



STATUTORY INSTRUMENTS.

**S.I. No. 335 of 2023**

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EUROPEAN UNION (MANUFACTURE, PRESENTATION AND SALE OF  
TOBACCO AND RELATED PRODUCTS) (AMENDMENT)  
REGULATIONS 2023

EUROPEAN UNION (MANUFACTURE, PRESENTATION AND SALE OF  
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I, STEPHEN DONNELLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014<sup>1</sup> on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC and giving effect to Commission Delegated Directive (EU) 2022/2100 of 29 June 2022<sup>2</sup> amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products, hereby make the following regulations:

1. These Regulations may be cited as the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) (Amendment) Regulations 2023.

2. In these Regulations, “Principal Regulations” means the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016 (S.I. No. 271 of 2016).

3. (1) Regulation 8 of the Principal Regulations is amended by the substitution of the following paragraph for paragraph (6):

“(6) Paragraphs (1), (2) and (4) shall not apply to tobacco products other than cigarettes, roll-your-own tobacco and heated tobacco products.”.

(2) This Regulation shall come into operation on 23 October 2023.

4. Regulation 20 of the Principal Regulations is amended by the insertion of the following paragraph after paragraph (10):

“(10A) The data storage facility referred to in paragraph (10) shall be physically located within the European Union.”.

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<sup>1</sup> OJ No. L 127, 29.04.2014, p. 1 as affected by Corrigendum (OJ No. L 150, 17.6.2015, p. 24).  
<sup>2</sup> OJ No. L 283, 3.11.2022, p. 4.



GIVEN under my Official Seal,  
26 June, 2023.

STEPHEN DONNELLY,  
Minister for Health.

## EXPLANATORY NOTE

*(This note is not part of the Instrument and does not purport to be a legal interpretation.)*

These Regulations amend the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016 to give effect to Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products. The Regulations also give further effect to Directive 2014/40/EU as regards the location of data storage facilities used as part of the traceability and security features systems for tobacco products.

These Regulations may be cited as the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) (Amendment) Regulations 2023.

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