Commission Implementing Regulation (EU) 2016/779 of 18 May 2016 laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/779

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laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 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[(1)], and in particular Article 7(3) thereof,

Whereas:

(1) Article 7(1) of Directive 2014/40/EU provides that Member States are to prohibit the placing on the market of tobacco products with a characterising flavour.

(2) In order to ensure that such prohibitions are applied in a uniform manner throughout the Union, it is appropriate to lay down, in accordance with Article 7(3) of Directive 2014/40/EU, common procedures for the determination as to whether or not a tobacco product has a characterising flavour.

(3) Where a Member State ('the initiating Member State') or the Commission considers that a tobacco product might have a characterising flavour, it should request the manufacturer or importer to communicate its assessment of the product. The procedure for determining the existence of a product with characterising flavour should be initiated by Member States in respect of products that are marketed only in one or a small number of Member States. Where a Member State considers that a product is marketed widely across a number of different Member States, it should be able to request the Commission to initiate the procedure.

(4) In order to avoid parallel procedures, Member States and the Commission should inform each other on the initiation of procedures. Where a Member State initiates a procedure, all other Member States should refrain from initiating a procedure for the same product. Member States may alternatively agree that another Member State become the initiating Member State. All procedures initiated in Member States other than the initiating Member State should be suspended pending the adoption of the decision by the initiating Member State.

Changes to legislation: *Commission Implementing Regulation (EU) 2016/779 is up to date with all changes known to be in force on or before 28 December 2020. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(5) The Commission should be able to initiate a procedure at any time, including after adoption of a decision concluding that a product has no characterising flavour. Where the Commission initiates a procedure, all national procedures concerning the same product should cease.

(6) If the manufacturer or importer does not dispute that the product has a characterising flavour, or fails to submit a reply to a request for its assessment as to whether or not a product has a characterising flavour, it should be possible to make a determination on the basis of a simplified procedure.

(7) If the manufacturer or importer contests that the product has a characterising flavour, the initiating Member State or the Commission should launch an in depth assessment. To this end the independent advisory panel may be consulted and information from other sources may be gathered. Information may also be exchanged with other Member States and the Commission.

(8) Following the in-depth assessment and before a decision is taken as to whether a product has a characterising flavour, the manufacturer or importer of the product should be provided with an opportunity to submit written observations. In its written observations the manufacturer or importer should also indicate, where applicable, whether its parent company has been consulted. Importers should also be encouraged to consult the manufacturer.

(9) The initiating Member State should submit a draft of its decision to the Commission including where applicable a copy of the opinion of the independent advisory panel. A copy of those documents should be sent to all the other Member States, accompanied by a summary in a language that is widely understood.

(10) The Commission and the other Member States may comment on the draft decision. An effort should be made to reach consensus on the draft decision and the key reasoning underpinning the decision. In the event that the opinions of Member States diverge as to whether or not a product has a characterising flavour, the Commission should aim to establish consensus. In the absence of consensus, and where necessary to ensure that the prohibition laid down in Article 7(1) of Directive 2014/40/EU is applied uniformly, the Commission should proceed to make a determination as to the existence of a characterising flavour in the product concerned.

(11) In view of the public health considerations underpinning the prohibition on products having a characterising flavour, and with due regard to the precautionary principle, it is appropriate for the initiating Member State to be able to adopt prohibition measures as soon as it is satisfied, in accordance with the procedure provided for in this Regulation, that a product has a characterising flavour. Nevertheless, where the Commission subsequently adopts a decision in respect of that product, the initiating Member State should then take immediate measures to ensure its law and practice is aligned with that decision in order that the prohibition laid down in Article 7(1) of Directive 2014/40/EU is applied uniformly throughout the Union.

(12) Member States and the Commission should make publically available non-confidential versions of decisions adopted according to this Regulation. Due account should be

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given to requests that commercially sensitive information remain confidential. Where such requests are considered justified, the information concerned should only be communicated using secure means of data transmission.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 25 of Directive 2014/40/EU,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour.

Article 2

Definition

For the purpose of this Regulation, ‘same product’ means products with the same ingredients in the same proportions in the tobacco blend composition, irrespective of the brand name or design.

CHAPTER II

INITIATION OF THE PROCEDURE

Article 3

Initiation by a Member State or the Commission

1 Where a Member State (‘the initiating Member State’) or the Commission considers that a tobacco product might have a characterising flavour, it may initiate the procedure for determining whether a tobacco product has a characterising flavour. A Member State may also request the Commission to initiate a procedure.

2 The Commission may initiate the procedure referred to in paragraph 1 even where one or more procedures were initiated or concluded by one or more Member States, in particular, when it is necessary to ensure the uniform application of Article 7 of Directive 2014/40/EU.

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Article 4

Initial request to the manufacturer or importer

1 The initiating Member State or the Commission shall inform the manufacturer and importer of the product of its view that a tobacco product might have a characterising flavour and request the manufacturer or the importer to provide its assessment.

2 The manufacturer or importer shall reply to and submit its written observations to the request within a period of four weeks from the receipt of the request referred to in paragraph 1, or by another date agreed with the initiating Member State or the Commission as applicable. In its reply, the manufacturer or importer shall identify, to the extent possible, any other Member States in which the same product has been placed on the market. The manufacturer shall also set out the views of its parent company, where applicable. The importer shall also set out the views of the manufacturer.

3 The manufacturer or importer shall, in its reply under paragraph 2, indicate if it considers that same products placed on the market in other Member States have different flavours in one or more of the Member States concerned. In such a case, the manufacturer or importer shall set out the grounds upon which this claim is based.

Article 5

Initial coordination

1 Where the procedure has been initiated by a Member State, that State shall notify the Commission and all other Member States of the initiation of the procedure without delay.

Where the Commission has initiated the procedure, it shall inform all the Member States of such initiation without delay.

The initiating Member State or the Commission shall communicate the information received from the manufacturer or importer in accordance with Article 4(2) to the other Member States and, where applicable, the Commission.

2 Where a Member State has initiated a procedure, other Member States shall refrain from initiating a parallel procedure concerning the same product. Where procedures concerning the same product have already been initiated in two or more Member States, only the Member State in which the procedure was initiated first shall continue the procedure. By way of derogation, Member States concerned may agree that another Member State shall act as initiating Member State. All procedures initiated in Member States other than the initiating Member State shall be suspended pending the adoption of the decision by the initiating Member State.

3 Where the Commission has initiated a procedure all Member States shall refrain from initiating procedures and, except insofar as provided for in the second subparagraph of Article 9(3), all pending national procedures shall cease.

4 Information already gathered shall be exchanged between Member States and with the Commission, upon request.

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Article 6

Assessment of the manufacturer or importer

1 Where the manufacturer or importer does not dispute that a tobacco product has a characterising flavour, it shall inform the initiating Member State or the Commission accordingly in its reply submitted pursuant to Article 4(2).

Where, in its reply, the manufacturer or importer has not disputed that a tobacco product has a characterising flavour, or where it has failed to provide a reply in accordance with Article 4(2), the initiating Member State or the Commission, as applicable, may proceed to make a determination in accordance with Article 9 or 10 respectively in cases where it considers that the information at its disposal is sufficient to make a determination.

Insofar as the Member State or the Commission considers it necessary to obtain further information in order to be able to make a conclusive determination on whether the product has a characterising flavour, it may gather further information in accordance with Article 7 before making a determination in accordance with Article 9 or 10.

2 Where the manufacturer or importer disputes that the product has a characterising flavour, the initiating Member State or the Commission shall continue the procedure in accordance with Articles 7 and 8.

CHAPTER III

INVESTIGATION

Article 7

Gathering of further information and consultation of the advisory panel

1 The initiating Member State or the Commission may request further information from the manufacturer or importer concerned, to be provided within a time limit to be specified in the request. It may also request information from other sources, exchange information with other Member States and, where applicable, the Commission and consult the independent advisory panel (hereafter the 'panel') established pursuant to Commission Implementing Decision (EU) 2016/786[(2)].

2 Where the panel is consulted, it shall submit its opinion within the time-frame applicable under Article 10(6) of Implementing Decision (EU) 2016/786.

Article 8

Right for manufacturers and importers to submit observations

1 Where, on the basis of Article 6(2), the initiating Member State or the Commission has carried out further investigation under Article 7, and where having due regard to information obtained from that investigation, the initiating Member State or the Commission considers that a product has a characterising flavour it shall, before adopting a decision, provide the manufacturer or importer with an opportunity to submit written observations.