



Brussels, **XXX**
[...] (2015) **XXX** draft

COMMISSION IMPLEMENTING DECISION

of XXX

laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determining whether tobacco products have a characterising flavour

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION

of **XXX**

laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determining whether tobacco products have 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/EC¹, and in particular Article 7(4) thereof,

Whereas:

- (1) Article 7 of Directive 2014/40/EU prohibits the placing on the market of tobacco products with a characterising flavour. Uniform rules for the procedures for determining whether a tobacco product has a characterising flavour are laid down in Commission Implementing Regulation (EU) .../.. of XXX.
- (2) Article 7(4) of Directive 2014/40/EU provides that, when determining whether a tobacco product has a characterising flavour, Member States and the Commission may consult an independent advisory panel ("the panel"). It further empowers the Commission to adopt implementing acts laying down the procedure for the establishment and operation of that panel.
- (3) The panel should be composed of highly qualified, specialised and independent experts with relevant expertise in the fields of sensory, statistical and chemical analysis. They should perform their functions impartially and in the public interest. They should be selected on the basis of objective criteria through a public call for applications and be appointed in a personal capacity. They should have the range of skills and expertise necessary for the panel to be able to perform its functions.
- (4) The panel should be assisted by a technical group recruited by means of a public procurement procedure. The technical group should carry out sensory and chemical assessments based on a comparison of the smelling properties of the test product with those of a reference group of products. Sensory, including smelling, analysis is an established scientific discipline that applies principles of experimental design and statistical analysis to assess and describe perceptions of the human senses, including smell, for the purpose of evaluating consumer products. It has been found to be a suitable method for producing valid, robust, reliable and reproducible results when

¹ OJ L 127, 29.4.2014, p. 1.

assessing whether a tobacco product has a characterising flavour. Such analysis should be conducted on the basis of established procedures and produce results that can be presented on the basis of statistical tools. More detailed provisions laying down the methodology for establishing the reference group and for differentiating between the test products and the reference group are to be specified in a separate implementing act. Where it is considered necessary, sensory analysis should be complemented by chemical analysis of the composition of the products.

- (5) In carrying out its advisory functions, the panel should examine, as applicable, data provided by the technical group, as well as any other information at its disposal that it may consider relevant, including information obtained as a result of the reporting obligations laid down in Article 5 of Directive 2014/40/EU. It should advise the Member States and the Commission in a timely manner as to whether it considers that the tested products have a characterising flavour within the meaning of Article 7(1) of Directive 2014/40/EU.
- (6) As scientific methods and techniques for determining the existence of a characterising flavour may evolve with time and experience gained, it is appropriate for the Commission to monitor developments in the field with a view to assessing whether the methodologies used to carry out such a determination should be revised.
- (7) The panel and the process by which it assesses the existence of a characterising flavour should be protected against external interference from any entities or associations with an interest in the outcome of its assessment. Confidential information should be protected against inadvertent disclosure. Members of the panel and the technical group who can no longer perform their duties or cease to comply with the requirements of this Decision should be replaced.
- (8) The work of the panel should be based on the principles of a high level of expertise, independence and transparency. It should be organised and conducted in conformity with best practice and high scientific standards.
- (9) The panel should contribute effectively to improving the functioning of the internal market while ensuring a high level of public health, in particular by helping the Member States and the Commission to assess tobacco products with a potentially characterising flavour. The panel's activities are necessary to ensure the effective and uniform implementation of Directive 2014/40/EU and the advice provided by the members of the panel is essential to reach the relevant Union policy objectives. Therefore, it is appropriate to provide the panel with adequate financial support in the form of a special allowance for its members, beyond the reimbursement of their expenses.
- (10) Personal data should be collected, processed and published in accordance with Regulation (EC) No 45/2001 of the European Parliament and the Council².

² Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

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

HAS ADOPTED THIS DECISION:

CHAPTER I GENERAL PROVISIONS

Article 1 ***Subject matter***

This Decision lays down the procedure for the establishment and operation of an independent advisory panel ('the panel') assisting Member States and the Commission in determining whether a tobacco product has a characterising flavour.

Article 2 ***Definitions***

For the purposes of this Decision, 'test product' means a product referred to the panel by a Member State or the Commission for an opinion as to whether or not it has a characterising flavour within the meaning of Article 7(1) of Directive 2014/40/EU.

Article 3 ***Tasks***

1. The panel shall provide opinions as to whether test products have a characterising flavour within the meaning of Article 7(1) of Directive 2014/40/EU.
2. The opinion shall be sent to the requesting Member State, where applicable, and to the Commission.

CHAPTER II ESTABLISHMENT OF THE INDEPENDENT ADVISORY PANEL

Article 4 ***Appointment***

1. The panel shall consist of six members.
2. The Director-General for Health and Food Safety acting on behalf of the Commission ('the Director-General') shall appoint the members of the panel from a list of suitable candidates established following publication of a call for applications on the Commission's website and in the Register of Commission expert groups and other similar entities ('Register of expert groups'). The members shall be selected on the basis of their expertise and experience in the fields of sensory, statistical and chemical analysis, and with due regard to the need to ensure independence and absence of conflicts of interests.
3. Persons on the list of suitable candidates who are not appointed to the panel shall be included in a reserve list of suitable candidates to replace members whose

membership has ceased in accordance with Article 5(3). The Director-General shall ask applicants for their consent before including their names on the reserve list.

4. The list of panel members shall be published in the Register of expert groups and be made available on the relevant Commission website.

Article 5 *Terms of office*

1. The members of the panel shall be appointed for a renewable term of five years.
2. If, at the end of a term, the renewal or replacement of the panel has not been confirmed, the existing members shall remain in office.
3. An individual shall cease to be a member of the panel if:
 - (a) he or she dies or becomes incapacitated to such an extent that he or she is incapable of performing his or her functions under this Decision;
 - (b) he or she resigns;
 - (c) the Director-General suspends his or her membership pursuant to paragraph 5, in which case he or she shall cease to be a member for the duration of the suspension; or
 - (d) the Director-General terminates his or her membership pursuant to paragraph 5.
4. A member wishing to resign shall notify the Director-General by email or registered post, giving at least six months' notice. Where he or she is in a position to execute his or her tasks and a replacement process is ongoing, he or she may, at the request of the Director-General, remain in office until the replacement is confirmed.
5. The Director-General may temporarily suspend or permanently terminate the membership of a member where it has been found, or there are reasonable grounds to consider, that:
 - (a) the member no longer complies with, or has acted in breach of, the conditions set out in this Decision or in Article 339 of the Treaty on the Functioning of the European Union;
 - (b) the member no longer complies with one or more essential conditions set out in the call for applications, or with the principles of independence, impartiality and confidentiality referred to in Article 15, or where the member's conduct or position is incompatible with declarations made in accordance with Articles 15, 16 and 17;
 - (c) the member is incapable of performing his or her tasks under this Decision;
 - (d) other significant factors are putting the functioning of the panel into question.
6. Where the membership of a member has ceased in accordance with paragraph 3(a), (b) or (d), the Director-General shall appoint a replacement for the remainder of the

term. The Commission shall launch a new call for applications once the reserve list is exploited.

CHAPTER III OPERATION OF THE PANEL

Article 6 Election of the Chair and Vice-Chair

1. At the beginning of each term, the panel shall elect a Chair and a Vice-Chair from among its members. The election shall take place by a simple majority of its total membership. In the event of parity, the Director-General shall select the Chair from the members with most votes, on the basis of an assessment of their qualifications and experience.
2. The term of office of the Chair and Vice-Chair shall coincide with the term of the panel and shall be renewable. Any replacement of the Chair or Vice-Chair shall be for the remainder of the term of the panel.

Article 7 Voting rules

1. The panel shall take decisions by the majority of members present at the vote.
2. Persons who have ceased to be members or whose membership is temporarily suspended pursuant to Article 5(5) shall not be taken into account for the calculation of the majority referred to in paragraph 1.
3. In the event of parity, the Chair shall have the casting vote.

Article 8 Rules of procedure

1. The panel shall adopt its rules of procedure on a proposal by and in agreement with the Director-General.
2. The rules of procedure shall ensure that the panel performs its tasks in compliance with the principles of scientific excellence, independence and transparency.
3. In particular, the rules of procedure shall provide for:
 - (a) the procedure for the election of the Chair and Vice-Chair of the panel, in accordance with Article 6;
 - (b) application of the principles laid down in Chapter IV;
 - (c) procedures for the adoption of an opinion;
 - (d) relations with third parties, including scientific bodies;
 - (e) other detailed rules on the functioning of the panel.

Article 9
Advice on test products

1. Where the panel is asked to provide an opinion on a test product, the Chair of the panel shall inform all members. He or she may appoint a rapporteur from among the members to coordinate the examination of a particular product. The Chair shall submit a final report to the Commission and, where applicable, the requesting Member State.
2. Where the panel considers it necessary for the purposes of providing an opinion, it shall request input from the technical group established in accordance with Article 11. In forming its opinion, the panel shall have regard to the information and data obtained from the technical group. It may also have regard to any other information at its disposal that it considers authoritative and relevant, including information resulting from reporting obligations pursuant to Article 5 of Directive 2014/40/EU.
3. With respect to the data and information provided by the technical group, the panel shall, in particular:
 - (a) verify whether the technical group respected applicable rules and scientific standards;
 - (b) assess the data and information, in particular to determine whether they are sufficient to reach a conclusion or whether additional data and information are needed;
 - (c) request such clarifications from the technical group as may be necessary to reach a conclusion.
4. If the panel considers the data or information to be insufficient or has doubts as to whether the applicable rules and standards were respected, it shall consult the Commission and, where applicable, the requesting Member State. Where it is considered necessary, the panel may ask the technical group to repeat certain tests taking into account the panel's comments.
5. Where the panel is satisfied that applicable rules and standards were respected, including, where applicable, following the procedure laid down in paragraph 4, and that the data and information are sufficient to reach a conclusion, it shall proceed to deliver an opinion in accordance with paragraph 2.
6. The panel shall submit its opinion within three months of the date of receipt of the request or by a date agreed with the Commission or the requesting Member State.

Article 10
Consultation on other matters

1. The Commission may consult the panel on other matters relating to the determination of a characterising flavour in accordance with Article 7 of Directive 2014/40/EU. In such cases, it shall decide, in consultation with the Chair, whether to convene a meeting or proceed by means of a written procedure.

2. The Chair may appoint a rapporteur from among the panel members to coordinate the task. He or she shall submit a final report to the Commission.
3. In its deliberations, the panel shall consider, as appropriate, data and information provided to it by the technical group and other relevant information at its disposal.

Article 11

Technical group of sensory and chemical assessors

1. A technical group of sensory and chemical assessors (the "technical group") shall be set up to provide the panel with an assessment of the sensory and, where appropriate, chemical properties of the test product as part of the procedure laid down in Article 9(2). The technical group shall be composed of:
 - (a) two qualified persons selected on the basis of their knowledge, skills and experience in sensory analysis who shall be responsible for recruitment, training and supervision of the sensory assessors;
 - (b) sensory assessors recruited on the basis of their olfactory discrimination ability and their capacity to perceive, analyse and interpret smells, and who have reached the age of majority as laid down in applicable national legislation; and
 - (c) two persons selected on the basis of their knowledge and skills in chemical and laboratory analysis who shall be responsible for the chemical analysis of test products.
2. A public procurement procedure shall be established for the selection of a contractor with responsibility for setting up the technical group. The contractor shall have at its disposal the minimum technical expertise and equipment as specified in the call for tender, to include the persons referred to in paragraph 2(a) and (c).

The call for tender and associated contractual documentation shall specify that the technical group is to act independently and is under an obligation to protect confidential information and personal data. It shall further contain:

 - (a) a description of the technical group's main functions;
 - (b) specifications relating to the establishment, management and operation of the technical group, including technical specifications applicable to the performance of the group's functions;
 - (c) specifications concerning the technical expertise and equipment that must be available to the contractor;
 - (d) specifications relating to the recruitment of sensory assessors. Such specifications shall include a requirement that sensory assessors may only be recruited following approval by the Commission of the candidates proposed;
3. The technical group's sensory analysis shall be based on a comparison of the smelling properties of the test product with those of a reference group.
4. The sensory analysis shall be complemented, where necessary, by a chemical assessment of the product composition through chemical analyses. This assessment shall be carried out in a manner that produces accurate, consistent and reproducible results. The process and results of the chemical assessment shall be documented.
5. The technical group shall deliver the results of the product testing to the panel and submit a copy to the Commission.

6. The work of the technical group shall be subject to the limits of the annual budget allocated to it by the Commission.

Article 12
Secretariat

1. The Commission shall provide a secretariat for the panel and for all other activities relating to the application of this Decision.
2. The secretariat shall be responsible for providing administrative support to facilitate the efficient functioning of the panel and to monitor compliance with the rules of procedure.

Article 13
Special allowance

1. The members of the panel shall be entitled to a special allowance compensating them for their preparatory work and participation, in person or remotely by electronic means, in the meetings of the panel and other activities relating to the application of this Decision and organised by the Commission, and for serving as rapporteur on a specific question.
2. The special allowance shall consist of a maximum of EUR 450 in the form of a daily unit cost for each full working day. The total allowance shall be calculated and rounded up to the amount corresponding to the nearest half working day.
3. The Commission shall reimburse travel and, where appropriate, subsistence expenses incurred by members and external experts in connection with the panel's activities in accordance with internal Commission provisions.
4. All allowances and reimbursements shall be subject to the annual budget allocated to the panel by the Commission.

Chapter IV
INDEPENDENCE, CONFIDENTIALITY AND
TRANSPARENCY

Article 14
Communication

1. The Chair of the panel shall act as the contact person for the Member States and the Commission.
2. The Chair shall immediately report to the Commission any circumstances that could jeopardise the functioning of the panel.

Article 15
Independence

1. The members of the panel shall be appointed in a personal capacity. They shall not delegate their responsibilities to any other person. In performing their functions, they

shall respect the principles of independence, impartiality and confidentiality and act in the public interest.

2. Experts applying to be appointed as members of the panel shall be required to submit a declaration indicating any interest that may compromise or reasonably be perceived to compromise their independence, including any relevant circumstances relating to their close family members or partners. Submission of a duly completed declaration of interests shall be necessary in order for an expert to be eligible to be appointed as a member of the panel. If the Commission concludes that no conflict of interest exists, the applicant shall be eligible for appointment, provided he or she is considered to possess the required expertise.
3. Panel members shall promptly inform the Commission if there is any change in the information provided in their declaration, in which case they must immediately submit a new declaration showing relevant changes.
4. At each meeting, panel members shall declare any specific interest that may compromise or reasonably be perceived to compromise their independence in relation to any item on the agenda. In such cases, the Chair may request that the member concerned withdraw from the meeting or from parts of the meeting. The Chair shall inform the Commission of such declaration and actions taken.
5. The panel members shall refrain from having any direct or indirect contact with the tobacco industry or its representatives.

Article 16

Confidentiality and protection of personal data

1. The panel members shall not divulge information, including commercially sensitive or personal data, acquired as a result of the panel's work or of other activities relating to the application of this Decision, even after they have ceased to be members. They shall sign a declaration of confidentiality to this effect.
2. The panel members shall comply with the Commission's security rules on the protection of EU classified and sensitive non-classified information, as set out in Commission Decisions (EU, Euratom) 2015/443³ and 2015/444⁴. Should they fail to respect these obligations, the Commission may take all appropriate measures.

Article 17

Commitment

The panel members of the panel shall undertake to contribute actively to the work of the panel. They shall sign a declaration of commitment to this effect.

³ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

⁴ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

Article 18
Transparency

1. The activities of the panel shall be carried out with a high level of transparency. The Commission shall publish all relevant documents on a dedicated website and provide a link to this website from the register of expert groups. In particular, it shall make available to the public, without undue delay:
 - (a) the members' names;
 - (b) the members' declarations of interests, confidentiality and commitment;
 - (c) the panel's rules of procedure;
 - (d) the opinions adopted by the panel;
 - (e) the agendas and minutes of the panel's meetings.
2. By way of derogation from paragraph 1, publication shall not be required where disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) No 1049/2001 of the European Parliament and of the Council⁵.

CHAPTER V
FINAL PROVISIONS

Article 19
Addressees

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission
Vytienis ANDRIUKAITIS
Member of the Commission

⁵ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).