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|                  |                                                                                                                                                                                                                                                                                        |
|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| From:            | Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director                                                                                                                                                                                                    |
| date of receipt: | 17 October 2023                                                                                                                                                                                                                                                                        |
| To:              | Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union                                                                                                                                                                                                            |
| No. Cion doc.:   | COM(2023) 639 final                                                                                                                                                                                                                                                                    |
| Subject:         | Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 1999/2/EC, 2000/14/EC, 2011/24/EU and 2014/53/EU as regards certain reporting requirements in the fields of food and food ingredients, outdoor noise, patients' rights, and radio equipment |

Delegations will find attached document COM(2023) 639 final.

Encl.: COM(2023) 639 final



EUROPEAN  
COMMISSION

Brussels, 17.10.2023  
COM(2023) 639 final

2023/0369 (COD)

Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Directives 1999/2/EC, 2000/14/EC, 2011/24/EU and 2014/53/EU as regards  
certain reporting requirements in the fields of food and food ingredients, outdoor noise,  
patients' rights, and radio equipment**

(Text with EEA relevance)

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE PROPOSAL**

#### **• Reasons for and objectives of the proposal**

In its Communication on ‘Long-term competitiveness of the EU: looking beyond 2030’<sup>1</sup>, the Commission stressed the importance of a regulatory system that ensures that objectives are reached at minimum costs. It has committed therefore to a dedicated effort to rationalise and simplify reporting requirements, with the ultimate aim to reduce such requirements by 25%, without undermining the related policy objectives.

Reporting requirements play a key role in ensuring correct enforcement and proper monitoring of legislation. Their costs are overall largely offset by the benefit they bring, in particular in monitoring and ensuring compliance with key policy measures. Reporting requirements can however also impose disproportionate burden on stakeholders, particularly affecting SMEs and micro-companies. Their cumulation over time can result in redundant, duplicating or obsolete obligations, inefficient frequency and timing, or inadequate methods of collection.

Streamlining reporting obligations and reducing administrative burden is therefore a priority. In this context, the present proposal aims to simplify initiatives included in headline ambition ‘An Economy that works for the people’, A ‘European Green deal’ and ‘Promoting our European way of life’ in the policy area of the Internal Market, Food safety and Health and impacting respectively the outdoor equipment and the radio equipment industry/sectors as well as sectors related to food treated with ionising radiation and on cross-border healthcare.

The proposal aims to rationalise reporting obligations by a combination of measures:

- for Directive 1999/2/EC on foods and food ingredients treated with ionising radiation<sup>2</sup>, and for Directive 2000/14/EC on the noise emission of outdoor equipment<sup>3</sup>, this proposal aims to remove reporting obligations that are not necessary;
- for Directive 2014/53/EU on radio equipment<sup>4</sup>, this proposal aims to reduce the frequency of the reporting obligation of Member States;
- for Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare<sup>5</sup>, this proposal aims to reduce the frequency of the reporting obligation.

With regard to Directive 1999/2/EC, the reporting obligation concerns both Member States and the Commission. Article 7(3) of Directive 1999/2/EC provides that Member States report annually to the Commission the results of official controls they have carried-out in food

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<sup>1</sup> COM(2023)168.

<sup>2</sup> 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 66, 13.3.1999, p. 16).

<sup>3</sup> Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1).

<sup>4</sup> Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).

<sup>5</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

irradiation facilities and on irradiated food placed on the market. Article 7(4) of that Directive provides that the Commission publishes in the *Official Journal of the European Union* a report based on the information provided every year by the national supervisory authorities.

These reporting obligations have become redundant, as annual reporting obligations for Member States' competent authorities and the Commission are respectively also laid down in Articles 113 and 114 of Regulation (EU) 2017/625<sup>6</sup>. Those obligations are sufficient to ensure enforcement and facilitate monitoring of the effectiveness of legislation. Therefore, the proposal provides for the deletion of the similar reporting obligations currently laid down in Article 7(3) and (4) of Directive 1999/2/EC.

With regard to Directive 2000/14/EC, those reporting requirements concern both companies and public authorities. Indeed, Article 16 of Directive 2000/14/EC provides that manufacturers, or their authorised representatives, shall send to both the authorities of Member States and to the Commission a copy of the EC declaration of conformity for equipment covered by that Directive. The Commission has then the obligation to collect the data and publish the relevant information periodically. According to recital 14 of Directive 2000/14/EC, one of the principal justifications for this reporting obligation was to provide for 'a basis for informed consumer choice'. However, it appears that this reporting obligation creates an unnecessary administrative burden in this respect, since consumers are already informed of the noise emission level via the mandatory noise marking affixed on all the equipment covered by that Directive.

Consumers are also informed on the noise emission of the specific equipment via the instructions for use for machines which are under the scope of both Directive 2006/42/EC<sup>7</sup> on machinery and its successor Regulation (EU) 2023/1230<sup>8</sup>, as those pieces of legislation cover 55 of the 57 equipment categories that fall within the scope of Directive 2000/14/EC.

Consequently, it is proposed to delete Article 16 of Directive 2000/14/EC.

With regard to Directive 2011/24/EU the reporting obligation concerns the Commission. However, indirectly it also concerns Member States, as the Commission's reporting relies largely on the Member States' contributions on how the Directive is being applied at national level.

Article 20(1) of Directive 2011/24/EU provides that the Commission shall by 25 October 2015 and subsequently every 3 years thereafter, draw up a report on the operation of the Directive and submit it to the European Parliament and to the Council. The European Reference Networks established under Directive 2011/24/EU are to be evaluated every 5 years in accordance with Article 14(1) of Commission Implementing Decision setting out criteria for establishing and evaluating European Reference Networks<sup>9</sup>.

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<sup>6</sup> 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 95, 7.4.2017, p. 1).

<sup>7</sup> Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

<sup>8</sup> Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (OJ L 165, 29.6.2023, p. 1).

<sup>9</sup> Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 147, 17.5.2014, p. 79).

The evaluation of the functioning and operations of all European Reference Networks is a key part of the content of the reports on the operation of Directive 2011/24/EU. Consequently, the current frequency of reporting is disproportionate and does not have added value in the absence of a parallel evaluation of the European Reference Networks. In addition to that, the current reporting period of 3 years is, in practice, insufficient for the Commission and Member States to address all follow-up actions expected. Furthermore, if the two processes (reporting on the operation of the Directive and evaluating the European Reference Networks) were aligned, synergies between the report and the evaluation could be ensured. Therefore, it is proposed to provide for the reporting on the operation of Directive 2011/24/EU to be carried out every 5 years.

With regard to Directive 2014/53/EU, the reporting obligation in question concerns Member States.

Indeed, Article 47(1) of Directive 2014/53/EU provides that Member States shall submit to the Commission, every two years, a report on the application of the Directive which is to contain a presentation of the market surveillance activities performed by the Member States and whether requirements of that Directive have been attained. The current frequency of that obligation does not match the reporting obligation from the Commission to the European Parliament and to the Council which takes place every five years.

In that spirit, it is proposed to reduce the frequency of the reporting obligation of Member States to every five years.

- **Consistency with existing policy provisions in the policy area**

The proposal is part of a first package of measures to rationalise reporting requirements. This is a step in a continuous process looking comprehensively at existing reporting requirements, with a view to assessing their continued relevance and to making them more efficient.

The rationalisation introduced by these measures will not affect the achievement of the objectives in the policy area, for the following reasons.

With regard to Directives 1999/2/EC and 2000/14/EC, the reporting requirements that are proposed to be removed from the respective Directives do not provide any longer any added value to the Union and to the functioning of the single market.

The obligation to report on the operation of Directive 2011/24/EU will be maintained, but the reporting frequency would be aligned with the periodical evaluation of the European Reference Networks, which is key in the implementation of Directive 2011/24/EU.

With regard to Directive 2014/53/EU, this proposal aims at reducing the frequency of the reporting obligation of Member States, so that it corresponds to the frequency of the reporting obligation of the Commission to the European Parliament and to the Council.

- **Consistency with other Union policies**

Under the Regulatory Fitness and Performance Programme (REFIT), the Commission ensures that its legislation is fit for purpose, targeted to the needs of stakeholders and minimizes burdens while achieving its objectives. This proposal is therefore part of the REFIT programme, reducing reporting burdens arising from the Union legislation.

While certain reporting requirements are essential, they need to be as efficient as possible, avoiding overlaps, removing unnecessary burden and using as much as possible digital and interoperable solutions.

The current proposals rationalise reporting requirements thus making the achievement of the objectives of legislations more efficient and less burdensome for companies and public authorities.

## **2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY**

- **Legal basis**

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union, in line with the original legal bases for the adoption of the sectoral frameworks, which this proposal aims to amend. These sectoral frameworks are Directive 1999/2/EC on foods and food ingredients treated with ionising radiation, Directive 2000/14/EC relating to the noise emission of equipment for use outdoors, Directive 2011/24/EU on the application of patients' rights in cross-border healthcare and Directive 2014/53/EU on radio equipment.

Directive 1999/2/EC on foods and food ingredients treated with ionising radiation aims at the smooth operation of the internal market by reducing differences between national laws related to the treatment of foodstuffs by ionising radiation. It sets out the conditions for manufacturing, marketing, importing and compulsory labelling of foods treated with ionising radiation, a process used to reduce the number of pathogenic micro-organisms in food and to increase its shelf life.

The Union sectoral frameworks laid down by Directives 2000/14/EC and 2014/53/EU, are so-called "product harmonisation legislation". Both Directives lay down harmonised rules regarding the design, manufacture, conformity assessment and placing on the market of products. Essentially, these sectoral frameworks introduce for each respective sector/product category the essential safety requirements which the products should meet and the procedures how to assess the compliance with these requirements.

Another common feature of these frameworks is that they are more or less closely aligned to the general principles laid down in Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products<sup>10</sup>, which lays down reference provisions for the drawing up of Union legislation harmonising the conditions for the marketing of products.

Directive 2011/24/EU on patients' rights in cross-border healthcare is the first piece of Union legislation in the area of healthcare services. It complements the more widely used Regulation on social security coordination by codifying Court of Justice jurisprudence and laying down more detailed and systemic rules to give patients the freedom to choose healthcare in another Member State and to be reimbursed (partially) for the medical costs. Furthermore, Directive 2011/24/EU, amongst others, provides that the Commission shall support Member States in the development of European Reference Networks for rare diseases.

All the above-mentioned pieces of legislation affected by this proposal contain provisions of a similar type, which impose obligations that have become unnecessary with time. Amending the mentioned Directives in the proposed manner will result in the rationalisation of reporting obligations in all of the affected legal frameworks.

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<sup>10</sup> Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

- **Subsidiarity (for non-exclusive competence)**

The reporting requirements concerned are imposed by Union law and can therefore only be amended at Union level. Member States, companies and the Commission will be benefiting from the rationalisation of reporting requirements that is the subject of this proposal.

- **Proportionality**

The rationalisation of reporting requirements simplifies the legal framework by introducing minimum changes to existing requirements that do not affect the substance of the wider policy objective. The proposal is therefore limited to those changes that are necessary to ensure efficient reporting without changing any of the substantial elements of the legislation concerned.

- **Choice of the instrument**

Directives 2000/14/EC and 2014/53/EU are both harmonised products legislations under the Single Market rules. Together with Directives 1999/2/EC and 2011/24/EU, these pieces of legislation contain redundant or ineffective reporting obligations. Therefore, in the interest of efficiency, a joint proposal for the rationalisation of the reporting obligation in the form of the present omnibus proposal appears to be the most suitable solution.

Having regard to Directive 2011/24/EU, in particular Article 12(4), points (b) and (c), Commission Implementing Decision 2014/287/EU<sup>11</sup> setting out criteria for establishing and evaluating European Reference Networks was adopted. Both instruments provide for periodic reporting and evaluations to be prepared by the Commission.

Therefore, considering that the results of the evaluation of the European Reference Networks are relevant for the measurement of the Directive operation, in the interest of creating synergies between the reports and to reduce the administrative burden for the Commission and Member States, the alignment of the reporting period for the rationalisation of the reporting obligations as part of this omnibus proposal is considered appropriate and efficient.

### **3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS**

- **Ex-post evaluations/fitness checks of existing legislation**

N/A

- **Stakeholder consultations**

N/A

- **Collection and use of expertise**

The proposed rationalisation measures have been identified following a process of internal scrutiny of existing reporting obligations and based on the experience from implementation of the related legislation. Since this is a step in the process of continuous assessment of reporting requirements arising from Union legislation, the scrutiny of such burden and of its impact on stakeholders will continue.

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<sup>11</sup> Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 147, 17.5.2014, p. 79).

- **Impact assessment**

The proposal concerns limited and targeted changes of legislation in view of rationalising reporting requirements. They are based on experience from implementing legislation. The changes do not have significant impact on the policy, but only ensure a more efficient and effective implementation. Their targeted nature and the lack of relevant policy options make an impact assessment not necessary.

- **Regulatory fitness and simplification**

This is a REFIT proposal, aiming to simplify legislation and cut burdens for stakeholders.

- **Fundamental rights**

N/A

#### **4. BUDGETARY IMPLICATIONS**

N/A

#### **5. OTHER ELEMENTS**

- **Implementation plans and monitoring, evaluation and reporting arrangements**

N/A

- **Explanatory documents (for directives)**

Considering the scope of the proposal, it is not justified or proportional to require explanatory documents.

- **Detailed explanation of the specific provisions of the proposal**

With regard to Directive 1999/2/EC:

Article 7(3) of Directive 1999/2/EC provides that Member States report annually to the Commission the results of official controls they have carried-out in food irradiation facilities and on irradiated food placed on the market. Article 7(4) of that Directive provides that the Commission publishes in the *Official Journal of the European Union* a report based on the information provided every year by the national supervisory authorities.

These reporting obligations are redundant, as annual reporting obligations on official controls and other official activities performed to ensure the application of food and feed law and applicable to Member States' competent authorities and the Commission are also laid down in Articles 113 and 114 of Regulation (EU) 2017/625. The latter obligations are sufficient to ensure enforcement and facilitate monitoring of the effectiveness of the Union legislation on food irradiation. Therefore, the proposal provides for the deletion of the reporting obligations currently laid down in Article 7(3) and (4) of Directive 1999/2/EC regarding the results of official controls carried out in food irradiation facilities or on irradiated food placed on the market.

With regard to Directive 2000/14/EC:

Article 16 of the Directive provides for an obligation for manufacturers, or their authorised representatives, to send a copy of the EC declaration of conformity of their products to both Member States and to the Commission. The Commission has the subsequent obligation to collect the data received and to publish the relevant information periodically.



As indicated in the evaluation of the Directive that reporting obligation seems ineffective since in accordance with Article 4(1) of the Directive, the manufacturers have the obligation to affix a noise marking on the equipment covered by that Directive. This noise marking is deemed to be sufficient to provide information with regard to the noise level of equipment to consumers.

In that spirit, it appears to be appropriate to delete Article 16, as there is no need for this reporting obligation anymore.

As Article 20 of that Directive mentions Article 16, it is therefore appropriate to amend that Article accordingly.

With regard to Directive 2011/24/EU:

Article 20(1) of Directive 2011/24/EU provides that the Commission shall by 25 October 2015 and subsequently every three years thereafter, draw up a report on the operation of the Directive and submit it to the European Parliament and to the Council. The last report on the operation of the Directive was published on 12 May 2022. According to the current rules, the next report of the Directive is to be ready by 2025.

The European Reference Networks established under Directive 2011/24/EU are evaluated every 5 years as provided in Article 14(1) of Implementing Decision 2014/287/EU. As the European Reference Networks were established in 2017, the Commission is evaluating the European Reference Networks for the first time in 2022-2023 and the next evaluation of the European Reference Networks would, in accordance with Article 14(1) of Implementing Decision 2014/287/EU, occur in 2027.

By aligning these two processes (reporting on the operation of the Directive and evaluating the European Reference Networks), synergies could be ensured. Therefore, the proposal will provide for the reporting on the operation of Directive 2011/24/EU to be carried out every five years, from 2027 onwards.

With regard to Directive 2014/53/EU:

Article 47(1) of the Directive provides for an obligation for Member States to report every two years to the Commission.

The report is to contain a presentation of the market surveillance activities performed by Member States and provide information on whether and to what extent compliance with the requirements of that Directive has been attained.

The frequency of that reporting obligation appears to be higher than necessary. In accordance with Article 47(2) of the Directive, the Commission has to report to the European Parliament and to the Council every five years. The proposal aims to modify the frequency of the reporting obligation for Member States to every five years. In such way, the information provided by Member States can be used by the Commission as a reference draft for the report to the European Parliament and to the Council.

This will also provide the Commission with the information necessary for the assessment it is to carry out when adopting delegated acts under Article 5(2) of Directive 2014/53/EU specifying which categories of radio equipment are concerned by the registration requirement and allow the Commission to use the information from Member States' reports more efficiently

Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Directives 1999/2/EC, 2000/14/EC, 2011/24/EU and 2014/53/EU as regards certain reporting requirements in the fields of food and food ingredients, outdoor noise, patients' rights, and radio equipment**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,  
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,  
Having regard to the proposal from the European Commission,  
After transmission of the draft legislative act to the national parliaments,  
Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,  
Acting in accordance with the ordinary legislative procedure,  
Whereas:

- (1) Reporting requirements play a key role in ensuring proper monitoring and correct enforcement of legislation. However, it is important to streamline those requirements, in order to ensure that they fulfil the purpose for which they were intended and to limit the administrative burden.
- (2) In its Communication on 'Long-term competitiveness of the EU: looking beyond 2030'<sup>2</sup>, the Commission has committed to rationalise and simplify reporting requirements, with the ultimate aim to reduce such burdens by 25%, without undermining the related policy objectives.
- (3) Directive 1999/2/EC of the European Parliament and of the Council<sup>3</sup>, Directive 2000/14/EC of the European Parliament and of the Council<sup>4</sup>, Directive 2011/24/EU of the European Parliament and Council<sup>5</sup> and Directive 2014/53/EU of the European

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<sup>1</sup> OJ C [...], [...], p. [...].

<sup>2</sup> COM(2023)168.

<sup>3</sup> 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 66, 13.3.1999, p. 16).

<sup>4</sup> Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1).

<sup>5</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

Parliament and of the Council<sup>6</sup> contain a number of reporting requirements in the fields of food and food ingredients, outdoor noise, patients' rights, and radio equipment.

- (4) In accordance with Article 7(3) of Directive 1999/2/EC, Member States are to report annually to the Commission the results of official checks that they have carried out in ionising irradiation facilities and checks carried out at the product marketing stage. Article 7(4) of Directive 1999/2/EC provides that the Commission is to publish in the *Official Journal of the European Union* a report based on the information provided every year by Member States. Articles 113 and 114 of Regulation (EU) 2017/625 of the European Parliament and of the Council<sup>7</sup> provide that that each Member State is to submit to the Commission, by 31 August every year, a report setting out the outcome of official controls performed in the previous year under its multi-annual national control plan ('MANCP'). The MANCP covers, inter alia, the scope of Directive 1999/2/EC. In addition, Article 114 of Regulation (EU) 2017/625 provides that the Commission is to make available every year to the public an annual report on the operation of official controls in Member States taking into account the annual reports submitted by Member States in accordance with Article 113 of that Regulation. Since the annual reporting obligations laid down in Articles 113 and 114 of Regulation (EU) 2017/625 already ensure enforcement and monitoring of legislation on irradiated foods and food ingredients, the similar annual reporting obligation currently laid down in Directive 1999/2/EC should be deleted in order to reduce administrative burden for competent authorities and the Commission.
- (5) In accordance with Article 16 of Directive 2000/14/EC, manufacturers, or their authorised representatives, are to send a copy of the EC declaration of conformity for equipment for use outdoors falling within the scope of that Directive to the Member States' authorities and to the Commission. The Commission is to collect the data and publish relevant information periodically.
- (6) Consumers can find the relevant information regarding the noise emissions of equipment covered by Directive 2000/14/EC directly on the equipment, as Article 4(1) of that Directive provides for a mandatory noise marking on the equipment. Therefore, the obligations on Member States and the Commission laid down in Article 16 of Directive 2000/14/EC to provide documentation and to collect and publish data are superfluous and should, in the interest of rationality and in order to limit the administrative burden of companies and of authorities, be deleted.
- (7) In accordance with Article 20(1), point (a), of Directive 2000/14/EC, the Commission is to submit to the European Parliament and to the Council a review of the noise data collected in accordance with Article 16 of that Directive. Since such noise data will no longer be collected, that obligation should also be deleted.
- (8) In accordance with Article 20(1) of Directive 2011/24/EU, the Commission is to submit to the European Parliament and to the Council a report on the operation of that Directive every three years. That report heavily draws on the reporting and

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<sup>6</sup> Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).

<sup>7</sup> 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 95, 7.4.2017, p. 1).

contributions of national competent authorities. The European Reference Networks established under Directive 2011/24/EU are to be evaluated every five years as set out in Article 14(1) of Commission Implementing Decision 2014/287/EU<sup>8</sup>. In order to align the reporting and evaluation requirements and to reduce the administrative burden for the Commission and for the Member States that are requested to provide information on the implementation of Directive 2011/24/EU, the frequency of the reporting by the Commission should be changed to every five years. Considering that the most recent report on the operation of Directive 2011/24/EU was published in 2022, the next report should be published in 2027.

- (9) In accordance with Article 47(1) of Directive 2014/53/EU, Member States are to submit to the Commission regular reports on the application of that Directive at least every two years. The frequency of that mandatory reporting is higher than necessary. In the interest of rationality and in order to limit the administrative burden of Member States, the frequency of the mandatory reporting by Member States should be changed to every five years, so that it corresponds to the Commission's obligation under Article 47(2) of Directive 2014/53/EU to report to the European Parliament and to the Council on the operation of that Directive. This will also provide the Commission with the information necessary for the assessment it is to carry out when adopting delegated acts under Article 5(2) of Directive 2014/53/EU specifying which categories of radio equipment are concerned by the registration requirement and allow the Commission to use the information from Member States' reports more efficiently.
- (10) Directives 1999/2/EC, 2000/14/EC, 2011/24/EU and 2014/53/EU should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

#### *Article 1* ***Amendments to Directive 1999/2/EC***

Article 7 of Directive 1999/2/EC is amended as follows:

- (1) paragraph 3 is replaced by the following:

‘3. Each Member State shall forward to the Commission the names, addresses and reference numbers of the irradiation facilities which it has approved, the text of the approval document, and any decision suspending or withdrawing approval.’;
- (2) paragraph 4 is replaced by the following:

‘4. On the basis of the data supplied in accordance with paragraph 3, the Commission shall publish in the *Official Journal of the European Union* the details of the facilities as well as any changes in their status.’.

#### *Article 2* ***Amendments to Directive 2000/14/EC***

Directive 2000/14/EC is amended as follows:

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<sup>8</sup> Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 147, 17.5.2014, p. 79).

- (1) Article 16 is deleted;
- (2) in Article 20(1), point (a) is deleted.

*Article 3*  
***Amendment to Directive 2011/24/EU***

In Article 20 of Directive 2011/24/EU, paragraph 1 is replaced by the following:

‘1. The Commission shall by 25 October 2027 and subsequently every five years thereafter, draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council.’

*Article 4*  
***Amendment to Directive 2014/53/EU***

In Article 47(1) of Directive 2014/53/EU, the first sentence is replaced by the following:

‘Member States shall submit to the Commission reports on the application of this Directive by 12 December 2027, covering the period since 13 June 2023, and every five years thereafter.’

*Article 5*  
***Transposition***

1. Member States shall adopt and publish, by *[Note to PO: insert exact date – [...] 12 months after entry into force of this Directive]* at the latest, the laws, regulations and administrative provisions necessary to comply with Article 2, point (1), of this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from *[Note to PO: insert exact date – [...] 12 months and one day after entry into force of this Directive]*.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 6*  
***Entry into force***

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

*Article 7*  
***Addressees***

This Directive is addressed to the Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*