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THE EUROPEAN PARLIAMENT

THE COUNCIL

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Subject: 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

DIRECTIVE (EU) 2024/...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of ...

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 Committee¹,

Acting in accordance with the ordinary legislative procedure²,

¹ OJ C, C/2024/1585, 5.3.2024, ELI: <http://data.europa.eu/eli/C/2024/1585/oj>.

² Position of the European Parliament of 14 March 2024 (not yet published in the Official Journal) and decision of the Council of ...

Whereas:

- (1) Reporting requirements play a key role in ensuring the proper monitoring and correct enforcement of Union legal acts. However, it is important to streamline such 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 of 16 March 2023 entitled ‘Long-term competitiveness of the EU: looking beyond 2030’, the Commission committed to rationalise and simplify reporting requirements, with the ultimate aim of reducing such burdens by 25 %, without undermining the related policy objectives.
- (3) Directives 1999/2/EC³, 2000/14/EC⁴, 2011/24/EU⁵ and 2014/53/EU⁶ of the European Parliament and of the Council contain a number of reporting requirements in the fields of food and food ingredients, outdoor noise, patients’ rights, and radio equipment.

³ 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).

⁴ 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).

⁵ 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).

⁶ 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).

- (4) Pursuant to Article 7(3) of Directive 1999/2/EC, Member States are to report annually to the Commission the results of checks carried out in the ionising irradiation facilities and of checks carried out at the product marketing stage. Article 7(4) of that Directive 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. Article 113 of Regulation (EU) 2017/625 of the European Parliament and of the Council⁷ provides 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. The multi-annual national control plans are to cover, 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 the enforcement and monitoring of Union legal acts 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 the administrative burden for competent authorities and the Commission.

⁷ 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, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

- (5) Pursuant to 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' responsible authorities and to the Commission. The Commission is to collect the data and publish relevant information periodically. 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,inter alia, for an indication of the guaranteed sound power level 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, collect data and publish information are superfluous and should, in the interest of rationality and in order to limit the administrative burden for companies and for authorities, be deleted.
- (6) Pursuant to 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.

- (7) Pursuant to 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 relies heavily on the assistance and information provided by national competent authorities. Article 14(1) of Commission Implementing Decision 2014/287/EU⁸ provides that the European Reference Networks established under Directive 2011/24/EU are to be evaluated every five years. 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.
- (8) Pursuant to 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 for 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 that Directive to report to the European Parliament and to the Council on the operation of that Directive. Such frequency will still provide the Commission with the information necessary for the assessment it is to carry out when adopting delegated acts pursuant to Article 5(2) of Directive 2014/53/EU, specifying which categories of radio equipment are concerned by the registration requirement, and will allow the Commission to use the information from Member States' reports more efficiently.

⁸ 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).

- (9) Since the objective of this Directive, namely to streamline the reporting requirements laid down in Directives 1999/2/EC, 2000/14/EC, 2011/24/EU and 2014/53/EU, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (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

In Article 7 of Directive 1999/2/EC, paragraphs 3 and 4 are 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.
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:

- (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 5 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 of Directive 2014/53/EU, paragraph 1 is replaced by the following:

- ‘1. Member States shall submit to the Commission reports on the application of this Directive by 12 December 2027, covering the period from 13 June 2023, and every 5 years thereafter. The reports shall contain a presentation of the market surveillance activities performed by the Member States and provide information on whether and to what extent compliance with the requirements of this Directive has been attained, including in particular requirements on identification of economic operators.’.

Article 5
Transposition

1. Member States shall adopt and publish, by ... [12 months from the date of entry into force of this amending Directive], the laws, regulations and administrative provisions necessary to comply with Article 2, point (1), of this Directive. They shall immediately inform the Commission thereof.

They shall apply those measures from ... [12 months and one day from the date of entry into force of this amending Directive].

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main measures 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 ..., ...

For the European Parliament
The President

For the Council
The President
