

**RULES OF PROCEDURE OF THE INDEPENDENT ADVISORY PANEL ASSISTING MEMBER STATES AND THE COMMISSION IN DETERMINING WHETHER TOBACCO PRODUCTS HAVE A CHARACTERISING FLAVOUR ESTABLISHED BY DECISION (EU) 2016/786**

THE INDEPENDENT ADVISORY PANEL ON CHARACTERISING FLAVOURS IN TOBACCO PRODUCTS,

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<sup>1</sup>,

Having regard to 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<sup>2</sup>,

Having regard to Commission Implementing Decision (EU) 2016/786 of 18 May 2016 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<sup>3</sup>,

Having regard to Commission Decision C(2016) 3301 of 30 May 2016 establishing horizontal rules on the creation and operation of Commission expert groups<sup>4</sup>,

HAS ADOPTED THE RULES OF PROCEDURE SPECIFIED IN THIS DOCUMENT.

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<sup>1</sup> OJ L 127, 29.4.2014, p. 1

<sup>2</sup> OJ L 131, 20.4.2016, p. 48

<sup>3</sup> OJ L 131, 20.4.2016, p. 79

<sup>4</sup> [http://ec.europa.eu/transparency/regexpert/PDF/C\\_2016\\_3301\\_F1\\_COMMISSION\\_DECISION\\_EN.pdf](http://ec.europa.eu/transparency/regexpert/PDF/C_2016_3301_F1_COMMISSION_DECISION_EN.pdf)

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## **1. INTRODUCTION AND BACKGROUND**

1. Article 7 of Directive 2014/40/EU (hereinafter "the Directive") prohibits the placing on the market of tobacco products with a characterising flavour. Article 7(4) of that Directive provides that, when determining whether a tobacco product has a characterising flavour, Member States and the Commission may consult an independent advisory panel (hereinafter "the IAP" or "the Panel"). It further empowers the Commission to adopt implementing acts laying down the procedure for the establishment and operation of that panel.
2. Uniform rules for the procedures for determining whether a tobacco product has a characterising flavour are laid down in Commission Implementing Regulation (EU) 2016/779 of 18 May 2016 (hereinafter "the Regulation").
3. Commission Implementing Decision (EU) 2016/786 of 18 May 2016 (hereinafter "the Decision") lays 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.
4. In accordance with Article 8 of the Decision, Rules of Procedure are to be adopted by the IAP on a proposal by and in agreement with the Director-General for Health and Food Safety acting on behalf of the Commission (hereinafter "the Director-General").
5. In accordance with Articles 4 and 16 of the Decision the panel consists of six members, selected on the basis of their expertise and experience in the fields of sensory, statistical and chemical analysis. They were appointed in a personal capacity and shall act independently and in the public interest.
6. Articles 9, 10 and 11 of the Decision provide that the IAP shall consider, as appropriate, information and data obtained from the Technical Group of Sensory and Chemical Assessors (hereinafter "Technical Group") referred to in Article 12 of the Decision. Articles 10 and 11 of the Decision provide that the IAP may also have regard to any other information that it considers authoritative and relevant for the purposes of providing an opinion or when consulted on other matters. To that end, the Secretariat, in consultation with the Panel, may invite external experts to contribute to the work of the IAP on an ad-hoc basis (hereinafter "external experts").
7. The IAP qualifies as 'Commission expert group' pursuant to Article 2(1) of Commission Decision C(2016) 3301.

## **2. OBJECTIVES AND SCOPE OF THE RULES OF PROCEDURE**

1. In accordance with Articles 8(2) of the Decision, the Rules of Procedure shall ensure that the IAP performs its tasks in compliance with the principles of scientific excellence, independence, and transparency. The Rules of Procedure shall in particular provide for the items listed in Article 8(3) of the Decision.

2. In order to ensure that the IAP operates effectively and in compliance with the applicable legislation, these Rules of Procedure regulate the functioning of the IAP, the role and responsibilities of the members of the IAP (hereinafter "members") and, as appropriate, external experts contributing to the work of the IAP on an ad-hoc basis (hereinafter "external experts"), the relationship to third parties including the Technical Group, other activities related to the functioning of the IAP, as well as the role and responsibilities of the Secretariat of the IAP (hereinafter "the Secretariat").

### **3. PRINCIPLES**

In line with the Decision, the IAP shall perform its tasks in compliance with the applicable legislation, these Rules of Procedure including the principles of scientific excellence, independence, confidentiality, commitment and transparency.

#### **3.1. Scientific Excellence**

1. The advice provided must represent the best information and guidance, that can be provided at the time of adoption of the advice under the conditions and deadlines imposed, on the assessment of test products, on methodology and on other matters related to the determination of characterising flavours in accordance with Article 7 of Directive 2014/40/EU and the Decision. It shall be based on the best data, scientific knowledge and methodology available at the time of preparation of an opinion.
2. The principle of excellence refers to the performance and outcome of the entire process. It refers in particular to the intrinsic quality of the opinion, its adequacy in relation to the aims of the task, its clarity, completeness and transparency. It also refers to the effective communication of the contents and conclusions of the opinions and the actual and perceived credibility of the process.

#### **3.2. Independence**

1. The advice provided must not be influenced by any consideration other than the assessment outlined in the tasks of the request.
2. This principle implies in particular, independence of the IAP and its members from any external economic or political interests, but also from bias related to political, economic, social, ethical, or any other non-scientific considerations.
3. The principle of independence refers to the organisation and results of the process, including in particular the independence criteria and conditions and arrangements for the participation of members and experts.

#### **3.3. Confidentiality and protection of personal data**

The advice delivered by the IAP might be based on confidential information. Participants and observers of the work of the IAP shall respect the principle of confidentiality and professional

secrecy, and to exercise due diligence in not divulging any information acquired as a result of the work of the panel, thematic workshops, or other activities related to the application of the Decision and these Rules of Procedure with the exception of publicly available information.

### **3.4. Commitment**

The members shall commit themselves to act independently, in the public interest and to contribute actively to the work of the IAP. They shall set an exemplary conduct in all activities related to the IAP.

### **3.5. Transparency**

The activities of the panel shall be carried out with a high level of transparency. In addition to the obligation to make relevant information publicly available, the meaning of the advice, the way conclusions were drawn, the limits of their validity and the relevant uncertainties must be clear and understandable for the users to which it is addressed (i.e. the Commission or Member States). Equally, the organisation and process leading to the advice, as well as their rationale, must be presented in a clear and understandable manner. Openness, dialogue and collaboration with other bodies, as appropriate, should also contribute to transparency.

## **4. RULES TO IMPLEMENT THE PRINCIPLES**

### **4.1. Scientific Excellence**

1. The Rules of Procedure shall be applied in such a way as to ensure that the principles and provisions of Directive 2014/40/EU and of the Decision are complied with.
2. The application of the principles and standards for advice shall be monitored by the Secretariat in collaboration with the Chair and Vice-Chair, in order to ensure that action is taken, as appropriate, to achieve conformity with the principles and standards in question.

### **4.2. Independence**

1. Members shall act independently and shall not delegate their responsibilities to any other person.
2. Members shall carry out their tasks independently from the Technical Group and thus cannot participate in that group.
3. Members shall make in writing a Declaration of Interests, set out in Annex Ia, at the beginning of their mandate and then annually.
4. Members shall be in a position to show beyond question that they can act independently. They are under a continuing duty to declare any activity, situation, circumstance or other fact potentially involving an interest, as indicated in Annex Ia, in order to enable the IAP and the Directorate General for Health and Food Safety (hereinafter "DG SANTE") to

identify those interests which might be considered prejudicial to their independence. They shall be required to promptly inform the Secretariat of any relevant change in the information previously provided, including as regards upcoming activities.

5. External experts, invited as independent experts, (hereinafter "independent external experts" (see section 5.6.1 of these Rules of Procedure)) shall make in writing a Declaration of Interests, set out in Annex Ib, before the meeting to which they are invited. Other external experts shall state their affiliation, i.e. the name of the body they are representing. This shall be noted in the minutes of the meeting.
6. The Chair of the IAP shall, before each meeting, remind all members of their obligation to promptly inform DG SANTE of any relevant change in the information previously provided, including as regards upcoming activities.
7. Specifically, members and independent external experts participating in meetings of the IAP, or in any other activity, shall declare at the beginning of each meeting or event any activity, situation, circumstance or other fact potentially involving an interest which may compromise their ability to act independently, in order to enable the IAP and DG SANTE identify those interests which might be considered prejudicial to their independence in relation to the items on the agenda for that meeting or event. This declaration shall be made in writing or verbally, following a request of the Chair or the Secretariat and should be noted in the minutes of the meetings. In respect to the declarations made at the meeting pursuant to Article 16(4) of the Decision, the Chair shall take the appropriate measures in line with this Article. Accordingly, measures may include the physical withdrawal from the meeting or from parts of the meeting.
8. Conclusions and decisions taken in relation to the Declarations of Interests, as well as their rationale, shall be recorded and reported in writing. In the case of declarations made at the meetings, the records shall be part of the minutes of the IAP's meeting. Information registered must be adequate, relevant and not going beyond what is necessary for the purpose of the management of the conflict of interest.
9. Declarations of Interests of members shall be published on the IAP's website and in the Register of Commission expert groups and other similar entities<sup>5</sup>. They must be complete and updated accordingly with any relevant additional or new information.
10. The Secretariat, the Chair and the IAP shall ensure that the principles of independence of members are complied with at all times. Members shall draw the IAP's and the Secretariat's attention through the Chair to any factual matter that could undermine the independence of IAP's work. The panel's discussions of the matter shall be recorded.
11. The Secretariat shall draw DG SANTE's attention to all cases where it appears that a member might have ceased to fulfil the requirement to act independently and address the measures to be taken, included as appropriate, the revocation of his/her appointment.
12. Members who intend to participate in the public procurement procedure for the establishment of the Technical Group referred to in Article 12 of the Decision shall

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<sup>5</sup> <http://ec.europa.eu/transparency/regexpert/>

immediately notify the Secretariat and shall be excluded from the work of the IAP as long as this procedure is ongoing. They shall resign from the IAP if their application is successful.

13. Members and external experts shall inform the Secretariat of any relevant contacts they might have with petitioners, special interest groups, other stakeholders or other Union or international bodies in relation to the fields of work undertaken by the IAP. The Secretariat, in consultation with the IAP, shall advise on any action to be taken if and when necessary should there be any possibility of a potential conflict of interest.
14. In particular, members or external experts contacted by third parties in connection with their participation on a specific question in a meeting or any other activity of the IAP shall inform the Secretariat and refer the third party to the Secretariat.
15. Any member who, in accordance with his/her Declaration of Interests or any other information at the disposal of DG SANTE, the Secretariat or the IAP may not be able to act independently, shall be temporarily or permanently excluded from the activities of the IAP or may only be allowed to participate to the extent and in a way compatible with the objective to preserve the process from any undue influence. The extent of the concerned member's participation in the IAP's work shall be decided by the Chair in consultation with the IAP and in agreement with DG SANTE. In cases of non-compliance with the principle of independence, the provisions of Article 5(5) of the Decision shall apply as appropriate and DG SANTE shall take all appropriate measures, in compliance with Commission Decision C(2016) 3301.

#### **4.3. Confidentiality**

1. Members, external experts, and any other participants present during deliberations of the panel shall not divulge any information acquired as a result of their work in the IAP, thematic workshops, or other activities related to the application of the Decision and these Rules of Procedure with the exception of publically available information. This will include in particular, documents provided by third parties concerning sensitive industrial and commercial matters, and/or for which confidentiality has been requested and agreed by the Commission services in accordance to the applicable provisions. Furthermore, individual views, whether expressed orally or in writing by members and external experts during deliberations within the IAP shall be confidential.
2. The obligation of the members, external experts and other participants not to disclose confidential information shall continue to apply even after their involvement in the work of the IAP has ceased.
3. Members shall make in writing a Declaration of Confidentiality (see Annex II) at the beginning of their mandate. External experts and observers shall make in writing the Declaration of Confidentiality before the meeting to which they are invited.
4. In case of non-compliance with the principle of confidentiality, the provisions of Article 5(5) of the Decision shall apply as appropriate.



5. All participants and observers of the work of the IAP shall comply with Commission's security rules for protecting European Union classified information and sensitive non-classified information, as laid down in Commission Decisions (EU, Euratom) 2015/443<sup>6</sup> and 2015/444<sup>7</sup>. Should they fail to comply with those obligations, the Commission may take all appropriate measures.

#### **4.4. Commitment**

1. Members shall make in writing a Declaration of Commitment set out in Annex IIIa, at the beginning of their mandate. Independent external experts shall make in writing the Declaration of Commitment before the meeting to which they are invited, set out in Annexes IIIb (for independent external experts).
2. Members shall contribute actively to the discussion and deliberations on subjects within their field of competence during meetings of the IAP and, when requested, with written comments. They shall take into account that meetings, in general, involve preparatory work and that requested contributions (e.g. studies, reports or drafting opinions) shall be provided in due time.
3. Members shall participate in the preparation of opinions when their expertise is required, and act as a rapporteur when appointed by the Chair.
4. The Secretariat may invite members to represent the IAP in meetings with stakeholders, conferences and workshops.
5. In each calendar year, members shall attend at least 70% of the meetings or teleconferences of the IAP to which they have been invited.
6. The extent to which members participated in the work of the IAP related to the particular work they were assigned to, will be assessed by the Secretariat on a yearly basis. After consultation with the Chair, the Secretariat shall examine the situation with the members who did not comply with the participation criteria. They could be dismissed from the IAP in line with Article 5(5) of the Decision.
7. When invited to represent the IAP, members shall ensure that they convey the views of the IAP, without expressing personal views or interpreting adopted opinions in a way that goes beyond the established position of the IAP. In such cases, they should inform and consult with the Secretariat in advance. Members shall use the formats, templates and logos provided by the Secretariat in order to make visible the attribution of their presentations to the IAP. Members shall report back to the Secretariat in writing and orally about these activities at relevant meeting(s) of the IAP.
8. Members shall not speak on behalf of the Commission.

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<sup>6</sup> Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

<sup>7</sup> 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).

9. Members shall inform the Secretariat on all issues concerning their external activities directly related to the IAP's work, e.g. relations with the media (interviews, articles, letters, etc.), presentations/speeches, and other communication regarding the work of the IAP.
10. In case of non-compliance with the principle of commitment, the provisions of Article 5(5) of the Decision shall apply as appropriate.

#### **4.5. Transparency**

1. The IAP shall operate in accordance with a high level of transparency, without prejudice to legitimate requests for confidentiality or the need to safeguard the freedom and scientific integrity of the debate and the independence of members and external experts vis-à-vis external influence.
2. The IAP shall be registered on the Register of expert groups.
3. DG SANTE shall publish all relevant documents on a dedicated website and provide a link to this website from the register of expert groups. Access to dedicated websites shall not be submitted to user registration or any other restriction. In particular, DG SANTE shall publish the agenda in due time ahead of the meeting, followed by timely publication of minutes.
4. In line with Article 19 of the Decision, in particular the following data shall be published without undue delay:
  - (a) the members' names;
  - (b) the members' declarations of interests, confidentiality and commitment;
  - (c) the IAP's rules of procedure;
  - (d) the opinions adopted by the IAP pursuant to Article 10 of the Decision;
  - (e) the agendas and minutes of the IAP's meetings; and
  - (f) the methodology established in accordance with Article 9 of the Decision.
5. For any other document, the Secretariat, in agreement with DG SANTE, shall decide about the publication and the dissemination on a case by case basis.
6. Availability of preparatory and draft working documents shall be restricted, on a need-to-know basis, to members, external experts, the Secretariat and representatives of Commission services with competence in the subject area. They shall not be given to third parties unless a different decision is taken in specific cases by the IAP in agreement with the Secretariat, in view of a specific need to involve or inform urgently a third party as part of the process to complete the relevant work.

7. The minutes of the IAP meetings shall list, as appropriate, the participants attending those meetings. Interests declared by independent external experts at the beginning of meetings shall be published as part of the minutes.
8. Without prejudice to Article 19 of the Decision, DG SANTE shall be responsible for determining the appropriate level of publicity to be given to an opinion and may request the assistance of the Chair, Vice-Chair, rapporteur or other members to ensure the scientific validity of its press releases or related communication actions.
9. In line with Article 19(2) of the Decision, exceptions to publication mentioned in point 4 shall be foreseen where it is deemed that 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 the Council<sup>8</sup>.

## **5. FUNCTIONING OF THE INDEPENDENT ADVISORY PANEL (IAP)**

### **5.1. Operation of the IAP**

The IAP shall act at the request of DG SANTE. DG SANTE will launch any consultations of the IAP including those set out in Article 7 of the Regulation.

### **5.2. Election of Chair and Vice-Chair of the IAP**

1. The IAP shall elect from among its members a Chair and a Vice-Chair.
2. The terms of office of the Chair and Vice-Chair shall coincide with the term of the panel, i.e. 5 years, and is renewable.
3. The names of the Chair and the Vice-Chair shall be made public.
4. The Chair and Vice-Chair shall be elected by open vote unless at least one member requests a vote in writing. In that case, a secret ballot by the members present at the meeting shall be carried out.
5. The election procedure shall be chaired by the Secretariat.
6. The procedure shall be as follows:
  - The election of the Chair and of the Vice-Chair shall be held separately. A separate record shall be kept of the election procedure.

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<sup>8</sup> 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).

- The names of those wishing to stand as candidates shall be notified to the Secretariat before the meeting or be announced at the meeting. Members may present themselves as candidates or be proposed by another member.
- The candidates must, prior to the vote, declare that they are prepared to accept the post of Chair (or Vice-Chair) of the IAP.
- The candidate receiving the simple majority of the IAPs total membership shall be elected. 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.
- Candidates may withdraw their candidature at any time during the procedure.

### **5.3. Role and replacement of the Chair and Vice-Chair of the IAP**

1. The Chair of the IAP, in collaboration with the Secretariat shall be responsible for the following:
  - plan the work of the IAP in agreement with the Secretariat;
  - chair, steer and moderate the discussions at meetings and drawing conclusions;
  - keep a good balance between rapporteurs and the number of dossier allocated;
  - advise DG SANTE on the need to consult external experts;
  - take the necessary measures to ensure that the deadline for delivery of the opinion is respected;
  - examine the information submitted by members and independent external experts regarding their ability to act independently, in particular the information in the Declarations of Interest and at meetings, deciding, as appropriate, in consultation with the IAP and in agreement with DG SANTE, the relevant conclusions and action in order to ensure the effective application of the independence requirements;
  - in collaboration with the Secretariat, monitor the conformity of the activities of the IAP with all the relevant procedural, methodological and substantive requirements, principles and standards established or deriving from the Directive, the Decision, the Regulation, these Rules of Procedure or with relevant new methodological developments, and taking, or requesting DG SANTE to take, as appropriate, the necessary measures;
  - act as the contact person for the Member States and the Commission;
  - inform all IAP-members about new requests for opinions on test products;
  - may appoint a rapporteur from among the members to coordinate the work on a particular request, including on the examination of a particular test product;

- submit the final report/opinion to the Commission and, where applicable, the requesting Member State, via the Secretariat;
  - immediately report to the Commission any circumstances that could jeopardise the functioning of the panel; and
  - represent the IAP on request by the Commission.
2. If the Chair is not in a position to fulfil his/her function, he/she shall be replaced by the Vice-Chair or, failing that, another member chosen in common accord by the members. In case of a permanent replacement of the Chair or Vice-Chair, the replacement shall be for the remainder of the term of the IAP.
  3. In case of conflict of interest of the Chair with an item on the agenda, he/she shall be replaced by the Vice-Chair or failing that another member chosen in common accord by the members.
  4. The Vice-Chair shall support the Chair in fulfilling his/her responsibilities. The Chair shall consult the Vice-Chair on a regular basis and, as appropriate, on emerging issues requiring urgent decisions that could not be postponed for discussion at meetings of the IAP.

#### **5.4. Requests for Opinions**

1. Requests for opinions (mandates) shall be submitted by DG SANTE or the Member State competent authority (the "requestor") to the Chair of the IAP via the Secretariat. The mandate shall be submitted in English and in line with the templates provided by the Secretariat. It shall be accompanied by all appropriate and available supplementary information of relevance. The Secretariat shall provide any additional information as soon as possible to the members.
2. The terms of reference of the mandate shall be confined to issues relevant to the tasks and the role of the panel as set out in the Decision.
3. The request shall consist of the background information explaining the interest of the Member State or the European Union interest in relation to the request, the context, and the terms of reference. Required timelines, respecting the provisions of Article 10(6) of the Decision and supporting documents may be indicated.
4. The requestor shall, as appropriate, specify in the request for an opinion the suggested consultations or collaboration with other bodies, aside from the Technical Group, deemed necessary for the preparation of the opinion.
5. The requestor shall provide information already collected as part of the procedure laid down in the Regulation, including e.g. consultation of manufacturers/importers, exchange of information among and between Members States and the Commission, consultation of other bodies as well as information gathered in the context of the reporting obligations pursuant to Article 5 of the Directive. The requestor shall also outline during which part of this procedure the panel is consulted.

6. All mandates shall be reviewed by the Secretariat before submission to the IAP, for conformity with the applicable template, clarity and completeness, relevance in relation to the field of competence of the IAP and appropriateness of the terminology used as well as specified timelines.
7. The Secretariat shall inform the Chair without delay of the mandate.
8. The IAP may ask the requestor or the Secretariat to clarify the mandate and/or to supply additional information. The IAP may also provide feedback on the feasibility of the requested timelines of the mandate.
9. The IAP shall take the necessary measures to ensure that the deadlines set out in Article 10(6) of the Decision are respected.

## **5.5. Designation and role of Rapporteurs**

1. The Chair of the IAP, in consultation with the Secretariat, may appoint a rapporteur among the members for a specific mandate. The designation may be revoked.
2. Rapporteurs shall be responsible for coordinating the examination of a particular product, for assembling information including from other members, editing and revising draft opinions and ensuring that draft reports, advices and opinions are prepared within a set time period, where appropriate. The rapporteur should ensure that these documents are well structured, written in clear and simple language and are coherent. The rapporteur shall work in close cooperation with the Chair, the other members of the Panel and the Secretariat. The rapporteur shall present the draft opinion to the IAP during a meeting.
3. The work of a rapporteur is concluded when the final opinion is published on the IAP's website.

## **5.6. External experts and observers**

### *5.6.1. External experts*

1. The Secretariat may invite external experts with specific and relevant expertise with respect to a subject matter on the agenda to contribute to the work of the IAP on an ad-hoc basis.
2. This will include in particular the preparation, compilation and presentation of the evidence base which serves as a basis for the opinions of the IAP. Their role is limited to testify and give specialist advice on specific issues by providing information and replying to any questions only (in written and oral form). Such experts can be invited to participate in meetings on an ad hoc basis for a limited period of time. They cannot be appointed as rapporteurs, cannot draft opinions and have no voting rights.
3. These experts may be invited in their personal capacity, acting independently and in the public interest (independent external experts) or they may be invited to represent a

company, an organisation, a consortium, an authority or any other public or private entity (other external experts).

#### *5.6.2. Observers*

1. The Secretariat, in agreement with the Chair of the IAP, may give observer status to staff of Commission services, Union bodies and Member State Competent Authorities concerned, as well as other individuals by direct invitation.
2. Although observers may be permitted by the Chair to take part in the discussion of the IAP and provide expertise, they shall not have voting rights and shall not participate in the elaboration of opinions.

### **5.7. Meetings (Notice, Agendas, Deadlines, Minutes, Access)**

#### *5.7.1. Convening a meeting*

1. The Secretariat shall establish with the IAP a tentative schedule for the meetings for the forthcoming calendar year.
2. As a general rule, the Secretariat shall confirm meetings of the IAP at the earliest possible date but, as far as possible, no later than ten working days before the date of the meeting and shall give notification of cancellation not less than two working days before the date of the meeting.
3. Meetings of the IAP may be called at short notice according to the urgency of the matters.

#### *5.7.2. Agenda*

1. The Secretariat shall prepare the draft agenda of meetings of the IAP and circulate it to members as soon as possible and, as far as possible, no later than two weeks before the date of the meeting. The draft agenda of meetings shall be published on the IAP's website before the meeting takes place.
2. The agenda shall be adopted at the beginning of the meeting taking account of any agreed amendments.

#### *5.7.3. Further documentation to be sent to and by IAP members*

1. As far as possible, the Secretariat shall send the invitation to the meeting to the IAP members no later than thirty calendar days before the date of the meeting.
2. The Secretariat shall send documents on which the IAP is consulted to the IAP members, as far as possible, no later than seven calendar days before the date of the meeting.
3. In urgent or exceptional cases, the time limits for sending the documentation mentioned in paragraphs 1 and 2 may be reduced.

4. Wherever possible, documents, including reports and draft opinions prepared by the Chair, Vice-Chair, rapporteurs or members, shall be made available to the Secretariat for distribution to the members and experts at the latest one week before the meeting where they will be discussed. Chair, Vice-Chair, rapporteurs and members entrusted with the drafting of documents, reports or draft opinions shall ensure that this requirement is complied with.

#### 5.7.4. *Minutes of the meetings*

1. The Secretariat of the IAP shall prepare draft minutes of meetings. The minutes shall contain at least:
  - the list of participants and absent members;
  - declarations of interests by participants concerning their independence including the relevant details, the action taken and its rationale. Information registered in the minutes must be adequate and relevant for the purpose of management of conflict of interest;
  - the adopted agenda;
  - summary of discussions and agreed actions; and
  - a record of decisions taken and opinions adopted.
10. The minutes shall not mention the individual positions of the members during the IAP's deliberations.
11. The draft minutes of the meetings shall be circulated to the members of the IAP for comments. They should be adopted not later than at the next meeting.
12. Without prejudice to the provisions on confidentiality, minutes shall be published on the IAP's website as soon as possible after their adoption. Legitimate requests for commercial confidentiality shall be respected.

#### 5.7.5. *Attendance list*

At each meeting, the secretariat shall draw up, under the responsibility of the Chair, an attendance list also specifying, where appropriate, the Member States' authorities, organisations or other public entities to which the participants belong.

#### 5.7.6. *Access to meetings*

1. Meetings of the IAP shall not be open to the public.
2. Where appropriate, Commission services, Union bodies and Member State Competent Authorities concerned with the topics on the agenda shall be entitled to be present in the meeting as observers. They may assist for the purposes of clarification or provision of information but shall not seek to influence the outcome of the discussions.



## **5.8. Process and timelines to deliver and adopt opinions / Voting Rules**

1. In line with Article 10(6) of the Decision, the panel shall submit its opinion to the Commission and any referring Member States within three months of the date of receipt of the request or by a date agreed with the Commission or the requesting Member State.
2. The IAP shall adopt its opinions, recommendations or reports as far as possible by consensus and should strive to reach common conclusions.
3. For votes other than the election of the Chair and Vice-Chair, the panel shall only take decisions when at least four members are participating in the vote (in person or via distance connection) one of whom must be either the Chair or the Vice-Chair. Decisions shall be taken by a simple majority.
4. In the event of parity, the person chairing the vote shall have the casting vote.
5. Persons who have ceased to be members or whose membership is temporarily suspended pursuant to Article 5(5) of the Decision shall not be taken into account for the calculation of the majority referred to in paragraph 3.
6. Meetings are considered in force when the absolute majority of the members of the IAP are present.

## **5.9. Written procedure**

1. If necessary, the IAP's opinion or recommendation on a specific question may be delivered and adopted via a written procedure. To this end, the secretariat sends the IAP members the document(s) on which the IAP is being consulted with a request for approval by a set deadline.
2. The panel shall only take decisions in form of a written procedure when at least four members are participating in the vote in writing, one of whom must be either the Chair or the Vice-Chair. The opinion shall be adopted when a simple majority of the IAP members have expressed their approval before the deadline.
3. However, if IAP members request before the set deadline that the question be examined at a meeting of the IAP, the written procedure shall be terminated without result and the Chair shall convene a meeting of the IAP as soon as possible.

## **5.10. Format and content of opinions**

1. The opinion should comprise:
  - the composition of the IAP;
  - the terms of reference providing the background and specific question(s);
  - an abstract (where appropriate);

- an executive summary (where appropriate);
- the considerations used by the IAP to reach its conclusions (scientific rationale);
- the conclusion (opinion), setting out the response to the question(s) posed;
- a description of the sources taken into account when developing the opinion, referring in particular to the consultation of the Technical Group and information acquired from the reporting obligations pursuant to Article 5 of Directive 2014/40/EU;
- a bibliography (where appropriate);
- a list of abbreviations (where appropriate); and
- a glossary (where appropriate).

13. More details about the format of the opinions may be provided in specific guidance papers prepared by the IAP and the Secretariat.

#### **5.11. Scientific and methodological issues raised by the IAP**

1. The IAP shall draw attention of the Secretariat to a specific issue falling within its remit, which it considers relevant in the context of its tasks including by adopting position statements.
2. The Secretariat shall arrange to publish on the IAP website such position statements and inform the IAP accordingly.

#### **5.12. Correspondence**

1. Correspondence relating to the IAP and their members shall be addressed to the Secretariat, for the attention of the Chair using the functional mailboxes indicated on the website.

### **6. COLLABORATION AND RELATIONS WITH THE TECHNICAL GROUP OF SENSORY AND CHEMICAL ASSESSORS**

1. In line with Article 12 of the Decision, the IAP shall be assisted by the Technical Group recruited by means of a public procurement procedure.
2. The IAP shall ensure that the provisions of the Decision regarding the role and mechanisms to collaborate with the Technical Group as well as applicable timelines are fully respected.
3. In line with Article 10(3) of the Decision and 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; and
  - 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. The IAP may invite members of the Technical Group to meetings of the IAP in consultation with the Secretariat.
  6. A Memorandum of Understanding describing the details of the cooperation between the IAP and the Technical Group shall be developed once the Technical Group has been established.

## **7. CO-OPERATION WITH OTHER EU, NATIONAL, AND INTERNATIONAL BODIES**

1. In order to fulfil its mandate, the IAP may have to collaborate with other relevant Union, national or international bodies.
2. In order to ensure that this cooperation is effective DG SANTE may organise meetings of the Secretariat and members of the IAP with the Secretariat and Members of the other bodies and the IAP may ask for the assistance of members of the committees or panels of other Union bodies as external experts.
3. DG SANTE may request and organise joint work of the IAP with the relevant Union, national or international bodies including bodies outside the European Union.
4. DG SANTE may in particular request the IAP to produce joint opinions, recommendations or reports with other bodies, upon agreement with such bodies. In such a case, the relevant mandate submitted by the Secretariat shall specify the sharing of tasks and responsibilities and the arrangements for the organisation of the work and adoption of the joint opinion, recommendation or reports.
5. Requests for collaboration from other bodies shall be addressed to the Chair through the Secretariat. The Secretariat shall define and manage the practical aspects and take the appropriate contacts.
6. The Secretariat may establish appropriate arrangements, which may take the form of common guidelines, with other EU bodies involved in a relevant area on sharing data. These guidelines shall be agreed by bodies participating in the exchange.

## **8. RELATIONS AND DIALOGUE WITH STAKEHOLDERS**

1. Relations with stakeholders as part of the procedure for determining whether a tobacco product has a characterising flavour are described in the Regulation and should be implemented accordingly by the Secretariat.

## **9. SECRETARIAT**

1. DG SANTE shall provide a secretariat for the IAP.
2. The Secretariat shall be responsible for providing administrative and scientific support necessary to facilitate the efficient functioning of the IAP and its interaction with the Technical Group, to monitor compliance with the applicable Union law and the Rules of Procedure, particularly in relation to the requirements for excellence, independence, commitment, confidentiality and transparency, to ensure communication on the IAP's activities, publication of the opinions and other relevant documents. Moreover, the Secretariat shall provide support to the IAP and organise and apply quality control of the opinions as far as completeness, consistency, clarity, correspondence with requests and with editorial standards are concerned. Specific duties shall include in particular:
  - ensure best use of resources and the planning to meet priorities and time limits;
  - ensure that requests for opinions comply with the relevant requirements;
  - where appropriate, in collaboration with relevant Commission services, organise scientific meetings, hearings, consultations, collaboration with other bodies;
  - ensure avoidance of overlapping or inconsistent opinions between the IAP and other Union bodies;
  - co-ordinate the administrative, scientific and technical work carried out within the IAP, in consultation with the Chair and Vice-Chair where appropriate;
  - provide information on the legislative/policy aspects of the questions and ensuring that relevant background information is made available to the IAP;
  - assist in identifying the appropriate experts to be invited to meetings;
  - coordinate communication between the IAP and the Technical Group;
  - coordinate and handle requests from the IAP for access to information collected as part of the reporting obligations pursuant to Article 5 of Directive 2014/40/EU;
  - coordinate communication between the IAP and Commission services as well as Member States Competent Authorities in relation to IAP's activities, including feedback from the Commission services or Member States Competent Authorities on the adopted opinions;

- assist the Chair and, as appropriate, the rapporteur, in the preparation of the draft opinions in particular by monitoring, assessing and reporting to the IAP, before adoption, the quality of draft opinions, in particular in relation to correspondence with the mandate, completeness, clarity and coherence, editorial standards, as well as conformity to the principles of excellence, independence and transparency and the other relevant principles and standards referred to in these Rules of Procedure;
- assure the scientific and technical coordination of the activities of the IAP in relation to the activities of other Union, national and international bodies involved in a relevant field of application;
- decide, in agreement, where applicable, with the interested Commission services, about the publication of memoranda, position statements, documents resulting from scientific meetings and thematic workshops;
- monitor compliance of members and experts with participation criteria and inform DG SANTE as appropriate; and
- provide administrative support in relation to calculation of a special allowance for members and experts, in accordance with the rules laid down in the Decision.

## **10. REPRESENTATION OF THE IAP**

The Secretariat may invite the Chair and Vice-Chair to represent the IAP in external events, contacts, missions, etc., as appropriate. The Chair, Vice-Chair and rapporteurs may be designated by the Secretariat to make presentations of the opinions to which they have contributed. Other members may be invited by the Secretariat to attend events, meetings, etc. in relation to the work of the IAP, but shall not speak on behalf of the IAP, unless explicitly requested to do so by the Secretariat.

## **11. THEMATIC WORKSHOPS, SCIENTIFIC MEETINGS, NETWORKS**

1. Thematic workshops shall be organised by the Secretariat
  - at the request of DG SANTE or
  - at the own initiative of the IAP, in agreement with DG SANTE.
2. The objective of such workshops may be to present an opinion, review data and scientific knowledge on particular issues in relation to the remit of the IAP. These workshops may involve members and experts, including experts from Union, national or international bodies carrying out similar tasks.
3. Workshops at the initiative of the IAP shall be organised by the Secretariat subject to consultation of DG SANTE and, as appropriate, other interested Commission services, availability of funds and adequate planning.

## **12. TRAVEL EXPENSES AND SPECIAL ALLOWANCE FOR MEMBERS AND EXPERTS, CHAIR, VICE-CHAIR AND RAPPORTEURS**

1. Travel and subsistence expenses incurred by members and experts in connection with IAP meetings and other activities are reimbursed in accordance with the provisions in force at the Commission.
2. As set out in Article 14 of the Decision, members and experts are entitled to a special allowance for their preparatory work and participation in meetings of the IAP.
3. Special allowance directly linked to attendance of meetings of the IAP or agreed external meetings shall be based on the attendance list. Participation through audio or video link shall be authorised by the Secretariat.
4. Special allowance for preparatory work, e.g. for the Chair, Vice-Chair or rapporteurs, shall be proportionate to any substantial workload requested from them, consisting e.g. in preparatory and follow-up work before and after the meetings, coordination work carried out as well as preparation of documents.
5. The amount of special allowance paid to members and experts shall be published if it exceeds EUR 15 000 for the task performed, in accordance with the Rules of Application of the Financial Regulation<sup>9</sup>.

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<sup>9</sup> Article 287(5) and (6) of the Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

## Annex Ia

### Standard declaration of interests (DOI) form for members of the Independent Advisory Panel Independent Advisory Panel (IAP) assisting Member States and the Commission in determining whether tobacco products have a characterising flavour

#### Legal basis:

Directive 2014/40/EU 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 (TPD), Commission Implementing Decision (EU) 2016/786 of 18 May 2016 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 and Commission Decision C(2016)3301 establishing horizontal rules on the creation and operation of Commission expert groups, Articles 2(4) and 11.

#### Definitions:

**"Conflict of interest"** means any situation where an individual has an interest that may compromise or be reasonably perceived to compromise the individual's capacity to act independently and in the public interest when providing advice to the Commission in relation to the subject of the work performed by the expert group or sub-group in question.

**"Immediate family member"** means the individual's spouse, children and parents. "Spouse" includes a partner with whom the individual has a registered non marital regime. "Children" means the child(ren) the individual and the spouse have in common, the own child(ren) of the individual and the own child(ren) of the spouse.

**"Legal entity"** means any commercial business, industry association, consultancy, research institution or other enterprise whose funding is significantly derived from commercial sources. It also includes independent own commercial businesses, law offices, consultancies or similar.

**"Body"** means a governmental, international or non-profit organisation.

**"Meeting"** includes a series or cycle of meetings.

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**Please answer each of the questions below. If the answer to any of the questions is "yes", please briefly describe relevant interests and circumstances, as appropriate.**

**If you do not describe relevant interests, your DOI form will be considered incomplete and, therefore, you shall be excluded from the independent advisory panel.**

First name:

Family name:

Expert group/sub-group:

## 1 EMPLOYMENT CONSULTANCY AND LEGAL REPRESENTATION

	<i>Within the past 5 years, were you employed or have you had any other professional relationship with a natural or legal entity, or held any non-remunerated post in a legal entity or other body with an interest in the field of activity of the expert group/sub-group in question?</i>	<b>yes</b>	<b>no</b>
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<b>1a</b>	<b>Employment</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>1b</b>	<b>Consultancy, including services as an advisor</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>1c</b>	<b>Non-remunerated post</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>1d</b>	<b>Legal representation</b>	<input type="checkbox"/>	<input type="checkbox"/>

Activity	Time period (from... until month/year)	Name of entity or body	Description

## 2 MEMBERSHIP OF MANAGING BODY, SCIENTIFIC ADVISORY BODY OR EQUIVALENT STRUCTURE

	<i>Within the past 5 years, have you participated in the internal decision-making of a legal entity or other body with an interest in the field of activity of the expert group/sub-group in question or have you participated in the works of a Scientific Advisory Body with voting rights on the outputs of that entity?</i>	<b>yes</b>	<b>no</b>
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<b>2a</b>	<b>Participation in a decision-making process</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>2b</b>	<b>Participation in the work of a Scientific Advisory Body</b>	<input type="checkbox"/>	<input type="checkbox"/>

Activity	Time period (from... until month/year)	Name of legal entity or body	Description



### 3 RESEARCH SUPPORT

	<i>Within the past 5 years, have you, or the research entity to which you belong, received any support from a legal entity or other body with an interest in the field of activity of the expert group/sub-group in question?</i>	<b>yes</b>	<b>no</b>
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<b>3a</b>	<b>Research support, including grants, rents, sponsorships, fellowships, non-monetary support</b>	<input type="checkbox"/>	<input type="checkbox"/>
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<b>Activity</b>	<b>Time period (from... until month/year)</b>	<b>Name of legal entity or body</b>	<b>Description</b>

### 4 FINANCIAL INTERESTS

	<i>Do you have current investments in a legal entity with an interest in the field of activity of the expert group/sub-group in question, including holding of stocks and shares, and which amounts to more than 10,000 EUR per legal entity or entitling you to a voting right of 5% or more in such legal entity?</i>	<b>yes</b>	<b>no</b>
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<b>4a</b>	<b>Shares</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>4b</b>	<b>Other stock</b>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Investment</b>	<b>Name of legal entity</b>	<b>Description</b>

## 5 INTELLECTUAL PROPERTY

	<i>Do you have any intellectual property rights that might be affected by the outcome of the work carried out by the expert group/sub-group in question?</i>	<b>yes</b>	<b>no</b>
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<b>5a</b>	<b>Patent, trademarks, or copyrights</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>5b</b>	<b>Others</b>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Intellectual property</b>	<b>Description</b>

## 6 PUBLIC STATEMENTS AND POSITIONS

	<i>Within the past 5 years, have you provided any expert opinion or testimony in the field of activity of the expert group/sub-group in question, for a legal entity or other body as part of a regulatory, legislative or judicial process? Have you held an office or other position, paid or unpaid, where you represented interests or defended an opinion in the field of activity of the expert group/sub-group in question?</i>	<b>Yes</b>	<b>no</b>
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<b>6a</b>	<b>For a legal entity or other body as part of a regulatory, legislative or judicial process</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>6b</b>	<b>Represented interests or defended an opinion</b>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Activity</b>	<b>Time period (from... until month/year)</b>	<b>Name of legal entity or body</b>	<b>Description</b>

**7 INTERESTS OF IMMEDIATE FAMILY MEMBERS** yes      no

<b>7a</b>	To your knowledge, are there any interests of your immediate family members which could be seen as undermining your independence when providing advice to the Commission in the field of activity of the expert group/sub-group in question?	<input type="checkbox"/>	<input type="checkbox"/>
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Interests	Time period (from... until month/year)	Name of legal entity or body	Description

<b>7b</b>	If interests of your immediate family members are declared, it is your responsibility to inform them about the collection and publication of information on their interests included in the DOI and to provide them with the privacy statement attached to the guidance for filling in this DOI, and this at the latest when you file the DOI form with the Commission.
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**8 OTHER RELEVANT INFORMATION** yes      no

<b>8a</b>	Are there any other elements that could be seen as undermining your independence when providing advice to the Commission in the field of activity of the expert group/sub-group in question?	<input type="checkbox"/>	<input type="checkbox"/>
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Description:

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**I hereby declare on my honour that I have read the guidance for completing this form. I also declare on my honour that the information disclosed in this form is true and complete to the best of my knowledge.**

**Should there be any change to the above information, including as regards upcoming activities, I will promptly notify the competent Commission department and complete a new DOI form describing the changes in question.**

**I am informed that my personal data are stored, processed and published by the Commission in accordance with Regulation (EC) N° 45/2001.**

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

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Your DOI form shall be made publicly available on the Register of Commission Expert Groups and Other Similar Entities, as long as you are appointed as member of the Independent Advisory Panel in a personal capacity. Technical measures will be taken to indicate to search engines that your DOI form should not appear in search results.

Guidance for filling in the declaration of interests (DOI) form for members of the Independent Advisory Panel Independent Advisory Panel (IAP) assisting Member States and the Commission in determining whether tobacco products have a characterising flavour

According to the Commission's horizontal rules on expert groups ('the horizontal rules'), Commission expert groups and other similar entities are consultative bodies<sup>10</sup>, the role of which is to provide advice and expertise to the Commission and its departments in relation to a number of tasks<sup>11</sup>. Individuals appointed as members of expert groups or sub-groups in a personal capacity are due to act independently and in the public interest<sup>12</sup>.

In order to ensure the highest integrity of experts, you are requested to duly complete the DOI form. You are required to disclose any circumstances that could give rise to a conflict of interest, i.e. any situation where your interests may compromise or may reasonably be perceived to compromise your capacity to act independently and in the public interest in providing advice to the Commission, in relation to the subject of the work performed by the expert group or sub-group in question. In particular, you must disclose in this DOI form any relevant professional and financial interests.

You must also declare relevant interests of your immediate family members. If interests of your immediate family members are declared, it is your responsibility to inform them about the collection and publication of information on their interests included in this DOI form and to provide them with the privacy statement attached to this guidance, and this at the latest when you file the DOI form with the Commission.

Please submit the completed DOI form to the competent Commission department, together with your CV, in order for Commission services to determine if you may continue participating in the work of the group. If there is any change concerning the information provided in the form, including on upcoming activities, you must promptly inform the competent Commission departments by completing a new DOI form which describes the changes in question.

Please note that having a declared interest does not necessarily mean having a conflict of interest. Answering "Yes" to a question on this DOI form does not automatically disqualify you or limit your participation in an expert group or sub-group. The competent Commission departments will review your answers in accordance with the horizontal rules and determine whether a conflict of interest relevant to the subject at hand exists<sup>13</sup>.

Where the competent Commission departments conclude that no conflict of interest exists, you may continue to be member of the group in a personal capacity. Where the competent Commission departments conclude that your interests may compromise or be reasonably perceived to compromise your capacity to act independently and in the public interest when advising the Commission, you shall be excluded from the group.

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<sup>10</sup> C(2016) 3301, Article 2.1.

<sup>11</sup> Idem, Article 3.

<sup>12</sup> Idem, Article 7.2 (a).

<sup>13</sup> Idem, Article 11.

Your DOI form shall be made publicly available on the Register of Commission Expert Groups and Other Similar Entities, as long as you are appointed as member of the expert group or sub-group in a personal capacity. Technical measures will be taken to indicate to search engines that your DOI form should not appear in search results.

If you decline to complete a DOI form, you shall be excluded from the group.

Personal data shall be collected, processed and published by the Commission in accordance with Regulation (EC) No 45/2001.

## Annex Ib

### Standard declaration of interests (DOI) form for external experts invited as independent external experts to contribute to the work of the Independent Advisory Panel (IAP) assisting Member States and the Commission in determining whether tobacco products have a characterising flavour

#### Legal basis:

Directive 2014/40/EU 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 (TPD), Commission Implementing Decision (EU) 2016/786 of 18 May 2016 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 and Commission Decision C(2016)3301 establishing horizontal rules on the creation and operation of Commission expert groups, Articles 2(4) and 11.

#### Definitions:

**"Conflict of interest"** means any situation where an individual has an interest that may compromise or be reasonably perceived to compromise the individual's capacity to act independently and in the public interest when providing advice to the Commission in relation to the subject of the work performed by the expert group or sub-group in question.

**"Immediate family member"** means the individual's spouse, children and parents. "Spouse" includes a partner with whom the individual has a registered non marital regime. "Children" means the child(ren) the individual and the spouse have in common, the own child(ren) of the individual and the own child(ren) of the spouse.

**"Legal entity"** means any commercial business, industry association, consultancy, research institution or other enterprise whose funding is significantly derived from commercial sources. It also includes independent own commercial businesses, law offices, consultancies or similar.

**"Body"** means a governmental, international or non-profit organisation.

**"Meeting"** includes a series or cycle of meetings.

\*\*\*

**Please answer each of the questions below. If the answer to any of the questions is "yes", please briefly describe relevant interests and circumstances, as appropriate.**

**If you do not describe relevant interests, your DOI form will be considered incomplete and, therefore, you shall be excluded from the activities of the independent advisory panel.**

First name:

Family name:

Expert group/sub-group:

## 1 EMPLOYMENT CONSULTANCY AND LEGAL REPRESENTATION

	<i>Within the past 5 years, were you employed or have you had any other professional relationship with a natural or legal entity, or held any non-remunerated post in a legal entity or other body with an interest in the field of activity of the expert group/sub-group in question?</i>	<b>yes</b>	<b>no</b>
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<b>1a</b>	<b>Employment</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>1b</b>	<b>Consultancy, including services as an advisor</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>1c</b>	<b>Non-remunerated post</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>1d</b>	<b>Legal representation</b>	<input type="checkbox"/>	<input type="checkbox"/>

Activity	Time period (from... until month/year)	Name of entity or body	Description

## 2 MEMBERSHIP OF MANAGING BODY, SCIENTIFIC ADVISORY BODY OR EQUIVALENT STRUCTURE

	<i>Within the past 5 years, have you participated in the internal decision-making of a legal entity or other body with an interest in the field of activity of the expert group/sub-group in question or have you participated in the works of a Scientific Advisory Body with voting rights on the outputs of that entity?</i>	<b>yes</b>	<b>no</b>
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<b>2a</b>	<b>Participation in a decision-making process</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>2b</b>	<b>Participation in the work of a Scientific Advisory Body</b>	<input type="checkbox"/>	<input type="checkbox"/>

Activity	Time period (from... until month/year)	Name of legal entity or body	Description

### 3 RESEARCH SUPPORT

	<i>Within the past 5 years, have you, or the research entity to which you belong, received any support from a legal entity or other body with an interest in the field of activity of the expert group/sub-group in question?</i>	<b>yes</b>	<b>no</b>
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<b>3a</b>	<b>Research support, including grants, rents, sponsorships, fellowships, non-monetary support</b>	<input type="checkbox"/>	<input type="checkbox"/>
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<b>Activity</b>	<b>Time period (from... until month/year)</b>	<b>Name of legal entity or body</b>	<b>Description</b>

### 4 FINANCIAL INTERESTS

	<i>Do you have current investments in a legal entity with an interest in the field of activity of the expert group/sub-group in question, including holding of stocks and shares, and which amounts to more than 10,000 EUR per legal entity or entitling you to a voting right of 5% or more in such legal entity?</i>	<b>yes</b>	<b>no</b>
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<b>4a</b>	<b>Shares</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>4b</b>	<b>Other stock</b>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Investment</b>	<b>Name of legal entity</b>	<b>Description</b>



## 5 INTELLECTUAL PROPERTY

	<i>Do you have any intellectual property rights that might be affected by the outcome of the work carried out by the expert group/sub-group in question?</i>	<b>yes</b>	<b>no</b>
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<b>5a</b>	<b>Patent, trademarks, or copyrights</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>5b</b>	<b>Others</b>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Intellectual property</b>	<b>Description</b>

## 6 PUBLIC STATEMENTS AND POSITIONS

	<i>Within the past 5 years, have you provided any expert opinion or testimony in the field of activity of the expert group/sub-group in question, for a legal entity or other body as part of a regulatory, legislative or judicial process? Have you held an office or other position, paid or unpaid, where you represented interests or defended an opinion in the field of activity of the expert group/sub-group in question?</i>	<b>Yes</b>	<b>no</b>
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<b>6a</b>	<b>For a legal entity or other body as part of a regulatory, legislative or judicial process</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>6b</b>	<b>Represented interests or defended an opinion</b>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Activity</b>	<b>Time period (from... until month/year)</b>	<b>Name of legal entity or body</b>	<b>Description</b>

**7 INTERESTS OF IMMEDIATE FAMILY MEMBERS** yes      no

<b>7a</b>	To your knowledge, are there any interests of your immediate family members which could be seen as undermining your independence when providing advice to the Commission in the field of activity of the expert group/sub-group in question?	<input type="checkbox"/>	<input type="checkbox"/>
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Interests	Time period (from... until month/year)	Name of legal entity or body	Description

<b>7b</b>	If interests of your immediate family members are declared, it is your responsibility to inform them about the collection and publication of information on their interests included in the DOI and to provide them with the privacy statement attached to the guidance for filling in this DOI, and this at the latest when you file the DOI form with the Commission.
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**8 OTHER RELEVANT INFORMATION** yes      no

<b>8a</b>	Are there any other elements that could be seen as undermining your independence when providing advice to the Commission in the field of activity of the expert group/sub-group in question?	<input type="checkbox"/>	<input type="checkbox"/>
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Description:

\*\*\*\*

**I hereby declare on my honour that I have read the guidance for completing this form. I also declare on my honour that the information disclosed in this form is true and complete to the best of my knowledge.**

**Should there be any change to the above information while being involved in the work of the IAP, I will promptly notify the competent Commission department and complete a new DOI form describing the changes in question.**

**I am informed that my personal data are stored, processed and published by the Commission in accordance with Regulation (EC) N° 45/2001.**

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

\*\*\*\*\*

Guidance for filling in the declaration of interests (DOI) form for external experts invited as independent experts to contribute to the work of the Independent Advisory Panel (IAP) assisting Member States and the Commission in determining whether tobacco products have a characterising flavour

According to the Commission's horizontal rules on expert groups ('the horizontal rules'), Commission expert groups and other similar entities are consultative bodies<sup>14</sup>, the role of which is to provide advice and expertise to the Commission and its departments in relation to a number of tasks<sup>15</sup>. Individuals appointed as members of expert groups or sub-groups in a personal capacity are due to act independently and in the public interest<sup>16</sup>. Furthermore, individuals invited as independent experts to contribute to the work of the IAP shall be required to inform the competent Commission department beforehand of any interest which may compromise their capacity to act independently and in the public interest when advising the Commission<sup>17</sup>. In order to ensure the highest integrity of experts and to ensure transparency of the work carried out by the IAP, you are requested to duly complete the DOI form. You are required to disclose any circumstances that could give rise to a conflict of interest, i.e. any situation where your interests may compromise or may reasonably be perceived to compromise your capacity to act independently and in the public interest in providing advice to the Commission, in relation to the subject of the work performed by the IAP. In particular, you must disclose in this DOI form any relevant professional and financial interests.

You must also declare relevant interests of your immediate family members. If interests of your immediate family members are declared, it is your responsibility to inform them about the collection and publication of information on their interests included in this DOI form and to provide them with the privacy statement attached to this guidance, and this at the latest when you file the DOI form with the Commission.

Please submit the completed DOI form to the competent Commission department, together with your CV, in order for Commission services to determine if you may contribute to the work of the group. If there is any change concerning the information provided in the form, including on upcoming activities, you must promptly inform the competent Commission departments by completing a new DOI form which describes the changes in question.

Please note that having a declared interest does not necessarily mean having a conflict of interest. Answering "Yes" to a question on this DOI form does not automatically disqualify you or limit your participation in the IAP. The competent Commission departments will review your answers in accordance with the horizontal rules and determine whether a conflict of interest relevant to the subject at hand exists<sup>18</sup>.

If you decline to complete a DOI form, you shall not be allowed to participate in any activities of the IAP. Personal data shall be collected, processed and published by the Commission in accordance with Regulation (EC) No 45/2001.

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<sup>14</sup> C(2016) 3301, Article 2.1.

<sup>15</sup> Idem, Article 3.

<sup>16</sup> Idem, Article 7.2 (a).

<sup>17</sup> Idem, Article 11.8.

<sup>18</sup> Idem, Article 11.

## Annex II

### DECLARATION CONCERNING CONFIDENTIALITY

**Independent Advisory Panel (IAP) assisting Member States and the Commission in determining whether tobacco products have a characterising flavour**

Name: | |

Position: Member of the IAP

Other (e.g. observer, external expert)

If other, please specify role: | |

I hereby declare that:

1. I am aware of my obligation to respect confidentiality. I know that I am obliged not to divulge information acquired as a result of the work of the IAP. I shall also respect the confidential nature of the deliberations and opinions expressed by members of the Panel or experts consulted during discussions. I undertake not to disclose such information even after my participation in the work of the IAP has ceased. I am aware of the Commission's security rules for protecting European Union classified information and sensitive non-classified information, as laid down in Commission Decisions (EU, Euratom) 2015/443<sup>19</sup> and 2015/444<sup>20</sup>.
2. Should I, the undersigned, receive confidential information or restricted information in the course and context of my duties for the IAP, it shall be treated under conditions of strict confidentiality, be used exclusively for the purpose for which it was made available to me and it shall not be divulged to any third party.

The above implies that I, the undersigned:

- will not at any point divulge, publish or otherwise make available to any third party information received from the IAP, without prior written consent of the IAP and its Secretariat, including after completion of the event or assignment involved in with the IAP. The duty of confidentiality exists vis-à-vis any third party, including employees, employers or affiliates or the general public;
- will not use information received from the IAP for a personal benefit or that of any third party;
- will ensure safe storage of the confidential information and restricted information, applying appropriate security measures if the information is managed electronically and not retain the information for longer than needed for the completion of the assignment or event with the IAP.

Done at: | | Date: | |

Signature: .....

<sup>19</sup> [Commission Decision \(EU, Euratom\) 2015/443 of 13 March 2015 on Security in the Commission \(OJ L 72, 17.3.2015, p. 41\).](#)

<sup>20</sup> [Commission Decision \(EU, Euratom\) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information \(OJ L 72, 17.3.2015, p. 53\).](#)

## Annex IIIa

### DECLARATION OF COMMITMENT

**Independent Advisory Panel (IAP) assisting Member States and the Commission in determining whether tobacco products have a characterising flavour**

*Version for members*

Name: | |

#### **1. Commitment**

While contributing to the activities of the IAP, I, the undersigned, shall:

- Act independently in the public interest and make complete declarations of any direct or indirect interests that might be considered prejudicial to my independence;
- Attend meetings regularly and contribute actively to the work of the IAP;
- Respect the Commission internal security policy and measure made available to me;
- Always set an exemplary conduct in all activities linked to the IAP;
- Comply with the IAP's rules on Conflict of Interests and independence;
- As far as applicable, comply with the rules on expert's reimbursement of travel expenses and payment of allowances and indemnities in place in the Commission;
- Read and understand the way personal data are processed as detailed in point 2 of the present Declaration;
- Ensure appropriate use of publications provided to the IAP and respect copyrights as explained in point 3 of the present Declaration;
- Refer any requests from media, stakeholders or the general public on a matter that falls within the remit of the IAP to the Secretariat of the IAP;
- Seek prior consent from the Secretariat of the IAP before communicating with media, stakeholders or the general public on a matter that falls within the remit of the IAP;
- Inform the Commission or the IAP immediately in case I am approached by any third party concerning matters dealt with by the IAP;
- When communicating with media, stakeholders or the general public on a matter that falls within the remit of the IAP always inform the Secretariat of the IAP.



## Annex IIIb

### DECLARATION OF COMMITMENT

**Independent Advisory Panel (IAP) assisting Member States and the Commission in determining whether tobacco products have a characterising flavour**

*Version for independent external experts*

Name: | |

#### **1. Commitment**

While contributing to the activities of the IAP, I, the undersigned, shall:

- Act independently in the public interest and make complete declarations of any direct or indirect interests that might be considered prejudicial to my independence;
- Respect the Commission internal security policy and measure made available to me;
- Always set an exemplary conduct in all activities linked to the IAP;
- Comply with the IAP's rules on Conflict of Interests and independence;
- As far as applicable, comply with the rules on expert's reimbursement of travel expenses and payment of allowances and indemnities in place in the Commission;
- Read and understand the way personal data are processed as detailed in point 2 of the present Declaration;
- Ensure appropriate use of publications provided to the IAP and respect copyrights as explained in point 3 of the present Declaration;
- Refer any requests from media, stakeholders or the general public on a matter that falls within the remit of the IAP to the Secretariat of the IAP;
- Seek prior consent from the Secretariat of the IAP before communicating with media, stakeholders or the general public on a matter that falls within the remit of the IAP;
- Inform the Commission or the IAP immediately in case I am approached by any third party concerning matters dealt with by the IAP;
- When communicating with media, stakeholders or the general public on a matter that falls within the remit of the IAP always inform the Secretariat of the IAP.

