



Council of the
European Union

Brussels, 22 February 2024
(OR. en)

6819/24

LIMITE

AGRI 151
DENLEG 12
SAN 109
FOOD 28
CODEC 589

Interinstitutional File:
2023/0369(COD)

NOTE

From:	General Secretariat of the Council
To:	Delegations
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 - <i>Mandate for negotiations with European Parliament</i> - <i>Confirmation of the final compromise text with a view to agreement</i>

I. INTRODUCTION

1. On 17 October 2023, the Commission submitted to the Council and the European Parliament a 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 (COM(2023)639 final – 2023/0369 (COD)).¹

¹ doc. ST 15890/23

2. The draft Directive is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure). It is part of a set of 26 additional proposals and initiatives to rationalise reporting requirements adopted or announced by the Commission in its 2024 work programme, Annex II, Section B.²
3. The European Economic and Social Committee delivered its opinion on 13 December 2023.³
4. In the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) has the lead responsibility, with input from the Committee on Employment and Social Affairs (EMPL) and the Committee on the Internal Market and Consumer Protection (IMCO). Ivan Vilibor SINČIĆ (NI, HR) was appointed rapporteur.

II. WORK WITHIN THE COUNCIL

5. The Counsellors/Attachés (Agri – Food and Food Systems) discussed the proposal at on 29 January 2024, with a focus on article 1 (food and food ingredients).
6. The Working Party on Public Health discussed the proposal at its 12 February 2024 meeting, with a focus on article 3 (patients' rights).
7. The Working Party on Technical Harmonisation (Motor Vehicles) discussed the proposal on 14 February 2024, with a focus on articles 2 and 4 (outdoor noise; radio equipment).
8. Delegations broadly supported the Commission proposal as it stands.

² doc. ST 13917/23 + ADD1

³ doc. ST 6933/24

III. CONCLUSION

9. In view of the above, the Permanent Representatives Committee is invited to:

- agree on the compromise text in Annex to this note, based on the Commission proposal (subject to revision by the lawyer linguists of both institutions);
 - confirm that should the European Parliament approve the Commission proposal as it stands, the Council would approve the European Parliament's position, resulting in the adoption of the Directive in the form of the Commission proposal (subject to revision by the legal linguists of both institutions);
 - authorise the Presidency to send a letter to the Chair of the ENVI Committee and to inform the European Parliament thereof.
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2023/0369 (COD)

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 Committee⁴,

Acting in accordance with the ordinary legislative procedure,

⁴ OJ C [...], [...], p. [...].

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 2030’⁵, 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 Council⁶, Directive 2000/14/EC of the European Parliament and of the Council⁷, Directive 2011/24/EU of the European Parliament and Council⁸ and Directive 2014/53/EU of the European Parliament and of the Council⁹ contain a number of reporting requirements in the fields of food and food ingredients, outdoor noise, patients’ rights, and radio equipment.

⁵ COM(2023)168.

⁶ 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).

⁷ 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).

⁸ 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).

⁹ 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) 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 Council¹⁰ 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.

¹⁰ 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).

- (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 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/EU¹¹. 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.

¹¹ 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) 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:

- (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