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EXECUTIVE SUMMARY OF THE EVALUATION

of the

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

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This staff working document presents the results of the retrospective evaluation of legislation related to the irradiation of food and food ingredients, as codified in Directives 1999/2/EC, and 1999/3/EC (hereinafter 'the Directives'). The evaluation is mainly based on an external support study commissioned by the European Commission's Directorate General for Health and Food Safety (DG SANTE) and carried out by ICF.

Purpose and scope

The Directives were adopted more than 20 years ago. They have not been significantly amended since, despite technological progress in 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 their objectives and provisions are still fit for purpose. Gathering relevant feedback was difficult because the EU food industry and NGOs either lacked knowledge about food irradiation, or were unwilling to participate for fear of being involved in what they perceived as a controversial issue.

Main findings

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 their requirements are no longer relevant, notably as regards recently developed irradiation technologies. Due to the lack of data on food irradiation and its alternatives, the evaluation could not conclude to what extent the Directives were relevant to preserve a high level of **consumer health** and **plant health,** and to achieve the objectives of the Farm to Fork strategy in term of **environmental protection**.

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 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 fully aligned to the latest updates of the standards of the Codex Alimentarius Commission, notably as regards the concept of absorbed doses.

Effectiveness

The assessment of the effectiveness criteria showed that the provisions of the Directives did not achieve all 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.

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 creates confusion in stakeholders and there is no equivalence between the EU regulatory framework and the ones used in third countries.

The direct costs for businesses and competent authorities of implementing 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. 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. 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.

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.

Lesson learned

It remains unclear, in which cases food irradiation would be considered the most suitable treatment with regard to consumer health, plant health and environmental health, because 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.

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 European 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 the main factor causing the decline of food irradiation in the EU is not regulatory. 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.