



Council of the
European Union

180086/EU XXVII. GP
Eingelangt am 12/04/24

Brussels, 12 April 2024
(OR. en)

Interinstitutional File:
2023/0313(NLE)

12851/1/23
REV 1

SAN 510
FISC 182
UD 182

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	3 April 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 514 final/ 2
Subject:	Proposal for a COUNCIL DECISION on the positions to be taken on behalf of the European Union at the tenth session of the Conference of the Parties to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC)

Delegations will find attached document COM(2023) 514 final/2. This is a downgraded version of the Commission proposal (12851/23) issued on 11 September 2023.

Encl.: COM(2023) 514 final/ 2



EUROPEAN
COMMISSION

Brussels, 3.4.2024

COM(2023) 514 final/ 2

DOWNGRADED on 1.4.2024

2023/0313 (NLE)

Proposal for a

COUNCIL DECISION

**on the positions to be taken on behalf of the European Union at the tenth session of the
Conference of the Parties to the World Health Organization (WHO) Framework
Convention on Tobacco Control (FCTC)**

EXPLANATORY MEMORANDUM

1. SUBJECT MATTER OF THE PROPOSAL

This proposal concerns the decision establishing the positions to be taken on the Union's behalf at the tenth session of the Conference of the Parties to the World Health Organization Framework Convention on Tobacco Control, which takes place in Panama City from 20 November to 25 November 2023.

2. CONTEXT OF THE PROPOSAL

2.1. WHO Framework Convention on Tobacco Control

The World Health Organization Framework Convention on Tobacco Control ('FCTC' or 'the Convention') aims to protect present and future generations from consequences of tobacco use by providing a framework for tobacco control measures to be implemented by the Parties at national, regional and international levels in order to reduce the prevalence of tobacco use and exposure to tobacco smoke. It entered into force on 27 February 2005.

The Union as well as all its Member States are Parties to the Convention.¹

2.2. Conference of the Parties

The Conference of the Parties ('COP') is a body established by the Convention whose task is to keep the implementation of the Convention under regular review and take the decisions necessary to promote its effective implementation. The COP may adopt protocols, annexes and amendments to the Convention. To this end, the COP, among others, promotes the exchange of information and the development and refinement of methodologies for research and the collection of data in the field of tobacco control, the evaluation of strategies, plans and programmes, as well as policies, legislation and other measures by adopting decisions with guidelines and recommendations that are developed through a wide consultative and intergovernmental process and are generally acknowledged by the Parties as a valuable and authoritative tool in the implementation of the Convention. The COP also adopts regular reports on the implementation of the Convention.

The regular sessions of the COP are held every 2 years. According to the Rules of Procedure of the COP, the Convention Secretariat (also the 'Secretariat') should submit to the Parties the provisional agenda together with other supporting documents (often containing draft decisions) for each agenda item at least 60 days before the start of the COP.² At the COP, decisions on budgetary and financial matters are taken by consensus. For all other decisions every effort should be made to reach agreement by consensus. As a last resort, decisions on substantive matters are taken by a three fourths majority vote of the Parties present and voting, and decisions on procedural matters should be taken by a majority vote of the Parties present and voting.³

¹ Council Decision of 2 June 2004 (2004/513/EC) concerning the conclusion of the WHO Framework Convention on Tobacco Control, OJ L 213, 15.6.2004, p. 8.

² Rule 8 of the Rules of Procedure of the Conference of the Parties (FCTC).

³ Rule 50 of the Rules of Procedure of the Conference of the Parties (FCTC).

2.3. Envisaged acts at the tenth session of the Conference of the Parties

In November 2023, at its tenth session ('COP10'), the COP is expected to hold substantive discussions and adopt decisions in particular on items deferred from the ninth session of the COP, due to its virtual format during the COVID-19 pandemic.

Those deferred items include decisions on the implementation of Articles 9 and 10 of the FCTC on the regulation of contents and disclosure of tobacco products; on guidelines and recommendations on the implementation of Article 13 of the FCTC regarding cross-border tobacco advertising, promotion and sponsorship and the depiction in the entertainment media; and on novel and emerging tobacco products.

It is also expected that a possible amendment to the Rules of Procedure of the COP will be discussed and decided upon.

COP10 is furthermore expected to discuss and adopt decisions in relation to Article 2.1 of the FCTC on forward-looking tobacco control measures; in relation to Article 19 of the FCTC on liability; on improving the reporting system of the FCTC; on the implementation review mechanism; and on the contribution of the FCTC to the promotion and fulfilment of human rights. Furthermore, under budgetary and institutional matters, the COP10 is expected to adopt decisions on the proposed workplan and budget for the financial period 2024-2025; on the FCTC investment fund: on payment of assessed contributions and measures to reduce Parties in arrears; on review of accreditation of nongovernmental organizations with the status of observer to the COP; on strengthening synergies between the Conference of the Parties and the World Health Assembly; and on the appointment of the Head of the Secretariat.

3. POSITIONS TO BE TAKEN ON THE UNION'S BEHALF

The COP is expected to take certain decisions that qualify as "decisions having legal effects" within the meaning of Article 218(9) of the Treaty on the Functioning of the European Union (TFEU). In addition, the COP is expected to take other decisions that do not have legal effects. For reasons of procedural efficiency, the current proposal contains the positions to be taken on the Union's behalf as regards both types of decisions.

The deferral of decisions from the ninth to the tenth session of the COP allows to already present elaborated Union positions on many items. This is because the related supporting documents were distributed before the ninth session of the COP. Conversely, for items where supporting documents have not yet been distributed, a more general line to take is proposed.

Concerning the implementation of Articles 9 and 10 of the FCTC on regulation of contents and disclosure of tobacco products, and in view of the need to continuously monitor the contents and emissions of (new) tobacco products, the Union should agree to continue with the work at the level of an expert group, and to keep the mandate of the related working group suspended.

Regarding cross-border tobacco advertising, promotion and sponsorship, in line with the earlier positions of the Union on this topic to support a full implementation of Article 13 of the FCTC, it is appropriate to approve the specific guidelines if they properly fulfil the mandate given by the eighth session of the COP.

On novel and emerging tobacco products, and in view of the worryingly fast-growing market of novel and emerging tobacco products and their effects on human health, it is appropriate to underline the importance of continuously monitoring the use of these products and to request the Secretariat and the WHO to follow up on their reports.

The Union should also acknowledge the need to cooperate internationally to address the contribution of the FCTC to the promotion and fulfilment of human rights and agree to work at the international level with a view to discussing forward looking tobacco control measures in accordance with Article 2.1 of the FCTC.

It is also appropriate that the Union agrees to cooperate and work together with all Parties to explore the possible link between Article 19 and Article 5.3 of the FCTC regarding the liability of the tobacco industry.

Given the importance of the reporting system of the FCTC for enabling the Parties to learn from each other's experience in implementing the FCTC, the Union should support further development of this system.

Concerning the Implementation Review Mechanism, it is appropriate that the Union agrees with its establishment, while drawing attention to the lack of full implementation of Article 5.3 and Article 6 of the FCTC.

The Union should also support the adoption of the proposed workplan and budget for the financial period 2024-2025 and suggest exploring potential savings to avoid future increases in the Assessed Contributions.

In line with the previous positions of the Union regarding the FCTC Investment Fund,⁴ the Union should support the proposed legal and administrative arrangements for the Fund, as appropriate in the light of the basic principles highlighted by the Union and the Member States at the ninth session of the COP.

Based on the analysis of their reports, the Union should support that the observer status to the COP of 26 nongovernmental organisations is maintained.

With regard to the expected discussion on a possible amendments of the Rules of Procedure of the COP, the Union should support amendments to simplify the work at the COP, to arrange for virtual sessions of the COP, and to define more clearly the participation of the Bureau of the Meeting of the Parties (MOP) in the appointment of the Head of the Convention Secretariat, as well as the amendment providing for the possibility of designating an acting Head of the Secretariat, when required. In addition, the Union should propose to increase the time period for the Secretariat to distribute the official conference documents at least 120 days before the start of the COP, instead of the present 60 days. This will support the proper preparation of the Union positions in the future.

To strengthen synergies between the COP and the World Health Assembly, the Union should welcome the opportunity to be updated on the resolutions taken by the World Health Assembly of relevance for the implementation of the FCTC.

Regarding the appointment of the Head of the Convention Secretariat, the Union should support the improvement of the process for the selection and appointment of the Head of the Secretariat,⁵ notably to simplify the process for a single renewal of the term, while respecting the objective performance criteria. In this context, the

⁴ Council document st13022/21 for positions at the ninth session of the COP.

⁵ Procedure has been established by decisions FCTC/COP8(8) and FCTC/MOP1(12).

Union should also support the improvement of the criteria for the selection of the candidates for the position of Head of the Secretariat, which should also include the aspects related to the Protocol to the FCTC.

These positions may need to be further adjusted during the on-the-spot coordination at the tenth session of the COP in the light of the positions of the other Parties and related developments at that COP.

4. LEGAL BASIS

4.1. Procedural legal basis

4.1.1. Principles

Article 218(9) TFEU provides for the adoption of decisions establishing ‘the positions to be adopted on the Union’s behalf in a body set up by an agreement, when that body is called upon to adopt acts having legal effects, with the exception of acts supplementing or amending the institutional framework of the agreement.’

The concept of ‘*acts having legal effects*’ includes acts that have legal effects by virtue of the rules of international law governing the body in question. It also includes instruments that do not have a binding effect under international law, but that are ‘*capable of decisively influencing the content of the legislation adopted by the EU legislature*’⁶.

4.1.2. Application to the present case

The COP is a body set up by an agreement, namely the WHO Framework Convention on Tobacco Control.

Certain acts that the tenth session of the COP is expected to adopt constitute acts having legal effects since they are binding or capable of decisively influencing the content of Union legislation, in particular Directive 2014/40/EU of the European Parliament and of the Council⁷ and Directive 2003/33/EC of the European Parliament and of the Council⁸.

The envisaged decision related to tobacco advertising, promotion and sponsorship, including the adoption of supplemental, specific FCTC Guidelines on Article 13 FCTC, constitutes an act with legal effect because they are capable to decisively influence the content of Union legislation on tobacco control.

Article 1 of Directive 2014/40/EU clearly specifies that one of the objectives of the Directive is to “*meet the obligations of the Union under the WHO Framework Convention for Tobacco Control (‘FCTC’)*”.

Moreover, recital 7 further clarifies that “*legislative action at Union level is also necessary in order to implement the WHO Framework Convention on Tobacco Control (‘FCTC’) of May 2003, the provisions of which are binding on the Union*”.

⁶ Judgment of 7 October 2014 in case C-399/12, *Germany v Council*, ECLI:EU:C:2014:2258, paragraphs 61 to 64.

⁷ 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, OJ L 127, 29.4.2014, p. 1.

⁸ Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products, OJ L 152, 20.6.2003, p. 16.

and its Member States. The FCTC provisions on the regulation of the contents of tobacco products, the regulation of tobacco product disclosures, the packaging and labelling of tobacco products, advertising and illicit trade in tobacco products are particularly relevant. The Parties to the FCTC, including the Union and its Member States, adopted a set of guidelines for the implementation of FCTC provisions by consensus during various Conferences”.

Further, as recitals 15 and 24 of Directive 2014/40/EU indicate, several provisions of the Directive were ‘called for’ by FCTC Guidelines.⁹ Moreover, Article 3(4) and Article 4(5) of Directive 2014/40/EU provide that the Commission ‘shall adopt delegated acts to integrate standards agreed by the parties to the FCTC’.¹⁰

With regard to the FCTC Guidelines, Directive 2014/40/EU thus indicates that they are accepted as a source of law by the Union institutions, decisively influencing the content of Union legislation in the area of tobacco control. The fact that FCTC Guidelines are capable of having a decisive influence on the content of the Union law also stems from the fact that FCTC Guidelines relate to the implementation of certain provisions of the Convention, which are binding upon all Parties to FCTC. Therefore, also in the future, the Union institutions will take into account the COP decisions containing Guidelines and policy recommendations when developing further legislation on tobacco and related products, notably in the upcoming revision of both Directives 2014/40/EU and 2003/33/EC, as announced in the Europe’s Beating Cancer Plan. More specifically, with regard to the envisaged specific FCTC Guidelines on Article 13 of the FCTC, the Union legislators will have to take them into account particularly when addressing new and innovative marketing strategies, such as on social media platforms and other digital media communication platforms, as well as tobacco depictions in increasingly various entertainment media.

The envisaged decision related to possible amendments to the Rules of Procedure of the COP constitutes an act with legal effect due to the binding nature of the Rules of Procedure, as well as due to the fact that the COP is a body with decision-making powers under the FCTC¹¹. Modifications of the Rules of Procedure of the COP would bind the FCTC Parties (and therefore also the Union) in a way equivalent to the main Agreement.

The envisaged decision related to the amendment of the procedure for the appointment of the Head of the Secretariat also constitutes a decision having legal effects. First, the Head of the Secretariat’s functions go beyond merely administrative functions and also include influence on the policy and substantive

⁹ Recital 15 recognises that “the FCTC guidelines in relation to the regulation of the contents of tobacco products and regulation of tobacco product disclosures call in particular for the removal of ingredients that increase palatability, create the impression that tobacco products have health benefits, are associated with energy and vitality or have colouring properties”. While recital 24 indicates that “adaptation of the provisions on labelling is also necessary to align the rules that apply at Union level to international developments. For example, the FCTC guidelines on the packaging and labelling of tobacco products call for large picture warnings on both principal display areas, mandatory cessation information and strict rules on misleading information.”

¹⁰ Article 3(4) provides that “the Commission shall adopt delegated acts “to integrate standards agreed by the parties to the FCTC or by the WHO relating to maximum emission levels for emissions from cigarettes other than the emissions referred to in paragraph 1 and for emissions from tobacco products other than cigarettes into Union law”. While in Article 4(5) it is provided that the Commission shall adopt delegated acts “to integrate standards agreed by the parties to the FCTC or by the WHO for measurement methods into Union law”.

¹¹ See section 2.2. above.

work of the FCTC. As a result, the appointment of the Head of Secretariat would constitute a decision having legal effects within the meaning of Article 218(9) TFEU. This conclusion then also extends to COP decisions amending the appointment procedure for the Head of Secretariat, which constitute decisions of an organisational nature impacting the decision-making process of decisions having legal effects (i.e. relating to the appointment of the Head of Secretariat).

The envisaged acts do not supplement or amend the institutional framework of the Agreement.

As several of the decisions expected to be adopted at the tenth session of the COP are considered to have legal effects, the appropriate procedural legal basis for the proposed Council decision establishing Union positions at the tenth session of the COP is Article 218(9) TFEU.

For reasons of procedural efficiency, the current proposal for a Council decision contains Union positions on all expected substantive discussions and decisions to be taken at the tenth session of the COP, regardless of whether they have legal effects or not.

4.2. Substantive legal basis

4.2.1. Principles

The substantive legal basis for a decision under Article 218(9) TFEU depends primarily on the objective and content of the envisaged act in terms of which the position is to be taken on the Union's behalf. If the envisaged act pursues two aims or has two components and if one of those aims or components is identifiable as the main one, whereas the other is merely incidental, the decision under Article 218(9) TFEU must be founded on a single substantive legal basis, namely that required by the main or predominant aim or component.

4.2.2. Application to the present case

The main objective and content of the envisaged act relate to the internal market, in particular the free movement of goods and services, taking as a base a high level of protection of human health, especially for young people. Therefore, the substantive legal basis of the proposed decision is Article 114 TFEU.

4.3. Conclusion

The legal basis of the proposed decision should be Article 114 TFEU, in conjunction with Article 218(9) TFEU.

Proposal for a

COUNCIL DECISION

on the positions to be taken on behalf of the European Union at the tenth session of the Conference of the Parties to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular

Article 114, in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Framework Convention on Tobacco Control ('FCTC') of the World Health Organization was concluded by the Union pursuant to Council Decision 2004/513/EC¹ and entered into force on 27 February 2005.
- (2) Pursuant to Article 23(5) of the FCTC, the Conference of the Parties ('COP') may take the decisions necessary to promote the effective implementation of the FCTC.
- (3) The objective of Directive 2014/40/EU² is to approximate the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products in order to ensure, among others, that the Union meets its obligations under the FCTC. The objective of Directive 2003/33/EC³ is to approximate the laws, regulations and administrative provisions of the Member States relating to advertising of tobacco products and their promotion.
- (4) At its tenth session from 20 to 25 November 2023, the COP is expected to adopt certain acts having legal effects, including an act that is capable of decisively influencing the content of Union law related to tobacco control. Therefore, it is appropriate to establish the positions to be taken on the Union's behalf at the tenth session of the COP pursuant to Article 218(9) TFEU.
- (5) As it is important to continuously monitor the contents and emissions of tobacco products, in particular new ones, it is appropriate to agree to continue with the work on this subject at the level of an expert group and to keep the mandate of the related working group suspended.

¹ Council Decision 2004/513/EC of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control, OJ L 213, 15.6.2004, p. 8.

² 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, OJ L 127, 29.4.2014, p. 1.

³ Directive 2003/33/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products, OJ L 152, 20.6.2003, p. 16.

- (6) In line with the Union's position expressed at the eighth session of the COP, the Union should support the adoption of the new proposed guidelines on tobacco advertising, promotion and sponsorship and the depiction of tobacco in the entertainment media, in line with the Union's overall objective to reduce the consumption of tobacco products.
- (7) In view of the worryingly fast-growing market of novel and emerging tobacco products and their effects on human health, it is appropriate to underline the importance of continuously monitoring the use of these products.
- (8) The Union should acknowledge the need to cooperate internationally to address the contribution of the FCTC to the promotion and fulfilment of human rights and agree to cooperate at the international level with a view to identifying and discussing forward looking tobacco control measures. The Union should also agree to work together with all Parties regarding the liability for tobacco harm.
- (9) The Union should support the further development of the FCTC reporting system and agree to the establishment of the FCTC Implementation Review Mechanism.
- (10) The Union should support the proposed legal and administrative arrangements for the FCTC Investment Fund, as well as the adoption of the proposed workplan and budget for the financial period 2024-2025 and suggest exploring potential savings to avoid future increases in the Assessed Contributions.
- (11) The Union should support that the observer status to the COP of 26 nongovernmental organisations is maintained and welcome the opportunity to be updated on the resolutions of relevance for the FCTC taken by the World Health Assembly.
- (12) In order to enable appropriate preparation and representation of the Union positions, the Union should propose an amendment to the Rules of Procedure of the COP to require the Secretariat to distribute the official conference documents at least 120 days before each COP.
- (13) For the purpose of simplifying the work at the COP and to arrange for virtual sessions of the COP, as well as to provide for the possibility of designating an acting Head of the Secretariat, the Union should also support the amendments to the Rules of Procedure of the COP proposed with these aims.
- (14) The Union should support the improvement of the process for the selection and appointment of the Head of the Convention Secretariat, notably to simplify a single renewal of the term of office, while respecting the objective performance criteria,

HAS ADOPTED THIS DECISION:

Article 1

The positions to be taken on the Union's behalf at the tenth session of the Conference of the Parties to the World Health Organization Framework Convention on Tobacco Control shall be in accordance with the Annex to this Decision.

Article 2

Adjustment of the positions referred to in Article 1 may be agreed to, in the light of developments at the tenth session of the Conference of the Parties to the World Health Organization Framework Convention on Tobacco Control, by the representatives of the Union, in consultation with Member States during on-the-spot coordination meetings, without a further decision of the Council.

Article 3

This Decision is addressed to the Commission.

Done at Brussels,

*For the Council
The President*