been met.

The process for the replacement of the initial EU list, which included only one foodstuff category ('dried aromatic herbs, spices and vegetable seasonings'), was launched in 2000. The Commission addressed a Communication to the European Parliament and the Council on Foods and food ingredients authorised for treatment with ionising radiation in the Community[49] offering three options:

- Option 1 was the inclusion of the only two foods for which a clear technological need had been identified through the consultation carried out at the time: "peeled shrimps" and "frog legs";
- Option 2 was, a list based on an opinion from the EU's Scientific Committee for Food and including the " deep frozen aromatic herbs", "dried fruit", "flakes and germs of cereals", "mechanically recovered chicken meat", "offal of chicken", "egg white", "gum Arabic", "frog legs" and "peeled shrimps";
- Option 3 was to consider the current list as complete, having regard to the divergence of views resulting from the consultation process.

The consultation showed that there were strong, polarised views on the matter, a lack of support for the proposals from a number of representative organisations for the food industry, consumer organisations and NGOs. The Communication of the Commission indicated that most of the food production and trade sectors were against the inclusion of their products into the EU positive list, mainly because they expected negative consumer reactions. Only some specific sectors were in favour of authorising irradiation of their products, like shrimps, frog legs, crayfish and blood products.

By a vote on 17 December 2002, the European Parliament adopted a resolution[50] in favour of Option 3, which stopped the process for adding new products to the EU positive list of products. The rapporteur of the resolution stated that the current EU list should not be extended at this stage and should be regarded as complete[51]. The European Parliament expressed several concerns around the establishment an extended EU list of foodstuffs authorised for irradiation, including that:

- there was evidence that the existing legislation was not being appropriately enforced;
- there was a lack of evidence regarding the long-term safety of eating a diet based largely on irradiated foods;
- there was a lack of evidence on how worker health and safety may be impacted by gamma irradiation; and
- there were concerns that irradiation could be used to mask poor hygiene standards in certain industries.

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49 Communication from the Commission to the European Parliament and the Council on Foods and food ingredients authorised for treatment with ionising radiation in the Community, COM/2001/0472, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52001DC0472&qid=1615977065383

50 European Parliament resolution on Commission communication on foods and food ingredients authorised for treatment with ionising radiation in the Community (COM(2001) 472 – C5-0010/2002 – 2002/2008(COS))

51 European Parliament Daily Notebook, 17-12-2002 https://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+PRESS+DN-20021217-1+0+DOC+XML+V0//EN#SECTION5

A persistent and fundamental disagreement between Member States on the potential role and acceptability of irradiation was pointed out as an obstacle. A broader debate was announced by the Commission, but never took place.

The 2011 EFSA opinions on the biological and toxicological safety of food irradiation addressed the concerns on food safety expressed in the European Parliament resolution, but this did not reopen the discussion on a possible extension of the EU list of foodstuffs authorised for irradiation.

5.3.5 Labelling of irradiated foodstuffs

The Directives harmonised the labelling requirements within the EU but this is difficult to conclude directly whether these labelling requirements are effective in informing consumers in order to ensure consumer choice and welfare.

The Directives ensure that consumers are provided with information that enables choice and consumer welfare, only where 1) the labelling requirement is followed, and 2) consumers understand the labelling.

Non-compliances on labelling requirements have been identified through the official controls carried out by Member States but their extent seems limited (see Section 3.4 “Results of official controls”).

There is no direct data on consumer perceptions and understanding of the mandatory particulars ‘irradiated' and ‘treated with ionising radiation', but based on the evidence available, it appears possible that they contributed to consumer confusion and misperceptions, and led consumers to interpret the irradiation labelling as a warning. The overall consumers’ awareness of irradiation is low. In the current context, most EU consumers would almost never encounter an irradiated product since food irradiation has become such a narrow share of the EU food production system. As an example, more than 300,000 tons of herbs and spices are consumed yearly in the EU while only 600 tons are being irradiated in EU facilities. Within the EU, frog legs are the only regularly sold irradiated product, and these are mostly consumed in France and Belgium.

Some studies [52], [53] showed that the lack of consumer acceptance stems from misconceptions about the technology, and when presented with more information, consumers are more likely to accept it.

Representatives of the irradiation industry were concerned that the labelling requirements provided by the Directives, acted as a main factor in the decline of food irradiation in the EU (See Section 5.4.6 “Main reasons for the decline of food irradiation in the EU”).

5.3.6 Approval of irradiation facilities

The provisions on theapproval and monitoring of irradiation facilities within the EU and in non-EU countries are effectively applied, and ensure that manufacturing of

[52] Lima Filho, T., Della Lucia, S. M., Lima, R. M., Scolforo, C. Z., Carneiro, J. C. S., Pinheiro, C. J. G., & Passamai Jr, J. L. (2014). Irradiation of strawberries: Influence of information regarding preservation technology on consumer sensory acceptance. Innovative Food Science & Emerging Technologies, 26, 242-247

[53] Junqueira-Gonçalves, M. P., Galotto, M. J., Valenzuela, X., Dinten, C. M., Aguirre, P., & Miltz, J. (2011). Perception and view of consumers on food irradiation and the Radura symbol. Radiation Physics and Chemistry, 80(1), 119-122.

irradiated foodstuffs is implemented in line with the Directives. This was confirmed in the survey of national competent authorities (see support study, Section 4.1.9). No non-compliance incidents related to irradiation facilities have been identified.

All facilities in the EU have been approved in line with the Directives.

So far, the approval of irradiation facilities in non-EU countries occurred after an audit of the Commission in these premises. The Commission rejects applications for facility approval if there is no confidence that competent authorities in non-EU countries will be able to provide official supervision to guarantee that the requirements of the Directives are upheld. This was the case, for example, following the results of an audit on facilities in China in 2009. They are no active controls of the use of irradiation in non-EU countries by the Commission after the initial approval of the facilities. After approval, the Commission relies on the competent authorities of third countries to ensure that facilities keep complying with the Directives. The approval of facilities in third countries is granted for all food and food ingredients, whereas only one product is included in the current EU list. As a consequence, it is often unclear to food business operators and competent authorities which foods they are authorised to irradiate and export to the EU, and in which Member State.

The Directives do not subject approved facilities in third countries to the same reporting requirements as those to which approved facilities in the EU are subject (annual reporting of the quantities and type of food irradiated). Certain national competent authorities considered this information could be useful to improve the control carried out at import to identify irradiated foodstuffs not labelled as such.

There have been some limited instances of products which have been irradiated in unapproved facilities finding their way on to the EU market (see Section 3.4 "Results of official controls").

5.3.7 Provisions on intra EU trade of irradiated foodstuffs

The provisions on intra EU trade of irradiated foodstuffs did not meet at all their objective of harmonising legislation on irradiation across the EU and ensuring free movement of irradiated foodstuffs within the single market.

Indeed, since the process provided by Directive 1999/2/EC to adopt a EU list of foodstuffs that may be treated with ionising radiation to the exclusion of all others did not take place (see Section 5.3.4 "Listing of foodstuffs authorised for irradiation"), the provisions to maintain the existing national authorisations of the Member States are still in force, whereas they were supposed to be transitional, and the rules applying to import and intra EU trade of irradiated foodstuffs have not been harmonised.

The maintaining of only one category of irradiated foodstuff listed at EU level and of several categories at the national level in six Member States prevented a consistent regime for irradiated foodstuffs and their free movement within the EU market to be established.

Currently, free movement within the single market is only ensured for the one category of foodstuffs included in the initial EU list ('aromatic herbs, spices and vegetable seasoning'). The rules applying to other foodstuffs are defined at national level by Member States, which may, in accordance with Directive 1999/2/EC, continue to apply existing national restrictions or bans on ionising radiation of foodstuffs and on trade in irradiated foodstuffs.

Whereas the national lists of foodstuffs authorised for irradiation are notified to the Commission and published in Official Journal of the European Union, this reporting obligation does not exist as regards the national rules applied to the trade of foodstuffs irradiated in other Member States or in third countries. This creates confusion among stakeholders and national competent authorities, who do not know exactly which irradiated foods are accepted by which Member State. According to the survey carried out on national competent authorities (See support study), only Germany laid down rules to ban or require specific approval for products not on the EU list (in particular, for the entry on its market of irradiated frog legs).

The lack of an EU positive list of foodstuffs authorised for irradiation to the exclusion of all others, and the persistence of different authorisations at the national level in several Member States created uncertainty for businesses interested in using irradiation, both within the EU and for third countries looking to import to the EU. Evidence from the consultations suggests that the difference between the EU and national lists may contribute, in part, to food business operators' decisions not to irradiate. However, it is difficult to assess the extent to which this has an impact, considering the business reluctance to irradiate for other reasons (such as perceptions of consumer acceptance and cost), see Section 5.4.6 "Main reasons for the decline of food irradiation in the EU".

5.3.8 Provisions on import of irradiated foodstuffs

The Directive 1999/2/EC provides that a foodstuff treated with ionising radiation may not be imported from a third country unless it complies with the conditions which apply to those foodstuffs, and was treated in a facility approved and listed by the Commission.

Industry stakeholders consulted expressed concerns as regards a potential lack of monitoring at import to check these requirements, which would result in irradiated products being imported from third countries without being properly controlled for or labelled. They perceived a lack of compliance among some international competitors to the Directives, which they believe creates an unfair competition between the EU and non-EU country producers (See Section 5.4.5 "Competition between EU and non EU businesses"). Industry representatives involved in dried vegetables, herbs and spices have notably mentioned that irradiated products from non-EU countries might be entering the EU without labels, some products having also been irradiated in non-approved facilities.

Whereas several cases of mislabelled or non-labelled imported irradiated products have been found by national competent authorities (see Section 3.4.2 "Notifications to the rapid alert system for food and feed (RASFF)"), there is no evidence of a broader issue. Industry monitoring does take place in the EU (retailers often perform their own checks on suppliers, which mean that they are aware when suppliers have used irradiation), but there are no associated reporting obligations.

Of surveyed national competent authorities, 17 out of 24 reported that they had established initiatives to monitor imports from non-EU countries through random sampling (See support study, Section 5.10.4). These mostly involved sampling plans for a range of different imported product types. One national competent authority also stated that they used RASFF data as a source of information for their checks, to support risk-based sampling. One national competent authority considered it possible that many unlabelled irradiated products enter the market, in particular

from non-EU countries, as only a small number of checks are carried out to verify the irradiation of unlabelled products.

The same proportion of national competent authorities agreed that it would be valuable to more actively monitor imports from non-EU countries for irradiation (e.g. to collect data on the quantities and types of imported irradiated foodstuffs): this would enable checks for correct labelling to be made on products that were on the market and information on tests and their findings could be shared between Member States or at EU-level.

5.3.9 Enforcement

The Directives have only partially ensured the enforcement of rules on the irradiation of foodstuffs.

Identification of non-compliances

The enforcement measures led to identify non-compliances, which were notified through the EU report on food irradiation, and also, when appropriate, to the RASFF (See Section 3.4).

Although the overall percentage of non-compliances detected in the EU is low and most of the non-compliances identified are not serious, it is difficult to draw conclusion on the real situation because the number of controls carried out within the EU is small, and because the approach applied by Member States for sampling (risk-oriented or random controls) is not known and not harmonized, and therefore not representative of the overall situation in the EU. However, 16 out of 17 national competent authorities that answered the evaluation survey indicated that they did not have any information to suggest that the problems were more widespread or serious than what the RASFF notifications indicate (See support study, Section 4.5.3). Non-compliances were observed on imported irradiated products, which led certain stakeholders to express concerns as regards a potential lack of monitoring at import (see Section 5.3.8 “Provisions on import of irradiated foodstuffs”).

The Directives do not include any specific provisions related to the enforcement of non-compliances but most Member States reported putting enforcement measures in place to deal with samples that tested positive for irradiation. These included formal notices and warnings, fines, seizure of products or returning them to the country of origin, and withdrawal of products from the market. However, national competent authorities also indicated that in many cases, these enforcement actions have not been applied as there have been no instances of non-compliance identified.

Variance in level of enforcement of official controls at marketing stage

Most Member States carry out checks at the product marketing level, which involves testing a sample of products—generally a risk-based sample—for unauthorised irradiation. This sample would include both products originating from the EU and from third countries.

Member State authorities and other stakeholders have indicated through the survey and through the public consultation (See Annex 2) that enforcement measures are effective. However, there is significant variance between enforcement practices in different Member States, notably in the levels of sampling and controls undertaken by Member States. As shown by Figure 6, several Member States carry out very few or no controls on irradiation, while one Member State carries more than 50% of the tests at EU-level. There does not appear to be a correlation between the level of

controls within Member States and the volume of products irradiated. The country where the greatest number of controls takes place (Germany) is not responsible for significant irradiation in the EU.

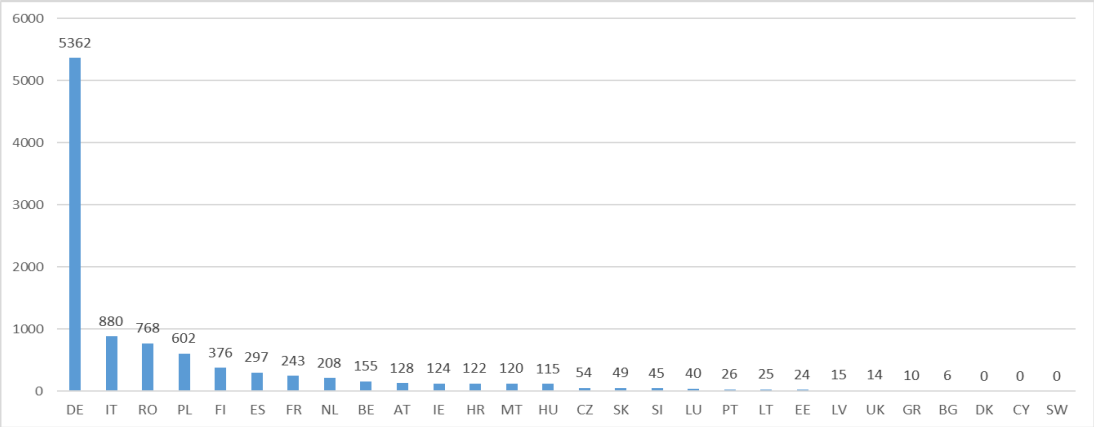

Figure 6 : Samples analysed at product marketing stage within each Member State in 2018-2019

Analytical methods for official checks

Some concerns were raised regarding the methods for the detection of irradiated food.

The Directives do not list the analytical methods authorised to carry out official controls, but only set general requirements, in particular that the methods used should be standardised or validated. A list of validated methods for the detection of irradiated foods (CXS 231-2001), which Member States can use for official controls, is published by the Codex Alimentarius.

Validated detection methods now exist for all the food types for which irradiation is permitted, apart from not plant-based food supplements (which is a growing area). However, the available methods are only suitable for the detection of irradiation, not to estimate with accuracy the irradiation dose, which they can only approximate. In the current situation, the dose used for irradiating a foodstuff can therefore only be certified by the facilities that proceeded to the irradiation.

The control system is not effective for the detection of low-level irradiated food, since the available methods are not currently suitable for detecting low levels of irradiation below 1 kGy, such as would be used as a plant health measure.

Some recent developments in analytical techniques are discussed in the literature and mentioned by experts as potentially promising for the detection of irradiated foods, e.g. Nuclear Magnetic Resonance and Near Infrared Spectroscopy. These are not yet validated and because there is only a small market for the detection of irradiated foods, there is little funding for the validation of new techniques.

Besides detection methods, concerns were also raised on the absence of an EU reference laboratory and of an EU network of official laboratories for the detection of irradiated foods. As a result no inter-laboratory comparisons (proficiency tests) are organized for these methods across the EU. This makes interpreting the results of controls at EU-level challenging, since procedures for the detection of irradiated food may vary between Member States.

5.3.10 Reporting

The reporting requirements of the Directives met their objective. The Commission published yearly or every two years a report on food and food ingredients treated with ionising radiation, which are accessible online[54]. National competent authorities considered the reporting obligations to be comprehensive, efficient and accurate.

The Directives largely allow for efficient policy monitoring, particularly within the EU. Eighteen out of 19 national competent authorities surveyed have indicated that the annual reporting requirement does not impose undue burden (See support study, Section 5.10). Four national competent authorities considered however that the reporting arrangements set in the Directives were not sufficient to identify issues associated with the manner controls were carried out,and provided the following context for their opinions:

- The legislation needs to include new methods and foods for sampling;
- TRACES-NT would be a useful tool to carrying out and reporting controls;
- Information on the quantities of irradiated products would be helpful;
- The inclusion of the country-of-origin of non-compliances would be helpful and would assist Member States in more efficient and risk-based sampling.

[54] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2019:0454:FIN

5.4 Efficiency

Main findings

The direct costs **for businesses** associated with the implementation of the Directives appear to be low and do not affect their ability to use food irradiation. The main determinants of the cost of irradiation of foodstuffs are the cost of setting up and running facilities and the cost of transportation of the food products.

The benefit **for consumers' safety** associated with the implementation of the Directives cannot be evaluated, notably because a multitude of factors, which cannot all be documented and controlled for, contribute to food safety within the EU, and because irradiated foodstuffs represented a very small proportion of the EU consumers' diet.

The **environmental impact** of the implementation Directives is also difficult to determine, due to a lack of comparable information on the environmental impacts of irradiation and its alternatives.

Surveyed national competent authorities indicated that the overall **costs of implementing the Directives** are in their view justified and proportionate and not overly burdensome.

The principal reason for the **decline in the use of irradiation** in the EU appears to be the concern of the food industry that consumers will react negatively to a label indicating that a food or one of its ingredients has been irradiated. In this sense, the Directives have affected businesses' ability to use irradiation as a decontamination technique. However, no evidence demonstrated the negative reaction of consumers anticipated by businesses.

The Directives have been mostly inefficient at **ensuring a level playing field** between EU Member States and third countries.

As regards the EU market, a level playing field between EU businesses and their international competitors is ensured as long as the products entering the EU fulfil the requirements of the Directives. But stakeholders from the EU industry expressed concerns that irradiated products may be imported from third countries without being properly controlled for or labelled, due to **insufficient monitoring at import**. Most national competent authorities considered it would be valuable to improve the monitoring at import, e.g. in carrying out more risk-oriented checks.

As regards the international market, the Directives do not permit EU manufacturers and traders to compete on such a level playing field with international competitors, since there is no equivalence between the EU regulatory framework and the regulatory frameworks used in third countries. Some stakeholders claimed that **a closer alignment to the Codex Alimentarius** General Standard on irradiation could help could resolve grey areas in relation to international trade, but such an alignment is unlikely to affect the level playing field, since the Codex Alimentarius set neither a list of foodstuffs that should be authorised for irradiation, nor the values to be applied for minimum and maximum absorbed doses.

5.4.1 Costs and benefits for consumers

The Directives include provisions, which contribute to the objective of preserving a high level of protection of consumer health (notably the requirements concerning the authorised sources and absorbed doses, as well as the approval procedures for

foodstuffs and facilities). However, it cannot be ascertained whether the implementation of the Directives has contributed to better food hygiene and reduced foodborne outbreaks for the following reasons:

- a multitude of factors contribute to food hygiene and foodborne outbreaks within the EU, which cannot all be documented and controlled for, particularly over the period that preceded the entry into force of the Directives and afterwards.

- the data are lacking to separate the effect of the Directives from that of many other steps taken to improve food hygiene or reduce foodborne outbreaks in the EU (at business, sector, country or EU level).

- irradiation has become such a marginal practice that even if it had an effect on food safety, it could concern a very small proportion of the food diet, and therefore very difficult to identify and measure.

- changes in the prevalence of the most reported foodborne diseases in the EU (Campylobacteriosis and Salmonellosis) have been linked to food products that are not or marginally irradiated in the EU (in particular meat, egg and milk products).

Whether the labelling requirements of the Directives have led to benefits for consumer information appears unlikely and it is possible that they have instead contributed to consumer confusion and misperceptions (see Section 5.3.5 “Labelling of irradiated foodstuffs”).

5.4.2 Costs and benefits for the environment

The extent to which environmental impacts differ between irradiation and its alternatives is largely unknown. No evidence on the quantitative environmental costs of irradiation in comparison to alternatives was identified. Searches on the environmental impacts of irradiation (including energy use and impacts related to the source of irradiation) yielded no quantitative data.

The use of food irradiation is often cited as a potential alternative to chemical treatment of food, such as methyl bromide, but as discussed in Section 5.1.3 “Relevance of food irradiation for reducing pesticide use”, the use of food irradiation is unlikely to reduce the use of pesticides on food produced or imported in the EU.

Qualitatively, the use of irradiation likely requires increased transportation as compared to alternative in-house treatment options. The evidence collected through interviews, case studies and surveys (see support study, Section 3.6) consistently point to the logistical challenges of irradiating food in dedicated irradiation facilities, which involves transporting food to the facilities, sometimes over significant distances. Moreover, the European Parliament wrote in its explanatory statement accompanying the motion for a resolution voted in 2002 (See Section 5.3.4 “Listing of foodstuffs authorised for irradiation”), that food irradiation undermines the objective of sustainable development by supporting the trend towards centralised mass production and distribution of foods world-wide, since extending shelf life to allow transportation of foods over greater distances contributes, among others, to increased fuel consumption, greenhouse gas emissions and air pollution. This statement was however not supported by quantitative data.

Certain technologies used for food irradiation produce radioactive waste which needs to be properly disposed. A radioactive source, Cobalt-60, is notably necessary for gamma irradiation. The source is shielded by water when not in use, and

becomes hazardous waste once its radioactivity levels become too low to be useful for application of treatment. Radioactive waste is also produced by electron beam irradiation. This is an environmental disadvantage for these irradiation types, but in general the problem of radioactive waste related to Cobalt-60 is minimal as compared to other radioactive sources and there are established procedures for disposal.

Emerging technologies that offer producers treatment solutions allowing for on-site integration and with reduced energy and water usage, would appear to be the most efficient options. These technologies do not penetrate the product as deeply as gamma rays and are therefore only suitable as surface treatments. However, these technologies are not specifically addressed by the Directives.

5.4.3 Costs and benefits for national competent authorities

The views of national competent authorities collected through an online survey suggest that the majority of them see the costs incurred for implementing the irradiation Directives as justified and proportionate (See support study, Section 5.5.1). They see the overall level of controls as proportionate considering the low use of the technique in Europe.

These results are illustrated in Figure 9. Only one national competent authority surveyed indicated that costs were high in comparison to the benefits, citing the annual reporting of data to the Commission and their publication in annual reports as disproportionately costly considering the low risks to consumers.

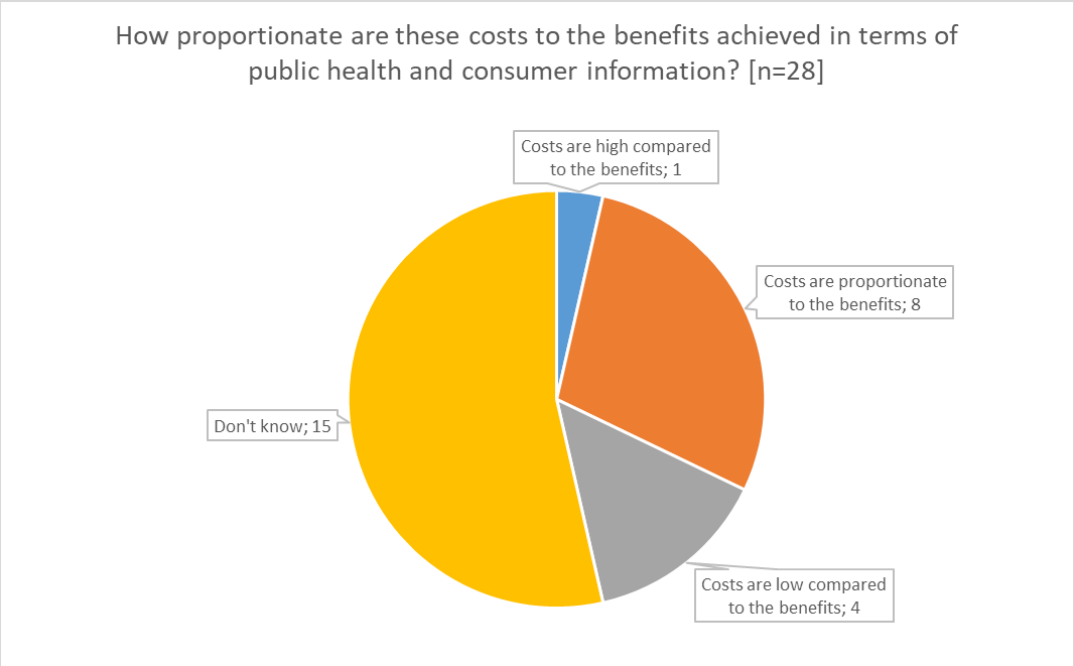

Figure 7 : National competent authorities' views on proportionality of costs

5.4.4 Costs and benefits for irradiation industry and food business operators

Costs of the technology

The key drivers for the costs involved in food irradiation are the capital costs in setting up facilities (estimated between EUR 2.5 and 10 million for a Cobalt-60 irradiation facility) and running them (which depend on the facility capacity: costs are reduced where facilities can operate at a higher throughput). Transport to and

from the irradiation facilities is also an important factor in the overall cost of irradiation treatment in the EU. In the case of some products (such as potatoes), transport prior to treatment risks damaging foods, such that product loss adds to the overall costs of using the technology. Evidence collected through the targeted survey of stakeholders for the support study has also indicated that the cost of irradiation does differ between countries.

There are **benefits and costs associated with all sources of ionising radiation**. The most efficient technology ultimately depends on the product undergoing irradiation. The three types of irradiation differ in their level of penetration of food. Gamma radiation and X-rays can penetrate the deepest into products (more than 60cm). The limit of electron beams penetration is around 3.5cm. Electron beam is therefore less suitable for those food products, such as frog legs, that require full penetration to address microbiological risks. The penetration achieved by gamma and X-ray irradiation means that these treatments can be used on shipping pallets, increasing processing efficiency. The limited penetration of electron beam irradiation means it can be used only to treat the surface of foods before they are packed for shipping.

Gamma irradiation occurs through the natural radioactive decay of Cobalt 60, while electron beam and X-ray irradiation are machine generated. Gamma irradiation is the least expensive option at low capacity, but at a certain quantity of product, electron beams become more economical. Unlike electron beam and X-ray, gamma irradiation cannot be turned off and therefore its efficiency falls if not in constant use. X-ray irradiation is the most expensive process as there is significant energy loss during the process of converting electron beams to photons to generate the X-rays.

Costs for implementing the irradiation Directives

The costs for implementing the irradiation Directives for the irradiation industry (corresponding to the procedure for the approval of the facilities and the reporting requirements) and for the food business operators (corresponding to labelling) are not well documented but are perceived to be low.

Given pre-existing labelling provisions from Council Directive 89/395/EEC, **the cost impact of the new labelling requirements** introduced by the Directives applied only to certain products in those countries already members of the EU in 1999 As reported in a study to inform an impact assessment of general food labelling issues[55], the costs of relabelling for a single product ranged from EUR 225 (small change) to EUR 7,000-9,000 (extensive redesign). Furthermore, the aforementioned study also indicated that companies would normally change their labels of their own accord regularly, and that 63% would do so within 2 years, which was the phase-in period for businesses to become compliant with the Directives (as stated in article 15 of Directive 1999/2/EC). As such, the costs associated with adherence to the Directives do not affect businesses' ability to use irradiation as a decontamination technique. According to the information received from food businesses and the irradiation industry, businesses were not deterred by

[55] European Commission (2008) Commission Staff Working Document accompanying the Proposal for a Regulation Of The European Parliament And Of The Council on the provision of food information to consumers - Impact Assessment Report On General Food Labelling Issues {COM(2008) 40 final}

the cost of labelling, but rather by the negative reaction they anticipated from consumers to foods labelled as irradiated.

The decrease in demand for irradiated products induced by the labelling requirements of the Directives (See Section 5.4.6 "Main reasons for the decline of food irradiation in the EU") could be considered as a significant indirect cost for businesses resulting from the Directive. The decrease in demand may in particular have led certain irradiation facilities to stop irradiating food (but most irradiation facilities in the EU obtain their main revenue from the irradiation of products other than food, and notably medical devices). In this sense, the Directives have affected businesses' ability to use irradiation as a decontamination technique. However, no evidence demonstrated the negative reaction of consumers anticipated by businesses.

5.4.5 Competition between EU and non EU businesses

The principle of a 'level playing field' is that competition is open and fair between manufacturing and trading partners. This relies on two main factors: firstly, whether the regulatory frameworks are similar or equivalent across markets, and secondly whether they are implemented similarly or uniformly across partners.

As regards import into the EU, a level playing field between EU businesses and their international competitors is ensured as long as the products entering the EU fulfil the requirements of the Directives. Some industry representatives expressed claims of unfair competition between the EU and third country producers, due to a lack of monitoring at import (see Section 5.3.8 "Provisions on import of irradiated foodstuffs").

As regards export to non-EU countries, the Directives do not permit EU manufacturers and traders to compete on such a level playing field with international competitors, since there is no equivalence between the EU regulatory framework and the regulatory frameworks used in third countries. EU irradiation facilities must meet the EU requirements, in particular with regard to the absorbed dose and the list of foodstuffs authorised for irradiation, even when the products they process are intended to be exported in countries with less restrictive requirements (e.g. authorising higher doses and/or additional foodstuffs).

For example, the maximum dosage specified for the EU in Directives 1999/2/EC and 1999/3/EC (10 kGy for dried vegetable seasonings, spices and aromatic herbs, with a dose uniformity ratio of less than three) differs from the maximum dosage set for herbs and spices in the US and Australia/New Zealand, which allow doses up to 30 kGy.

Some stakeholders claimed that a closer alignment to the most recent version of the Codex Alimentarius General Standard on irradiation could help could resolve grey areas in relation to international trade (See Section 5.2.4, "Coherence with international standards"), but such an alignment is unlikely to affect the level playing field, since the Codex Alimentarius sets neither a list of foodstuffs that should be authorised for irradiation, nor the values to be applied for minimum and maximum absorbed doses for these foodstuffs (the Codex Alimentarius only sets the cumulative maximum absorbed dose to 10 kGy, and tolerates higher doses in exceptional cases). It also does not provide specific recommendations regarding the labelling of irradiated ingredients in composite products.

Despite the fact that EU businesses are subject to stricter regulation than third country businesses, no evidence could be found of market opportunities that have not materialised because the Directives have prevented European producers from exporting irradiated products to third countries.

5.4.6 Main reasons for the decline of food irradiation in the EU

The decline of food irradiation in the EU has not been continuous. The most significant decline occurred in most Member States in the years immediately following the implementation of the Directives.

The decline of irradiated foodstuffs on the EU market can be attributed largely to the requirement to label irradiated ingredients, and the associated belief shared widely among businesses that consumers would not accept foods labelled as irradiated, as shown by the survey results presented in Figure 8. The relevance of the labelling requirements has been contested by some stakeholders (notably food business operators and the irradiation industry), many of whom feel that the requirement to label irradiated ingredients within processed products is overly burdensome. No consumer organisations or other NGOs responded on this point.

Other factors that may have contributed to the decline and continued low use of irradiation include:

- the cost of irradiation as compared to alternative treatments and the cost of irradiation as compared to the value of foods undergoing this process;
- a general lack of knowledge of irradiation among food businesses;
- uncertainty among food business operators around the differences between EU and national approved lists of irradiated foodstuff; and
- some additional regulatory requirements related to required storage temperatures may have also contributed to the decline in irradiated mechanically separated meat, See paragraph “Specific hygiene rules for food of animal origin” in Section 5.2.3 “Coherence with other EU acts”.

The EU market has not made use of irradiation for plant health purposes while this has been the main area of growth for food irradiation in third countries.

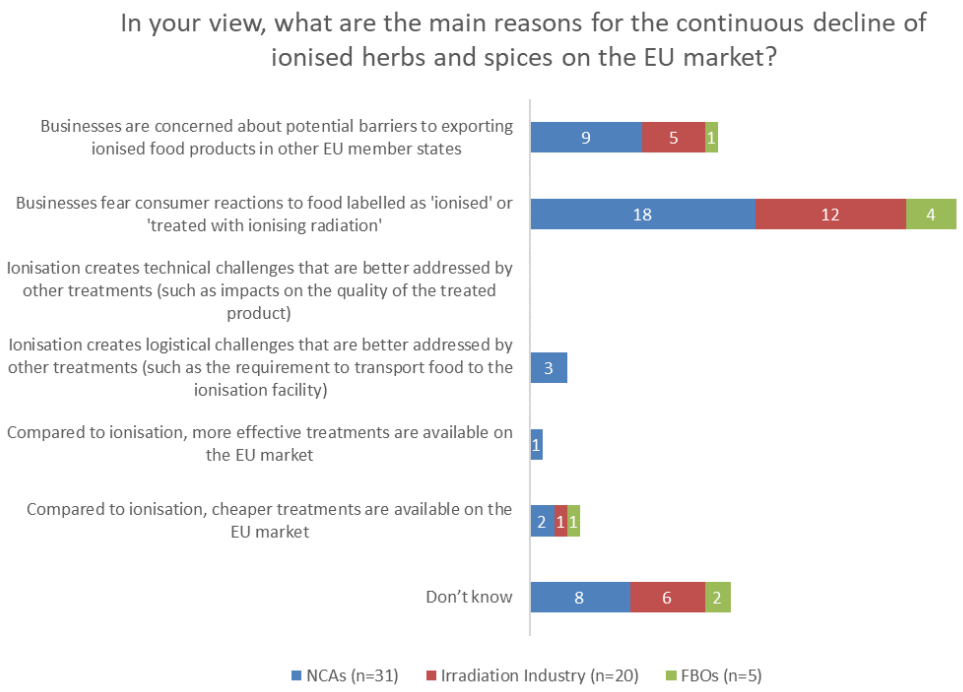

Figure 8 : Reasons for the decline in irradiated herbs and spices

All Member States had to transpose EU rules on the labelling of food products in the early 1990s, which included a requirement to label irradiated foods (Council Directive 89/395/EEC), well before Directives 1999/2/EC and 1999/3/EC were implemented. However, these labelling requirements were more general than those provided by the Directives, stipulating simply that "any foodstuff which has been treated with ionizing radiation" must bear a label, and they were generally interpreted in a way that the products containing small amount of irradiated ingredient had not be labelled. This had presented a problem in particular for herbs and spices, which are one of the most commonly irradiated foods and which are generally used as ingredients in other products in small quantities.

Several stakeholders expressed grievance that consumers do not get a complete and balanced information on the treatment applied to their food, since the labelling obligation established in the Directives is asymmetric, in that the food chain is required to label for certain treatments, such as irradiation, but not necessarily for others, such as steam treatment or chemical treatments.

5.5 EU added-value

Main findings

The legislative framework at EU level has **added limited value** to the irradiation of foodstuffs, since different national approaches remain, notably as regards the list of foodstuffs authorised for irradiation and their circulation in the single market, and as regards the official controls, on which the emphasis of Member States varies greatly.

It has provided **some level of harmonisation** of regulatory approach within the EU, notably on the authorised sources of irradiation and doses absorbed, for labelling irradiated foodstuffs and in particular irradiated ingredients, approving irradiation facilities, importing irradiated foodstuffs and monitoring the use of irradiation on foodstuffs

Stakeholders expressed **continued support for EU intervention on food irradiation**, considering it benefits the internal market and provides greater legal certainty (although much uncertainty remains).

If EU rules were to be phased out, historical differences in Member State legislation and approaches to irradiation would remain and could widen. Existing gaps in enforcement would likely be exacerbated, which may affect consumers negatively (in terms of choice and welfare).

5.5.1 Harmonisation of regulatory approaches within the EU

The legislative framework at EU level harmonised provisions on the authorised sources of irradiation and doses absorbed, for labelling irradiated foodstuffs, approving irradiation facilities, importing irradiated foodstuffs and monitoring the use of irradiation on foodstuffs. The establishment of the initial EU list of foodstuffs authorised for irradiation ensured the free movement for the sole product category listed ("Dried aromatic herbs, spices and vegetable seasonings") within the EU market. In this way, the EU legislative framework has provided greater legal certainty as compared to the situation prior to the implementation of the Directives.

Surveyed national competent authorities were asked about the measures introduced in their Member State when the Directives entered into force (See support study, Section 4.5.1).

For some, changes related to the implementation of the Directives were minor, either because there were no in-country irradiation facilities and/or a lack of evidence to indicate that irradiated foods were being imported (e.g. Cyprus), or because regulating measures were already in place (e.g. Belgium).

For others (e.g. France, Italy, Ireland), in particular where production or import of irradiated foods was more common, more work was carried out to implement the Directives. For example, irradiation facilities were indexed and inspected, as were food business operators that were known to handle irradiated foods. Sampling plans and procedures were introduced to detect food that had been irradiated, including establishing a minimum number of samples, setting out methods for testing and confirmatory analysis and disseminating application notes for correct sampling. Most national competent authorities also reported that national sampling plans encompassed initiatives to control food products from non-EU countries to ensure compliance with the Directives. Additionally, a national competent authority also

described validating new laboratory methods for testing and setting up a process for approving irradiation facilities.

The survey investigated whether the EU legislation had the added value of achieving economies of scale. Surveyed national competent authorities (n=17) indicated that they did not know whether economies of scale been achieved thanks to the Directives (e.g. if the burden of national controls has been reduced), see support study, Section 6.1.2. This is likely a reflection of the fact that significant time has passed since the introduction of the Directives. Of those who were able to respond, four indicated that costs had neither increased nor decreased, two indicated that costs have increased slightly and two indicated that costs have increased significantly. One national competent authority indicated that this increase was due to increased staffing and laboratory costs.

5.5.2 Existence and effectiveness of additional rules at national level

In the absence of a positive EU list of foodstuffs authorised for irradiation to the exclusion of all others, the transition measures are still in force and the scope of harmonisation achieved is less than what was projected when the Directives came into force. Member States' national legislations set the rules for the circulation of irradiated foods, beyond herbs and spices, in the single market. National legislations have also been responsible for the implementation of official control plans, with varying emphasis.

When surveyed, the majority of national competent authorities (15 out of 17) indicated that they did not have any additional national rules that were more effective than EU rules, see support study, Section 6.1.2. The Member States which answered positively were:

- Italy, which indicated the existence of an official control plan at national level, stipulating both the number of samples to be taken in each region, as well as the number of samples for Border Control Points. However, it is likely that other Member States have similarly implemented official control plans, but as indicated by the absence of controls reported to the Commission in several Member States, some do not.
- Germany, which referred to its additional legislation on ultraviolet treatments.

There is no evidence to suggest that national rules have been more effective than EU rules, but they have provided additional rules to those implemented by the Directives, specifically permissions for the irradiation of foods not included on the current EU list, techniques not addressed by EU legislation (such as UV treatment), rules for enforcement and official controls.

5.5.3 Interest of stakeholders in maintaining an intervention at EU level

As far as stakeholders are concerned, those who contributed to consultations (which reflect a limited sample of all potentially interested parties as far as the food industry and civil society are concerned, as discussed in section 4.3) expressed continued support for EU intervention in this area. Both national competent authorities and industry have indicated the importance of harmonisation in relation to irradiation rules. Many of the criticisms of the Directives relate to areas where harmonisation has not been fully achieved (e.g. through the absence of the EU positive list of authorised foodstuffs to the exclusion of all others). Where

harmonisation has been achieved (such as the common process for authorising irradiation facilities), it has been generally welcome by stakeholders, considering that it benefits the internal market and provides greater legal certainty.

Although some food business operators and some sector organisations have expressed interest in the potential benefits of food irradiation, in general there appears to be low awareness or low interest in the technology within the EU's food industry. The lack of interest appears to be largely due to the fact that producers and retailers believe that consumers will not purchase irradiated foods (even if there is no publicly available information on the current perceptions of food irradiation among food business operators in the EU).

Despite the lack of interest, several food business operators (e.g. from the fruit importing and red meat sectors) have indicated in interviews that even if they would not foresee using it in the near future, if irradiation is considered a safe and effective treatment, they would like to see it approved as a treatment option for their products.

5.5.4 Potential consequences of a phasing out of the EU rules

If EU rules were phased out, historical differences in Member State legislation and approaches to irradiation (as described in Section 2.2), some of which have endured through national lists and national legislation, would remain. They could widen if Member State authorities applied different labelling regimes regarding irradiated ingredients (as was the case before the Directives came into force) although none of the evidence collected and reviewed in the study hints at the current state of preferences on that matter regard at Member State level.

Regulation (EU) No 1169/2011 refers to Directive 1999/2/EC and echoes certain of its provisions (see Section 5.2.2 "Coherence with the EU food legislation"). Should the irradiation Directives be repealed, the obligation to label irradiated foodstuffs and ingredients would remain, but the reference to Directive 1999/2/EC included in Regulation (EU) No 1169/2011 would need to be amended, and the specific rules applying in the case of irradiated products not intended for the ultimate consumer and mass caterers (Article 6.2.b and 6.3 of Directive 1999/2/EC) would be repealed.

Since most irradiated food is currently processed in Belgium and France one could speculate that both countries could legislate further in that space. In Germany, the very high proportion of controls it has been carrying out signals also the importance given to continued control over the practice of food irradiation. However, the overall very low volumes of food irradiated in the rest of the EU and lack of interest or engagement from the food industry and civil society on the topic suggests that it is unlikely to be at the forefront of policymakers' agenda in most Member States in the foreseeable future. This could change if there was a renewed interest in food and feed irradiation, either because of plant health risks becoming a greater issue with climate change (as some experts anticipate), or to accommodate new technologies that would respond to business needs for more sustainable, effective or cheaper decontamination solutions.

If EU rules were to be phased out and different levels of control were set on the irradiation of foodstuffs in different Member States (beyond the differences that already exist), it is likely that existing differences in enforcement (in particular difference between the levels of sampling and controls undertaken by Member States) would be exacerbated. If the requirement to label irradiated ingredients would be phased out, Member States would likely take different approaches to this

requirement, which could undermine the provision of information to consumers to ensure choice and welfare.

6 CONCLUSIONS

The Directives on food irradiation were adopted more than 20 years ago. They have not been significantly amended since, despite technological progress in the area of ionising radiation, the adoption in 2002 of a new and comprehensive EU legislative framework for food safety, and other significant evolutions, such as the increasing globalisation of food trade and growing environmental concerns.

The purpose of the evaluation was to assess whether the objectives and provisions of the Directives are still fit for purpose. Gathering relevant feedback was difficult because the EU food industry and NGOs either lacked knowledge about food irradiation, which is currently only marginally used in the EU, or were unwilling to participate for fear of being involved in what they perceived as a controversial issue.

Relevance

While all of the stated objectives of the Directives are still relevant considering the evolution of societal needs and scientific and technological developments, some of the requirements they laid down are no longer relevant, notably as regards recently developed technologies, such as the "low energy electron beam" technology. The evaluation could not conclude to what extent the Directives were relevant to preserve a high level of **consumer health**. Indeed, while irradiation is considered to be an effective and safe treatment by EFSA, the evaluation of the overall impact of the Directives on consumers' health was made impossible by the multitude of factors involved and the marginal share of irradiated food in the EU consumers' diet.

Similarly, the relevance of the Directives for **plant health** could not be evaluated. Irradiation can be an effective tool to manage plant health risks, but so far food irradiation for plant health purposes has not been used in the EU or on food plants imported into the EU. Despite the great interest expressed by some non-EU countries exporting fruits into the EU, EU stakeholders favour other approach to control for plant pests (including strategic sourcing, systems approaches and inspections). Under these circumstances, food irradiation applied for plant health purpose is not likely to reduce consumer exposure to pesticides in the EU.

The Directives do not include objectives or provisions related to the **environmental impact of irradiation**, and as such their relevance to achieve the objectives of the Farm to Fork strategy are difficult to evaluate. There was no comparable information on the environmental impacts of food irradiation and its alternatives. No evidence confirmed the claim of some stakeholders that food irradiation is more sustainable than its alternative treatments The potential contribution of food irradiation in protecting the environment is challenged by the fact that certain irradiation technologies generate radioactive waste and/or are associated with increased transportation as compared to in-house treatment, and that food with extended life are likely to be transported on longer distance,.

Coherence

The provisions of the Directives appeared to be coherent with each other. Even if the Directives were adopted before the entry in force of the basic acts forming the current general framework for the EU legislation on food hygiene (the "general food law" and the "hygiene package"), no major inconsistencies between the Directives and these acts have been identified.

Further, no incoherence have been identified between the Directives and other EU legislation. However, the Directives are not aligned to the latest updates of the standards of the Codex Alimentarius, notably as regards the concept of absorbed doses.

Effectiveness

The assessment of the effectiveness criteria showed that the provisions of the Directives did not all achieve their objectives. In particular, the Directives did not achieved the harmonisation of the legislation on irradiation across the EU as to ensure the **free movement of all irradiated foodstuffs** within the single market. Member States may continue to apply national authorisations and bans on other irradiated foodstuffs than "herbs and spices", because the initial EU list and the national lists of foodstuffs authorised for irradiation have not been replaced by an extended EU list of foodstuffs authorised for irradiation to the exclusion of all others, as planned by the Directives. The process was launched in 2000 but was opposed by a number of food business and consumer organisations, and was finally stopped by a motion adopted by the European Parliament in 2002. Among other concerns, MEPs mentioned the lack of evidence regarding the long-term safety of eating a diet based largely on irradiated foods, and the risk that food irradiation could be used to mask poor hygiene practices in production processes. The 2011 EFSA opinions on the biological and toxicological safety of food irradiation addressed the concerns on food safety expressed in the resolution, but this did not reopen the discussion on a possible extension of the list.

Efficiency

The Directives have been mostly inefficient at ensuring a **level playing field** in the EU, and between EU food business operators and their international competitors. The remaining differences between Member States legislations hinder the free movements of irradiated foodstuffs other than herbs and spices within the single market and creates confusion in food business operators and competent authorities of Member States and of third countries. There is no equivalence between the EU regulatory framework and the regulatory frameworks used in third countries. EU irradiation facilities must meet the EU requirements even when the products they process are intended for export in third countries with less restrictive requirements (e.g. authorising higher doses and/or additional foodstuffs). It is unlikely that the level playing field could be improved by a closer alignment of the EU legislation on the Codex Alimentarius standard, since the latter sets neither a list of foodstuffs that should be authorised for irradiation, nor the values to be applied for minimum and maximum absorbed doses. It also does not provide specific recommendations regarding the labelling of irradiated ingredients.

The direct costs for businesses and national competent authorities associated with the implementation of the Directives, which were considered to be low and proportionate, seem not to have played a significant role in the **decline of food irradiation in the EU.** The principal reason for this decline appears to be the concern of the food industry that consumers would refuse to buy foodstuffs labelled as irradiated, although this concern has not been demonstrated. The requirement to label irradiated ingredients within processed products was considered overly burdensome by some representatives of the food and irradiation industries, whereas no consumer organisations or NGOs responded on this point. It is difficult to conclude on the effectiveness of the labelling requirements to provide information

to consumers to ensure choice and welfare, in absence of direct data on consumer perceptions and understanding of the labels.

The **enforcement** of irradiation legislation has been only partially achieved. Member States competent authorities carry out official checks but the control intensity differs greatly among them, one being responsible for more than 50% of the samples analysed in the EU. Almost all non-compliances identified relate to imported foodstuffs, suggesting potential gaps in the enforcement of irradiation legislation at import, although the extent of this issue is difficult to evaluate. Several stakeholders expressed concerns that these gaps create an unfair competition between EU producers and their international competitors. Most of national competent authorities considered it would be valuable to improve the monitoring at import, e.g. in carrying out more risk-oriented checks.

EU-added value

Despite all the issues identified, the legislative framework at EU level has added value to the irradiation of foodstuffs in that it has provided some level of harmonisation of regulatory approach within the EU, the most important one being the labelling of irradiated ingredients. The stakeholders who contributed to consultations (which reflect a limited sample of all potentially interested parties as far as the food industry and civil society are concerned) still warrant intervention at EU level considering it benefits the internal market and provides greater legal certainty for food business operators. If EU rules were to be phased out, historical differences in Member State legislation and approaches to irradiation would remain and could widen. Existing differences in enforcement would likely be exacerbated, which may affect consumers negatively in terms of choice and welfare, e.g. where the requirement to label irradiated ingredients would be phased out.

Lesson learned

The evaluation showed that, while the objectives of the Directives are still relevant, several of them have not been achieved. In particular, the Directives have failed to harmonise the legislation on food irradiation throughout the EU in a way that ensures the free movement of all irradiated foods, because the EU list of authorised foodstuffs for irradiation to the exclusion of all others has not been adopted.

This and other minor regulatory problems identified during the evaluation process have certainly played a role in the decline of food irradiation in the EU. But the main factor explaining the decline of food irradiation in the EU is the concern of the food industry that European consumers will refuse to buy food labelled as irradiated. Because they anticipate the negative reaction of consumers, food business operators prefer to seek and use alternative treatments, even for those food categories where irradiation is technologically relevant and where EU legislation has been harmonised, i.e. herbs and spices.

The reluctance of the food industry to have recourse to food irradiation can have serious consequences, when no suitable alternatives exist, as shown by the recent Ethylene oxide (ETO) incident[56]. In September 2020, residues of ETO, a substance banned in the EU and dangerous to human health, were detected in sesame seeds from India. The seeds had been treated with this hazardous substance to eliminate

[56] https://ec.europa.eu/food/sites/food/files/safety/docs/rasff_ethylene-oxide-incident_crisis-coord_sum.pdf

microbiological contamination, while food irradiation could have been used for the same purpose.

It is unclear however, in which cases food irradiation would be considered the most suitable treatment with regard to consumer health, plant health and environmental health, since the lack of data did not allow a comparative assessment. Data are especially missing on the effect of food irradiation on the environment and biodiversity. A deeper knowledge in that regard could contribute to better-informed decision-making on food irradiation legislation.

It is important to note in this respect the emergence of a new technology called "low energy electron beam" (only one food operator is being equipped worldwide at the time of writing). This technology, which can be implemented in-house, does not rely on radioactive sources, consumes less water and energy than most alternatives and does not penetrate the food while being effective against the main foodborne pathogens (Salmonella, Campylobacter and Escherichia Coli), seems to have a higher environmental benefit than the traditional food irradiation technologies.

The findings of the evaluation do not lead to favour or exclude any particular option for the future of the European food irradiation legislation, among the four main options identified: status quo, adoption of a EU list of foods authorised for irradiation to the exclusion of all others, amendment of the Directives, or repeal of the Directives.

Whichever option is chosen, the choice of food operators regarding the strategies and treatments applied to ensure the safety of the products they place on the EU market is unlikely to be affected, since, as mentioned before, the main factor affecting the decline of food irradiation in the EU is not regulatory. Therefore, as long as the EU food industry and/or the EU consumers are reluctant towards irradiated foods, legislative initiatives will have a negligible impact on the use of this technology and, consequently, on its contribution to public, plant and environmental health.

ANNEX 1: PROCEDURAL INFORMATION

1. Lead DG, D*e*cide Planning/CWP references

Lead DG: Directorate General Health and Food Safety (DG SANTE)

Decide planning: PLAN/2016/506

2. Organisation and timing

This evaluation was included in the DG SANTE evaluation plan. It followed the Better Regulation guidelines with regard to evaluations. The evaluation work was carried out through an external evaluation study, conducted in conformity with the DG SANTE procedure for the organisation and management of policy evaluations carried out by external contractors. The work was supervised under the technical as well as the contractual management of SANTE unit G4 with the support of unit A1.

An Inter-service Steering Group (ISG) was set up by the Commission in 2017, with the mandate to provide information, prepare the terms of reference, monitor the work of the external study team, discuss and give advice on the approval of the final report, comment on the draft evaluation SWD.

The ISG was composed of the Secretariat-General of the Commission and DGs SANTE, GROW, TRADE, RTD, SANTE, AGRI and JRC. COMP, ENER, ENV and JUST were invited but did not nominate a representative. The Steering Group started its meetings on 21 March 2018.

The evaluation roadmap was published on the 05 September 2017. It set out the context, scope and aim of the exercise. The roadmap presented the questions to be addressed under the five criteria of effectiveness, efficiency, relevance, coherence and EU added value. During the feedback period on the roadmap (05 September – 3 October 2017), 32 contributions were received. These did not require changing the approach towards the evaluation, but helped to further enrich the Terms of reference.

The open public consultation[57], which aim was to gather the views of public authorities, stakeholders and EU citizens, was planned from 02 March 2020 to 25 May 2020 but was extended by 6 weeks, i.e. until 06 July 2020, because of the COVID-19 crisis.

The support study carried out by the external contractor started in August 2018 and finalised in December 2020. The end of the study, initially planned for January 2020, has been rescheduled a first time to May 2020 and a second time to December 2020 to compensate for unexpected delays due to COVID-19 in organising the public consultation. This external support study, together with the outcome of the public consultation provided the basis for this SWD.

[57] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1477-Evaluation-of-the-EU-legal-framework-on-food-irradiation/public-consultation

3. Exceptions to the better regulation guidelines

As mentioned above, the open public consultation of reference for this evaluation was extended of 6 weeks due to the COVID-19 crisis, and the end of the study has itself been rescheduled from January 2020 to December 2020.

4. Consultation of the RSB (if applicable)

The RSB will not scrutinize this evaluation SWD.

5. Evidence, sources and quality

The evaluation required gathering of relevant data and information from European Union, as well as national and local levels, international organisations and some third countries. The overall approach therefore combined three main sources and types of evidence: EU level data and information gathering, review and analysis. In addition, 5 case studies have been developed in order to supply additional evidence on subjects agreed by the ISG. The study findings have been presented during a stakeholder workshop carried out on 21 October 2020.

ANNEX 2: STAKEHOLDER CONSULTATION – SYNOPSIS REPORT

1. Introduction

This report presents the synopsis of all stakeholder consultation activities undertaken as part of the 'Study to support the retrospective evaluation of legislation related to the irradiation of food and food ingredients'.

The consultative process helped the study team address questions concerning the relevance, effectiveness, efficiency and EU added value of the legislation. Four main forms of consultation were completed:

- A Web-based Public Consultation, targeting all four areas of the evaluation criteria;
- Two workshops with key stakeholders held at the beginning and end of the study;
- Targeted telephone interviews; and
- Four targeted surveys.

The sections below provide an overview of the stakeholders and the activities covered, as well as the main results of the consultation activities.

2. Stakeholder groups covered by the consultation activities

Input was collected from a wide range of stakeholders. These included EU and Member States competent authorities, the irradiation industry, Food Business Operators (FBOs) and business associations, experts, third countries competent authorities and individuals (including third-country nationals and EU citizens).

The table below provides an overview of the types of stakeholders consulted and the data collection method used to reach those stakeholders.

Table 1. Overview of conducted stakeholder consultations

Stakeholder type	Data collection method
Competent authorities in Member States	• Public Consultation • Targeted survey • Interviews
Experts on food irradiation	• Public Consultation • Targeted survey • Interviews
Industry (irradiation industry and FBOs)	• Public Consultation • Targeted survey • Interviews
Third country competent authorities	• Public Consultation
International organisations	• Public Consultation
Non-governmental and civil	• Public Consultation

society organisations	
Wider public	• Public Consultation

3. Overview of consultation activities

3.1 Public consultation

The survey for the web based public consultation was launched on March 3rd, 2020. It remained open until July 6th, 2020.

The public consultation received a total of 72 responses from:

- 5 academics/research institutions;
- 8 business associations;
- 7 businesses;
- 2 EU Member State national competent authorities;
- 2 Third Country Competent Authorities;
- 1 consumer organisation;
- 2 NGOs;
- 1 international organisation;
- 1 trade union;
- 39 EU citizens; and
- 4 non-EU citizens.

Of the academics, business associations and businesses who responded, the majority appeared to be associated with the irradiation industry.

The geographic spread ofpublic consultation respondents is indicated in Table 2.

Table 2. Country of origin of Public Consultation respondents

	Country of origin	Number of respondents
EU Member States	Austria	1
	Belgium	6
	Finland	1
	France	8
	Germany	6
	Italy	6
	Latvia	1
	Netherlands	1
	Poland	3
	Portugal	1
	Spain	22
Third	Australia	1

Israel	2
Switzerland	3
Turkey	1
Ukraine	1
United Kingdom	6
United States	2

3.2 Workshops

Two workshops were held as part of the consultation strategy: one at the beginning of the study, following the inception phase, and one at the end, following the completion of the draft final report. Both workshops included the following participants:

- Member States' authorities;
- Industry actors and representative organisations;
- NGOs;
- Academics;
- International organisations;
- European Commission DG SANTE, the Joint Research Centre (JRC) and the European Food Safety Authority (EFSA); and
- ICF.

The first workshop aimed to raise awareness of the evaluation among stakeholders, discuss stakeholders' views about the EU legislative framework for food irradiation, and gather initial insights from participants to address the evaluation's objectives. The workshop was held in person in Brussels.

The second workshop aimed to provide stakeholders with an overview of the initial results of the study in relation to each of the evaluation criteria. It also aimed to gather feedback from stakeholders on these findings. This workshop was held as a webinar.

3.3 Targeted consultations

Three online surveys were conducted to validate the findings of the desk research and the case studies. The surveys were addressed to three categories of stakeholder:

- National Competent Authorities in charge of implementing controls on irradiation facilities and irradiated products (doses, labelling).
- The irradiation industry, which provides irradiation services to Food Business Operators (producers, importers, processors).
- Food Business Operators (FBOs) – the potential or actual clients of food irradiation businesses in Europe.

A total of 56 responses were received, corresponding to 31 national competent authorities in 22 Member States, 20 irradiation industry representatives from 7 Member States and 6 Third Countries, and 5 FBO representatives.

A second follow-up survey was held with national competent authorities to address some remaining gaps in the data collection. This survey received 17 responses from national competent authorities in 14 Member States.

Responses were reviewed and follow-up contacts made with three stakeholders. In addition, 16 interviews have been conducted with representatives from the following sectors:

- 2 national competent authorities
- 5 members of the irradiation industry
- 1 expert from DG SANTE; and
- 8 food industry representatives.

This included interviewees from EU-level associations, as well as interviewees from Belgium, France, Germany, the Netherlands, Poland, Spain, Sweden and Switzerland.

Written contributions were also received from 2 further food industry representatives.

4 Methodology

4.1 Public consultation

The public consultation responses were analysed following the Commissions' better regulation toolbox . The received data was transferred to a 'master' Excel spreadsheet containing responses to both 'closed' and 'open' text questions.

In a first step, the data was cleaned, removing duplicates and incomplete answers. The data was prepared for analysis by dividing the answers across the respondent groups and by separating out open-ended answers. Although the team had sight of differences between respondent categories, these were largely not maintained during analysis due to the small sample sizes.

Furthermore, as part of the public consultation respondents had the opportunity to provide open-ended answers. These answers and additional documents received were analysed separately using qualitative analysis techniques.

Of the academics, business associations and businesses who responded, the majority appeared to be associated with the irradiation industry. Because the Public Consultation was not targeted and received a relatively low level of responses, it is difficult to make conclusions based on the quantitative results of the survey. However, the Public Consultation also allowed for a number of open comments, many of which have been reflected and quoted in the report.

4.2 Targeted consultations

The results from the targeted consultations, including interviews, workshops, and surveys were analysed following the Commission's Better Regulation guideline on stakeholder consultation. All write-ups, data and documents received as a result of the consultation were examined using qualitative analysis techniques. The comments and contributions from stakeholders were assessed against the evaluation questions. Distribution of respondents across Member States and respondents by stakeholder categories was taken into account.

4.3 Limitations to the method and use of the results

The main limitation of the consultation activities has been the lack of information and knowledge regarding irradiation in the EU food industry by stakeholders. This reflects the marginal nature of the practice and its absence from the agenda of stakeholder groups, including consumer organisations, NGOs, and in much of the EU food industry.

Consultation activities had many non-responses or refusals to take part. For example, in response to the targeted survey only 6 of the 68 FBO invitees responded. Most of the data collected through consultations for this project came directly from the irradiation industry or from national competent authorities.

Another major data gap related to consumer views on food irradiation. Despite a strong belief among FBO organisations and others that food irradiation would not be accepted by EU consumers, few recent studies have sampled the EU consumer population and are relevant to this aspect of the evaluation. The methodology undertaken for this study was not able to fill in this gap. There were a small number of responses to the public consultation from the general public, but these did not provide any generalisable evidence.

5 The results of the stakeholder consultation

The sections below include a description of the results of the consultation activities per evaluation criteria.

5.1 Relevance

Under this criterion, the aim is to analyse the extent to which the EU legislation on techniques for ionisation treatments of food, including food irradiation, are still fit-for-purpose and meeting current regulatory needs.

5.1.1 Contribution to food safety

Where irradiation has been used for food safety purposes, consulted stakeholders, including irradiation experts, industry representatives and national competent authorities, were largely in agreement that it is an effective method for ensuring microbiological food safety and has minimal impact on food quality for foods low in fat.

Responses to the public consultation indicate some scepticism among EU citizens on the safety of irradiation, but due to the small sample size (39 EU citizens), these are not generalisable.

In the consultation that took place in 2002, one of the main concerns expressed by food businesses and other stakeholders regarding irradiation was the potential for irradiation to replace good hygiene practices, despite the requirement in the directives that irradiation should not be used as a substitute for good hygiene. The various consultations for this study have not identified any significant evidence of this occurring.

The only evidence identified to suggest that irradiation has been used to replace hygiene, health or good manufacturing or agricultural practice is anecdotal and comes from the case study on the use of irradiation in Poland. According to a member of the spice industry there, a large share of spices sold in Poland is imported, often from Egypt, Vietnam, Turkey or India. The production process in these countries has been modernized over last years and new, higher hygienic standards have been introduced,

such that there is no longer a need to irradiate imported spices. According to this interviewee, there is, however, still a need to irradiate spices produced in Poland due to low hygienic standards at the production sites. However, no corroborating evidence has been identified that would confirm this as an issue and in the survey of national competent authorities, representatives from all 14 of the Member States that responded indicated that they had no evidence of potential uses of irradiation to replace hygiene good practices.

Input from stakeholders in the irradiation industry and FBOs indicates that irradiation is the preferred food safety treatment for certain products in the EU. It is considered to be the best or better option for frog legs, as this is an imported product at high risk of contamination and is generally imported frozen, making it suitable for irradiation. According to one interviewee from the irradiation industry, there are no suitable alternatives for the treatment of frog legs. Stakeholders from food businesses also indicated that it is sometimes a preferred method for herbs and spices, but that heat and steam treatments are generally used as an alternative, due to their lower cost and the absence of labelling requirements.

Stakeholders confirmed that irradiation does not appear to be used for reasons other than food safety in the EU. Some information received through targeted interviews suggested that there may be interest in using low level irradiation (e.g. doses below 1 kGy as used for plant health protection) to help with insect disinfestation for grains, such as rice. However, one European rice producer noted that, despite growing problems with infestation, a lack of alternative treatments, and the likely benefits of irradiation, it would likely not use irradiation - even if it were approved - due to the need to label and the likely consumer concerns this would trigger.

5.1.2 Contribution to protecting the EU from plant health risks

Irradiation is not currently used in the EU as a plant health treatment. According to industry stakeholders (one FBO and one EU level association), strategies such as choice of low-risk sourcing locations, inspections, systems approaches and physical treatments (e.g. hot or cold treatments) are currently preferred to chemical treatments, such as fumigation. Industry stakeholders also noted that these would be preferred over irradiation, even if irradiation were permitted, because of likely consumer concern about products labelled as irradiated.

In responses to the public consultation, both a research institute in Israel and the Australian Government noted the comparative effectiveness of irradiation and its suitability for certain types of produce. The research institute in Israel stated that irradiation for plant health purpose is a more effective treatment option for dealing with pests in traded products such as mangoes and red peppers when exporting to nearby markets, as compared to the 'cold treatment alternative' currently used. Given that the EU is Israel's main export market for fruits and vegetables, the respondent concluded that Israel would consider setting up a facility for commercial plant health irradiation if the EU changed its current stance on use of the technology. The representative from the Australian Government noted that, given irradiation technology is a proven plant health treatment for fruit flies and other pests of biosecurity concern for products such as mangoes, summer fruits, cherries and table grapes, the EU should 'streamline regulation' to permit trade of irradiated products from outside Member States.

5.1.3 Extent to which the objectives of the irradiation directives are still relevant considering the evolution of societal needs and scientific and technological developments

Although the objectives of the directives remain relevant, some stakeholders from the irradiation industry mentioned that certain requirements are no longer relevant considering scientific and technical developments. These are:

- the use of overall average absorbed dose, rather than minimum and maximum dose; and
- assigning maximum doses to food classes, which does not take into account differences in processing or preparation (e.g. if a food is frozen or not).

Given the appearance of a small set of novel technologies, questions have been raised by various stakeholders (legal expert, irradiation expert, manufacturer of food treatment technology) regarding the scope of the legislation and the manner it is written, to suggest that it could provide more certainty to businesses and particularly to innovating businesses, so as to facilitate technological development in this area.

5.1.4 New problems emerging related to irradiation of foodstuffs and its impact on the human health and environment

Stakeholders involved with the irradiation industry have mentioned that the legislation's focus on maximum doses obscures the importance of ensuring a minimum dose is applied – particularly when irradiation is used to ensure food safety. Where the necessary minimum dose is not applied, there is a risk that foodstuffs will not be properly decontaminated. According to one national competent authority interviewed, however, inspections of food irradiation facilities also take the minimum dose into account in practice.

During the targeted interviews, one stakeholder did mention a potential long-term risk of irradiation leading to development of irradiation-resistant bacteria. No evidence on this was identified and existing science on irradiation resistance predates the directives. A concern was also raised by one national competent authority about possible migration of elements from packaging and into food in the context of food irradiation. This is not a new issue, and under the EU directives, packaging materials used for foods undergoing irradiation "must be suitable for the purpose".

Otherwise, stakeholders did not report any new problems related to irradiation.

5.2 Effectiveness

Under the effectiveness criterion, the consultation process focused on assessing whether the objectives of the directives were achieved, the effects of the directives on stakeholders and what other factors might influence the achievement of the objectives.

5.2.1 Effectiveness at meeting objectives

The directives have only partially met their objective of providing a unified legal status for irradiated food products in the EU. The lack of an EU positive list creates uncertainty for businesses interested in using irradiation, both within the EU and for third countries looking to export to the EU. This view was expressed by the majority of respondents to the public consultation, as well as in interviews with the irradiation industry.

The directives have only partially ensured fair competition with regards to irradiated foodstuffs in the EU and with third countries. A few claims of unfair competition between EU and third country producers relating to irradiated food products have been heard. Industry representatives involved in dried vegetables, herbs and spices have mentioned that irradiated products from third countries might be entering the EU without labels (some products have also been irradiated in non-approved facilities). An interview with an industry body involved in importing spices also indicated that suppliers from third countries would sometimes try to provide spices that had been irradiated, not understanding the EU restrictions and requirements.

Several stakeholders in interviews have noted that the labelling obligation established in the directives is asymmetric. The food chain is required to label for treatment by irradiation but not necessarily for other treatments, such as steam treatment or chemical treatments.

5.2.2 Effectiveness of enforcement and controls

National competent authorities and other stakeholders have indicated through the targeted surveys and through the public consultation that enforcement measures are effective. One potential issue highlighted by national competent authorities in response to the targeted survey relates to the monitoring of foods imported from third countries for irradiation. The majority of non-compliances identified through RASFF come from products originating in third countries, but in general neither Member States nor the EU actively collect data on the quantities of irradiated products coming from third countries. Seventeen national competent authorities indicated that collecting this data would help to improve their ability to conduct risk-based controls.

Stakeholders from both national competent authorities and the irradiation industry largely agreed that the manufacturing control mechanisms in place are sufficient for identifying irradiation in food products and ensuring it complies with the EU directives.

The majority of surveyed national competent authorities reported being ‘very’ or ‘quite’ confident that the effort expended on controls by Member State authorities was sufficient to ensure that food products irradiated in the EU were treated within required dose limits, and that the analytical methods to detect irradiated food were adequate. national competent authorities considered methods for detection of irradiation to be validated and standardised, and irradiation facilities themselves adequately monitored and controlled. It was also pointed out that the results over time had consistently reflected low levels of irradiation use. Experts responding to the public consultation, including public authorities, business associations and academic/research institutions, expressed similar views. Despite these positive views, some concerns were still raised. A national competent authority said that there were no quantitative methods for analysing the delivered dose of irradiation and only the treatment plant could certify this, so there was a need to validate and accredit quantitative methods. A business similarly noted that verification of irradiated status was usually “verified on paper” but in cases of doubt there was not an EU-level list of laboratories to test this. A few stakeholders from FBO organisations and national competent authorities also expressed distrust in products imported into the EU and emphasised the need for good control mechanisms at points of entry (i.e. import controls, in addition to those currently done at product marketing level).

5.3 Efficiency

The consultation activities targeted for the efficiency criterion aimed to collect the stakeholders' perspectives on the cost and benefits associated with the implementation of the directives, and the implications of these.

5.3.1 Costs to businesses and the decline of irradiation

Stakeholders from the irradiation industry perceived the direct costs for industry/food business operators/consumers associated with the implementation of the Directives to be low. However, irradiation industry and FBO stakeholders indicated that there are indirect costs associated with the labelling requirement. The labelling obligation imposed by the directives reduced demand, meaning that businesses were no longer able to apply the technique. In this sense, the directives have affected businesses' ability to use irradiation as a decontamination technique. The requirement to label irradiated foods was mentioned most frequently by stakeholders in the irradiation industry and FBOs as the main factor that contributed to the decline of irradiated foodstuffs on the EU market following the implementation of the directives. This was evident in stakeholder interviews, as well as in the response to the targeted survey.

Stakeholders indicated other reasons for the decline in the use of irradiation. One stakeholder (an irradiation facility) indicated that one reason the technique is not used more widely is due to a lack of knowledge of the method within the food industry. Although this would not have contributed to the initial decline in irradiation, it may have contributed to the continued low level of use. To some extent, this lack of knowledge was confirmed through many of the consultations held with food industry stakeholders and through the targeted survey results. The food industry stakeholders consulted frequently lacked knowledge on food irradiation, its costs and benefits. Response rates from the food industry were low, and within interviews, some stakeholders suggested that there could be an interest in the use of irradiation, but not enough was known about it in relation to their products and in comparison to existing techniques. It is difficult to determine the extent to which this has contributed to the lack of use or whether it is a consequence of a lack of interest due to the need to label.

Two interviewees (one in France and one in the Netherlands) mentioned EU Regulation EC/852/2004 as a contributing factor to the decline of the irradiation of frozen chicken, as this set a new maximum temperature for storage throughout the process at -18 degrees Celsius. This new maximum temperature was colder than before, and maintaining that temperature throughout the irradiation process proved challenging. It led to both interviewees stopping the irradiation of mechanically separated chicken.

Despite the lack of interest, several FBO stakeholders (e.g. from the fruit importing and red meat sectors) have indicated in interviews that even if they would not foresee using it in the near future, if irradiation is considered a safe and effective treatment, they would like to see it approved as a treatment option for their products.

5.3.2 Impact on trade and a level playing field

In the targeted survey, stakeholders were asked whether EU legislation on food ionisation has an impact on the sector trading with countries outside of the EU. Five out of 18 reported that it did, whilst most did not know (10 respondents). When asked to describe how trade is impacted, respondents suggested that this mainly related to restrictions on imports from countries outside the EU. No evidence has been identified of market opportunities that have not materialised because the directives have prevented

European producers from exporting irradiated products to third countries. When public consultation respondents were asked if the directives impose additional costs on European manufacturers and traders that competitors in third countries do not have, a majority of respondents (13 out of 20) disagreed. However, all four business associations that responded agreed, as did two companies and one international organisation. When asked to provide reasons for additional costs, responses mainly related to economies of scale in countries with fewer controls, which enabled manufacturers to operate with lower costs. By contrast, the restrictions in the EU mean that manufacturers who want to export food and compete in the international market must use alternative treatments for the same purpose. In some cases, such alternative treatments may be more costly and/or less effective. An example given by one respondent from the UK was the higher processing costs of steam treatment, although other evidence received from the herbs and spices industry in consultation suggests that steam treatment is a cheaper alternative.

5.3.3 Efficiency of monitoring and controls

Regarding monitoring, the majority of national competent authorities considered that the costs involved in implementing the irradiation directives justified, proportionate and affordable given the benefits which have been achieved. Only one national competent authority surveyed indicated that costs were high in comparison to the benefits, citing the annual reporting of data to the European Commission and their publication in annual reports as disproportionately costly considering the low risks to consumers.

Of the national competent authorities surveyed (n=17), only one indicated that aligning EU rules with those of the Codex Alimentarius would be undesirable, and the majority (12 of 17) indicated that it would be either “desirable” or “very desirable”, with several indicating that this would help to avoid conflicts and grey areas in relation to international trade. One expert and one industry association representing the irradiation industry also called for a better alignment between the directives and the Codex Alimentarius.

The majority of surveyed national competent authorities (65%; n=17) considered that the reporting arrangements set in the directives were sufficient to identify issues associated with the manner controls were carried out. Two said they did not know, and four disagreed.

The majority of surveyed national competent authorities (71%; n=17) reported that they had established initiatives to monitor imports from non-EU countries through random sampling. These mostly involved sampling plans for a range of different imported product types. One national competent authority also stated that they used RASFF data as a source of information for their checks, to support risk-based sampling.

The same proportion of national competent authorities (71%; n=17) agreed that it would be valuable to more actively monitor imports from non-EU countries for irradiation (e.g. to collect data on the quantities and types of imported irradiated foodstuffs): this would enable checks for correct labelling to be made on products that were on the market and information on tests and their findings could be shared between Member States or at EU-level.

5.4 EU Added Value

The EU added value criterion refers to the positive effects and results resulting from the implementation of the EU legislation compared to legislation at Member State level.

Stakeholders consulted expressed continued support for EU intervention in this area. Both national competent authorities and industry have indicated the importance of harmonisation in relation to irradiation rules.

In the survey of national competent authorities (n=17), respondents were asked how the costs of controls have been impacted by the implementation of the directives. A majority (9) indicated that they did not know. This is likely a reflection of the fact that significant time has passed since the introduction of the directives. Of those who were able to respond, four indicated that costs had neither increased nor decreased, two indicated that costs have increased slightly and two indicated that costs have increased significantly. One national competent authority indicated that this increase was due to increased staffing and laboratory costs.

When surveyed, the majority of national competent authorities (15 out of 17) indicated that they did not have any additional national rules that were more effective than EU rules. One positive response to this question (from Italy) indicated the existence of an official control plan at national level, stipulating both the number of samples to be taken in each region, as well as the number of samples for Border Control Points. It is likely that other Member States have similarly implemented official control plans, but as indicated by the absence of controls reported to the Commission in several Member States, many do not. The other positive response to this question, from Germany, referred to Germany's additional legislation on ultraviolet treatments.

ANNEX 3: METHODS AND ANALYTICAL MODELS

1. CONSULTATION ACTIVITIES

Consultation activities can be divided between targeted consultation activities and the online public consultation:

- Open public consultation in 23 EU languages. This activity provided any interested party, not consulted under the other activities, the possibility to contribute to the evaluation. A dedicated webpage page was available on the Commission's Better Regulation Portal;
- Targeted consultation activities included:
    - Two workshops held as part of the consultation strategy: one at the beginning of the study, following the inception phase, and one at the end, following the completion of the draft final report. Both workshops included Member States' authorities, Industry actors and representative organisations, NGOs, Academics, International organisations, contractor and Commission's representatives
    - Three online targeted surveys addressed to i) National Competent Authorities (national competent authorities), ii) the irradiation industry, iii) Food Business Operators (FBOs).
    - 16 interviews conducted with representatives from the national competent authorities (2), the irradiation industry (5), expert from DG SANTE (1), food industry representatives (8).

2. MAIN MEETINGS, EVENTS AND TOOLS USED TO INFORM STAKEHOLDERS

- Workshops with stakeholders (see above)
- Meetings of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee);
- Regular consultative committees such as the Advisory Group on the Food Chain and Animal and Plant Health;
- The EU Platform digital tool, DG SANTE's website and the Commission Better Regulation portal have been regularly updated with the most recent developments all along the evaluation process.

3. EXTENSIVE DESK RESEARCH

Desk research was conducted to extract qualitative and quantitative information relevant to the evaluation questions from published sources. The scope of the desk research task includes relevant legislation, statistics, complaints, case law and infringements (including RASFF notifications and audits on third country irradiation facilities), studies, reports, research and materials issued or endorsed by the EU institutions, European or national stakeholders' associations, individual stakeholders, as well as Member States' authorities.

A data collection template was used to structure the research and directly compare information collected on the same questions from different sources. Literature and data

were retrieved online. The research covered international and EU documentation, and included both academic studies and grey literature.

4. CASE STUDIES

Five case studies have been completed, which topics were: labelling requirements in herbs and spices in France (1) and in Poland (2), advantages and disadvantages of irradiation and other available treatments for herbs and spices in the EU (3), use of irradiation to address plant health risks (4) and to prevent sprouting, extend shelf life and reduce food waste (5). The case studies involved interviews with industry, national competent authorities and experts from various EU countries and the United States, as well as desk research.

5. INTERVENTION LOGIC

The initially developed intervention logic served as valuable tool for the contractor to establish a clear link between the evaluation questions to be addressed and the corresponding methodology. The intervention logic helped the contractor to understand the initial intention of the Commission at the time of the adoption of the strategy and how the strategy evolved with the time.

6. EVALUATION MATRIX

The study team developed an extensive evaluation matrix (see annex 1 of the study) that articulates evaluation questions to sub-questions, success or judgment criteria, targets or indicators, data sources, stakeholders involved, and data analysis methods.

7. TRIANGULATION

To ensure robustness of findings, triangulation of methods/data/sources was used by the study team in both quantitative and qualitative evidence. Triangulation was done with available statistically representative sources, such as official controls results, as well with non-representative sources from a statistical point of view, including surveys and interviews.

ANNEX 3: LIST OF EVALUATION QUESTIONS

Relevance

- To what extent do the objectives of the irradiation directives still correspond to those of the EU on food safety policy?
- To what extent can irradiation of foodstuffs contribute to food safety? Are there specific cases (both for the competent authorities and for food business operators (FBOs)) where irradiation appears as the best or a better option? To what extent is the irradiation of foodstuffs used for other reasons (e.g. to prolong shelf-life, prevent sprouting, reduce food waste and losses)?
- To what extent can the irradiation of foodstuffs contribute to protecting the EU against phytosanitary risks? What are the practices in that regard?
- To what extent can irradiation serve as a healthier alternative for pesticide use as a phytosanitary import option for plant produce, while avoiding the risk for pesticide residues?
- To what extent are the objectives of the irradiation directives still relevant considering the evolution of societal needs and scientific and technological developments? Are there requirements that are no longer relevant, given the progress of science and technology, over the last twenty years?
- Are there any new problems/issues related to irradiation, its use on foodstuffs and its impact on human health and the environment that are currently not addressed through the irradiation directives?

Coherence

- To what extent are the irradiation directives coherent with other EU legislation (i.e. – with other EU food legislation)?
    - Do provisions co-act as intended? Do they overlap or contradict each other and if so, what are the impacts of these overlaps/contradictions? (Legislation and policy activities to be considered include those 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 of the current legislation on trade of irradiated foodstuffs and what are the reasons for such impact (taking into account the level of coherence between EU and international rules)? What in particular could be improved to ease the export of irradiated foodstuffs from the EU?

Effectiveness

- To what extent do the food irradiation directives meet their objectives and in particular: Which provisions or parts of the directives have met their objectives (i) most effectively, (ii) less effectively or (iii) not at all and why?
- 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?
- Have any food safety problems or impacts on the nutritional quality of food been reported in relation to irradiated foodstuffs?
- How effective are the controls in place to ensure that food products are treated within the required dose limits?
- Effectiveness of national implementation measures: 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 (e.g. measurable improvement in food hygiene or reduction in foodborne outbreaks) associated with the implementation of the food irradiation directives?

- What are the quantitative and qualitative costs and benefits for the environment associated with the implementation of the food irradiation directives?

- What are the key drivers for the costs involved in the irradiation of foodstuffs (facilities, equipment, different sources of ionising radiation)?

- What are the main reasons for the continuous decline of irradiated foodstuffs on the EU market?

- To what extent are costs involved in implementing the irradiation directives justified, proportionate and affordable given the benefits which have been achieved (e.g. 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)?

- What factors influence any particular discrepancies (e.g. 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)?

- Which source(s) of ionising radiation (taking into account emerging technologies, consumer and environmental concerns) could be considered as most efficient in the treatment of foodstuffs?

- Do the food irradiation directives permit EU manufacturers and traders to compete on a level playing field with their international competitors?

- Is there a potential/need to simplify and attain the objectives of the food irradiation directives more efficiently? (e.g. do the legislative requirements create any unnecessary administrative burden for Member States and could EU rules be aligned with the Codex Alimentarius General Standard for Irradiated Food?)

- To what extent do the directives allow for efficient policy monitoring? Does the annual reporting allow for collection of all relevant information without imposing undue administrative burden on enterprises and competent authorities? Given that the EU accepts the import of irradiated foods from third countries (provided that they are treated in facilities approved by the EU) and there is no requirement in the directive to monitor these imports, how successful is this practice in Member States? Would it be useful to monitor these imports (e.g. collect information on the quantity and type of imported irradiated foodstuffs)?

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 intervention at EU level still warranted?