

Framework Convention on Tobacco Control  
Tenth Conference of the Parties (COP-10)  
**Commentary on the Annotated Agenda**

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<p>CONFERENCE OF THE PARTIES TO THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL</p>	<p><a href="#">FCTC/COP/10/1(annotated)</a> 10 July 2023</p>	<p>Comments by: <b>Clive Bates</b> <b>Counterfactual Consulting</b> <b>London</b></p>	<p>This document will be updated. Access the latest version here: <a href="#">FCTC COP-10 agenda commentary</a></p>
<p><b>Tenth session</b> <b>Panama City, Panama, 20–25 November 2023</b> <b>Provisional agenda item 1.1</b></p>		<p><b>Disclosure:</b> I have no conflicts of interest or issues arising under Article 5.3. I was part of an NGO heavily involved in the formation of the FCTC in 1999-2003 and my purpose is to secure the best health and welfare outcomes from the FCTC.</p>	
<p><b>Provisional agenda annotated<sup>1</sup></b></p>		<p><b>This commentary is to assist delegates, observers, journalists and all other interested stakeholders in their engagement in the FCTC COP-10 meeting.</b></p>	
<p><b>1 Opening of the session*</b></p>			
<p>1.1 Adoption of the agenda and organization of work</p> <p><i>Documents <a href="#">FCTC/COP/10/1</a> and <a href="#">FCTC/COP/10/1(annotated)</a></i></p> <p>The provisional agenda was prepared by the Convention Secretariat in consultation with the Bureau of the Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC), in accordance with Rule 6 of the <a href="#">Rules of Procedure of the COP</a>.</p> <p>In considering the method and organization of its work, the COP may wish to keep the existing approach by establishing two committees, A and B, working in parallel. Committee A could be entrusted with work on treaty instruments and technical matters under provisional agenda item 6, and reporting, implementation assistance and international cooperation under provisional agenda item 7. Committee B could work on budgetary and institutional matters under provisional agenda item 8. Provisional agenda items 1–5 and 9–12 would be considered in the plenary session.</p> <p>The COP is invited to review and consider adopting the provisional agenda and to decide on the organization of work of the session.</p> <p><i>1. At the recommendation of the Bureau of the COP, it is proposed that the agenda items marked with an asterisk be webcast.</i></p>		<p><b>Absence of strategy.</b> The agenda lacks any searching discussion of <b>strategy</b> – how best to meet the <a href="#">SDG 3.4 objectives</a> to reduce NCDs by one-third by 2030, a target that is likely to be missed.</p> <p>The key to reducing NCDs is to <i>reduce smoking</i> in adults as rapidly and deeply as possible – switching from high-risk to low-risk nicotine products is a good way to achieve this, yet most of the agenda and papers are devoted to opposing or obstructing this strategy without a credible alternative. See these commentaries in The Lancet:</p> <p>Beaglehole, R., &amp; Bonita, R. (2024). Harnessing tobacco harm reduction. <i>The Lancet</i>, 0(0). <a href="https://doi.org/10.1016/S0140-6736(24)00140-5">https://doi.org/10.1016/S0140-6736(24)00140-5</a></p> <p>Beaglehole, R., Bates, C., Youdan, B., &amp; Bonita, R. (2019). Nicotine without smoke: fighting the tobacco epidemic with harm reduction. <i>The Lancet</i>, 394(10200), 718–720. <a href="https://doi.org/10.1016/S0140-6736(19)31884-7">https://doi.org/10.1016/S0140-6736(19)31884-7</a></p> <p><b>A complete rethink is necessary to bring tobacco harm reduction (see FCTC Article 1d) into the FCTC.</b></p> <p><b>Webcasting and public access.</b> There is no reason to limit the webcasting of the COP meeting to only those agenda items with an asterisk (excluding most substantive discussion). <u>The whole COP meeting</u> should be publicly accessible via webcast, and the positions adopted by delegates and observers should be open for all to see.</p>	

<p>1.3 Credentials of participants</p> <p>Document <a href="#">FCTC/COP/10/2</a></p> <p>In accordance with Rule 18 of the Rules of Procedure of the COP, credentials shall be submitted to the Convention Secretariat if possible no later than 24 hours after the opening of the session. In accordance with Rule 19 of the <a href="#">Rules of Procedure of the COP</a>, the Bureau of the COP, with the assistance of the Convention Secretariat, shall examine the credentials and report thereon to the COP in document FCTC/COP/10/2, which will be prepared during the session. Pursuant to Rule 20 of the Rules of Procedure of the COP, representatives shall be entitled to participate provisionally in the session, pending a decision by the COP to accept their credentials.</p>	<p>Parties and observers are, of course, entitled to send whoever they wish to represent them at COP. However, the COP would benefit from the inclusion of a range of skills and experience that are often underrepresented, especially in practical and efficient regulation, economic insights into regulation and taxation, youth risk behaviours and the consumers' perspective. The art of policymaking in this field is about understanding markets, consumers and suppliers and how they respond to regulation.</p>
<p><b>2 Applications for the status of observer to the Conference of the Parties</b></p> <p>Document <a href="#">FCTC/COP/10/3</a></p> <p>The COP is invited to review the applications for the status of observer, in accordance with Rules 30 and 31 of the <a href="#">Rules of Procedure of the COP</a>. Document FCTC/COP/10/3 contains, in its annex, a draft decision for consideration by the COP.</p>	<p>The so-called civil society representatives with observer status at the COP are not necessarily neutral guardians of the public interest. They are carefully selected activists, chosen for their allegiance to the WHO and almost always funded by foreign interests. Only 26 hand-picked NGOs are currently accredited to the FCTC. This is in marked contrast to the approach taken by the UNFCCC on climate change, which welcomes all perspectives and interests in this complex issue. See comparison: <a href="#">The WHO tobacco control treaty meetings are closed bubbles of cultivated groupthink – a comparison with the UN climate change treaty</a></p> <p>The problem with the selection process used by the FCTC Secretariat and Bureau is that it deliberately filters out any person or organisation that might be critical of the policy proposals or conduct of the institutions involved by specifying that only organisations “whose aims and activities are in conformity with the spirit, purpose and principles of the Convention” and then requiring reporting on what they have done to further the treaty (see <a href="#">FCTC/COP/10/20</a>).</p> <p>It also unfairly excludes small organisations and individuals not part of the umbrella group, the Global Alliance for Tobacco Control (formerly Framework Convention Alliance), which has pro-WHO membership criteria and only allows <i>transnational</i> NGOs to join unless they are part of this alliance.</p> <p>The effect is to create a bubble, an echo chamber of uncritical applause and a lack of diversity and experience in and around the COP meetings, supposedly done to prevent “tobacco industry interference” while overlooking the presence of tobacco industry interests present on several delegations. The small consumer organisations are entirely excluded, yet they are the most directly affected and at-risk stakeholder group.</p>

<p><b>3 High-level segment*</b></p>	<p>Some scepticism is required as WHO celebrates its achievements. There is significant capture of WHO through opaque project funding and voluntary contributions. The private foundation of billionaire Michael Bloomberg, Bloomberg Philanthropies, funds significant WHO work products such as the <a href="#">WHO report on the global tobacco epidemic</a> and draws on contributions from organisations funded by Bloomberg (see Bloomberg’s foreword and page xxii for acknowledgement). Mr Bloomberg has shaped WHO’s approach to track his own favoured suite of tobacco control measures, MPOWER. He has spent his funds aggressively to suppress the tobacco harm reduction strategy.</p>
<p>The Bureau of the COP has identified the opportunity to raise the visibility of the WHO FCTC this year, which marks the 20th anniversary of the adoption of the treaty. The high-level segment will promote a discussion and examine initiatives, best practices and potential avenues for cooperation, including intersectoral collaboration, in the area of tobacco control.</p>	<p>Any speakers at this event will be hand-picked to avoid controversy and most definitely not to challenge WHO’s “abstinence only” or prohibition agenda. When listening to such speakers, delegates should consider the general questions set out in my <a href="#">Evidence Brief 4: Policies for Novel and Emerging Products</a>.</p>
<p><b>4 Invited speaker(s), if any*</b></p>	<p>High-level speakers will share their experience and insights in relation to achievements since the adoption of the WHO FCTC and opportunities to accelerate implementation of the treaty.</p>
<p><b>5 Global progress in implementation of the WHO FCTC, followed by a general debate*</b></p> <p>Document <a href="#">FCTC/COP/10/4</a></p> <p>The Head of the Convention Secretariat will provide an overview of global progress in implementation of the WHO FCTC. The COP is invited to note document FCTC/COP/10/4. A general debate on the theme “Together, promoting healthier lives” will follow the introduction of this agenda item.</p> <p>Delegations wishing to speak in the general debate are invited to notify the Convention Secretariat as soon as possible by email with the subject line “Request for general debate statement” to cop10-mop3@who.int. Delegations are encouraged to opt for group or regional statements, in lieu of individual statements.</p>	<p>The paper finds the FCTC has not been implemented as rapidly as expected (para 27).</p> <p><i>“Even though the current analysis revealed some positive developments, the level of acceleration in implementation of the WHO FCTC that was anticipated through uptake of the Global Strategy has not been achieved.”</i></p> <p>However, this progress report focuses only on <i>measures</i>, not on <i>outcomes</i>. Any assessment of the FCTC should be based on outcomes (e.g. smoking prevalence) and be assessed relative to a meaningful counterfactual (i.e. what would have happened without the FCTC). Many countries experienced a significant decline in smoking before the FCTC came into effect. Many countries would introduce tobacco control measures without the FCTC. Non-parties such as the United States offer a helpful control. According to <a href="#">WHO data</a>, US smoking prevalence declined from 30% to 21.9% between 2005 and 2020. Global smoking prevalence declined from 23.7% to 17.0%, the same proportionate decline (27%). Academics (<a href="#">Hoffman et al. 2019</a>) have studied the impact of the FCTC, taking these factors into account and concluded:</p> <p><i>This study finds no evidence to indicate that global progress in reducing cigarette consumption has been accelerated by the FCTC treaty mechanism.</i></p> <p>There is also a more disturbing question now: is the effect of the FCTC and WHO slowing the decline of smoking through its campaign against non-combustible alternatives to smoking that smokers can switch to (vaping, heated tobacco, etc)? In evaluating the FCTC, we must assess whether the FCTC is doing more harm than good.</p>

6 Treaty instruments and technical matters	Section 6 of the agenda and related papers represent the “meat” of the COP proceedings, and there is much here for government officials to be sceptical about. The proposed policies are crude and lack any evidential basis, ignoring likely unintended consequences and trade-offs.
6.1 Implementation of Articles 9 and 10 of the WHO FCTC (Regulation of contents and disclosure of tobacco products): reports by the Bureau, by the Expert Group and by WHO	The three papers address the implementation of Article 9 (regulation of contents) and Article 10 (regulation of product disclosures) of the FCTC with reports from the Bureau (10/5), and Expert Group (10/6) and the WHO (10/7).
Documents <a href="#">FCTC/COP/10/5</a> , <a href="#">FCTC/COP/10/6</a> and <a href="#">FCTC/COP/10/7</a>	<b>The Bureau paper (10/5)</b>
<p>In accordance with decision <a href="#">FCTC/COP9(2)</a>, document FCTC/COP/10/5 is submitted to the COP as one of the items that were deferred from the Ninth session of the COP (COP9). The document contains a report with the recommendations of the Bureau with respect to the future work of the Working Group on the implementation of <a href="#">Articles 9 and 10 of the WHO FCTC</a>, in accordance with decision FCTC/COP8(21). The COP is invited to note document FCTC/COP/10/5 and consider adopting the draft decision annexed to it.</p>	<p>This asks delegates to remove their own experts from work on Articles 9 &amp; 10 and to hand responsibility to an appointed “expert group”. This would be selected by WHO and the Secretariat rather than Parties and configured to press WHO’s agenda despite clear divisions of opinion (para 9). WHO already has an expert group, the <a href="#">WHO Study Group on Tobacco Product Regulation (TobReg)</a>. Parties should not allow themselves to be excluded by experts chosen by WHO’s bureaucrats.</p>
<p>In accordance with decision <a href="#">FCTC/COP9(2)</a>, document FCTC/COP/10/6 is resubmitted to the COP without change from document <a href="#">FCTC/COP/9/6</a>. It provides an overview of the work, key observations and recommendations of the Expert Group established to examine the reasons for low implementation of Articles 9 and 10 of the Convention, pursuant to decision <a href="#">FCTC/COP8(21)</a>. The COP is invited to note document FCTC/COP/10/6 and provide further guidance.</p>	<p><b>The Expert Group paper (10/6)</b></p> <p>This just explains the difficulties member states have reported in implementing Articles 9 &amp; 10: (a) Understanding requirements under Articles 9 and 10; (b) Technical capacity and human resources; (c) Financial needs; (d) Collaboration between Secretariat, WHO and Parties; (e) International collaboration.</p> <p><u>These are not the most critical issues with Articles 9 &amp; 10:</u> the real challenge is finding a <b>clear regulatory purpose</b>, i.e. what is the intended public health outcome of these articles? How can it be achieved once this is clear (which it is not)? The purpose should be to encourage consumers to migrate from high-risk to low-risk products and to know the difference based on reliable information underpinned by safety standards.</p>
<p>In accordance with decision FCTC/COP9(2), document FCTC/COP/10/7 is an updated version of document <a href="#">FCTC/COP/9/8</a>. It reports on progress made by the World Health Organization (WHO) in work related to tobacco product regulation, in pursuance of implementation of Articles 9 and 10 of the WHO FCTC. The COP is invited to note document FCTC/COP/10/7 and provide further guidance.</p>	<p><b>The WHO paper (10/7)</b></p> <p>This paper is highly problematic and contains multiple misleading statements and advice that would do more harm than good if acted upon.</p>
	<p>WHO appropriately starts the paper by highlighting 8 million deaths annually. According to the <a href="#">Global Burden of Disease study</a>, these deaths arise almost entirely (99.4%) from <u>smoking or secondhand smoke</u>. That should set up the case to address <i>smoking</i> by encouraging people to switch to much safer, smoke-free tobacco and nicotine products. But WHO ignores that opportunity and improperly casts it as a threat.</p> <p><b>The focus of the paper 10/7.</b> Much of the WHO paper discusses ENDS and e-liquids (6-29), nicotine pouches (53-59), disposable ENDS (60-64), and e-liquid flavours (65-</p>

67). Hardly any attention is paid to *smoking*, the primary cause of disease. These products are not tobacco products and fall outside the scope of Articles 9 and 10 of the FCTC, which concern *tobacco*. The paper's title is *Progress report on technical matters related to Articles 9 and 10 of the WHO FCTC (Regulation of contents and disclosure of tobacco products, including waterpipe, smokeless tobacco and heated tobacco products)*. This is a case of WHO trying to extend the FCTC by stealth and without negotiation. ENDS may interest delegates, but FCTC Articles 9 & 10 cannot be simply applied to ENDS without renegotiation. In trying to extend the FCTC in this way, WHO is also diminishing focus on what Articles 9 & 10 are meant to be about – reducing the harms attributable to tobacco and, above all, cigarettes.

**Policy recommendations in 10/7.**

**69. ENDS/ENNDS.** WHO starts 69a with an assumption that the default would be to ban these products. WHO has *never* provided a justification or evidence for this policy (banning a much safer product while allowing cigarettes to be available everywhere). Given ENDS are substitutes for cigarettes, we would expect this measure to increase smoking, promote illicit trade in ENDS, and increase harm to health and welfare. WHO calls for bans on sales and marketing of ENDS to children, which I support. But COP must recognise that these products can *divert* young people from becoming smokers, and therefore, they can be beneficial – see, for example, [Sokol et al. High School Seniors Who Used E-Cigarettes May Have Otherwise Been Cigarette Smokers](#). Also, [Selya & Foxon](#) and [Walker et al.](#) show youth vaping *displacing* youth smoking.

WHO claims (69.c) that there is insufficient evidence to show that these products displace smoking at the population level. That is not true. There is a wide range of evidence from randomised controlled trials, observational studies, population trend data, quasi-experimental economic studies, market observers, and user testimony, all showing that ENDS use displaces smoking. Also, we would expect that innovation with new, safer products should displace incumbent dangerous products. See [Evidence brief: ENDS reduces smoking](#). On what basis does WHO claim there is no evidence? What standards of evidence does it apply to its own assertions?

**70. Ban marketing of novel and emerging products.** WHO, as usual, implies the default should be prohibition: “*where countries have not banned the importation, sale and distribution of novel and emerging tobacco products*”. There is no evidence to support this position, and there is plenty to suggest it would do more harm than good. See [The Evil Twins](#) (prohibition and illicit trade). It has yet to explain why banning far safer products than cigarettes while allowing cigarettes to be sold everywhere could ever be a good policy.

Based on the evidence presented in paragraphs 30-34, WHO recommends banning “*all*

	<p><i>commercial marketing of novel and emerging tobacco products, including in social media and through organizations funded by and/or associated with the tobacco industry.”</i> But WHO’s evidence is mainly an unweighted list of marketing tactics. WHO does not evaluate the effect of banning all marketing or consider the alternative of regulating acceptable and unacceptable marketing practices. The effect would be a protection of the incumbent cigarette trade from much safer entrants to the market. Marketing of these smoke-free products is effectively anti-smoking promotion as the companies are trying to win over smokers to their products - and it does not require public spending. Once again, WHO’s proposals fortify the cigarette trade with regulatory barriers to entry for safer products.</p> <p><b>74. Nicotine pouches.</b> WHO provides a regulatory agenda (74.a-d) that effectively defines these products as a threat while ignoring the opportunity to have what is likely to be the safest form of consumer nicotine. It suggests indirectly that pouches should be banned in the European Union: “(c) <i>regulate non-therapeutic nicotine products in the same manner as products of similar appearance, content and use;</i>”. The EU (other than Sweden) bans snus, which looks like nicotine pouches but use tobacco rather than pure nicotine in a synthetic base. Yet this policy has been a disaster in Europe, denying smokers across the Union the opportunity to replicate the success of snus in Scandinavia in reducing smoking and protecting health.</p> <p>The right policy would control marketing and branding themes and placement, limit the total amount of nicotine per pouch to 25-40mg, insist on pharmaceutical-grade ingredients, add warnings and consumer risk information, and ban sales to under-18s.</p> <p><b>75. Disposable ENDS.</b> WHO calls for an outright ban: “<i>Parties should consider very strong regulations, which could include a ban, to protect children and adolescents.</i>” It makes no effort to understand the appeal to poorer smokers of the simple, low-cost, effective replacements for cigarettes. A much better regulatory approach would be controlling these products like other ENDS but encouraging or mandating recycling schemes or replaceable batteries. WHO’s approach is to try to stop pro-health product innovations with bans rather than create an efficient and compliant market for products that people want.</p> <p>In general, WHO’s favoured approach of excessive or prohibitionist regulation has three main effects:</p> <ol style="list-style-type: none"> <li>1. Adverse behaviour change, for example, more smoking.</li> <li>2. Nurturing illicit trade in products people wish to buy.</li> <li>3. Encouraging users or suppliers to develop workarounds.</li> </ol>
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**Original FCTC/COP/10/1(annotated)**

**Commentary**

<p>6.2 Tobacco advertising, promotion and sponsorship: depiction of tobacco in entertainment media: report by the Working Group</p>	<p>There is a broad public health consensus on banning all forms of advertising, promotion and sponsorship of smoking products, the dominant cause of tobacco-related disease. However, advertising that encourages switching from high-risk to low-risk nicotine products (including smoke-free tobacco products) functions as <i>anti-smoking advertising</i> but without a burden on public finances.</p>
<p>Document <a href="#">FCTC/COP/10/8</a></p>	<p>The paper aims to supplement <a href="#">Guidelines for implementation of Article 13 of the WHO Framework Convention on Tobacco Control</a> (2013) in response to changes in the media landscape, e.g. entertainment media [see <a href="#">FCTC/COP7(5)</a> &amp; <a href="#">FCTC/COP8/7</a>]</p>
<p>In accordance with the decision, the <a href="#">FCTC/COP9(2)</a> document FCTC/COP/10/8 is submitted to the COP as one of the items that were deferred from COP9. The document provides an overview of the work of the Working Group established by decision <a href="#">FCTC/COP8(17)</a> to develop specific guidelines to address cross-border tobacco advertising, promotion and sponsorship and the depiction of tobacco in the entertainment media under Article 13 of the WHO FCTC. In accordance with decision <a href="#">FCTC/COP8(17)</a>, the Guidelines for implementation of Article 13 of the WHO FCTC remain fully relevant. The COP is invited to note document FCTC/COP/10/8 and consider adopting the specific guidelines contained in its Annex 1.</p>	<p>The paper and recommendations mostly make sense and are compatible with updating regulation to address changing technology. However, there is evidence of creeping scope:</p> <ol style="list-style-type: none"> <li>1. The paper uses an overly broad definition of tobacco advertising, promotion, and sponsorship (TAPS) that infringes on the rights to legitimate speech and may serve to suppress fair comment and opinion on tobacco harm reduction or prevent truthful communication of risks and benefits of different tobacco products. The FCTC provides the following definition at Article 1(c): <ul style="list-style-type: none"> <li>(c) <i>“tobacco advertising and promotion” means any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly;</i></li> </ul> <p>Some examples in the Appendix to <a href="#">FCTC/COP/10/8</a> go beyond this definition and the Guidelines on Article 13. For example:</p> <p><i>Corporate promotion campaigns and actions portray tobacco companies as innovative performers and socially responsible actors, and often advance novel tobacco products as less harmful alternatives to traditional cigarettes, often despite a lack of independent scientific evidence to support such claims.</i></p> <p>This is not about promoting products but communicating corporate strategy to stakeholders such as investors and decision-makers. These products ARE far less harmful.</p> </li> <li>2. It is essential to apply restrictions only to “commercial communications, recommendation or action” to limit the scope of paid-for marketing by tobacco manufacturers and not to inhibit discussion of the merits of reduced-risk tobacco products in academic, policy think tanks, among consumers and public health advocates.</li> </ol>



	<p>3. The paper fails to recognise that <a href="#">Article 13 FCTC</a> does not impose a mandatory ban on all tobacco advertising. For example, para 23 of <a href="#">FCTC/COP/10/8</a> is expressed as follows:</p> <p style="padding-left: 40px;"><i>23. Parties that have not prohibited the sale of novel and emerging tobacco products should ensure a comprehensive ban on advertising, promotion and sponsorship of novel and emerging tobacco products, including devices used with them, the function of which is to enable the consumption of such products.</i></p> <p>Article 13 requires bans (13.2) <i>or restrictions</i> (13.3) in line with constitutional constraints or principles. This flexibility is essential to allow for a distinction between regulation of the advertising of <i>smoking</i> products (which should be banned) and <i>smoke-free</i> tobacco products (which should be permitted but restricted) because the latter can displace the former: see the case of snus in Scandinavia and the success of heated tobacco products in reducing smoking in Japan. In the United States, the iQOS heated tobacco product has been <a href="#">designated by the FDA</a> as “appropriate for the protection of public health”. FDA has <a href="#">authorised modified risk claims</a> as “appropriate for the promotion of public health” for a heated tobacco product and snus. It follows that banning such promotion would be <i>inappropriate</i> for the protection of public health – causing more harm than good.</p> <p>4. The language must not creep into regulating non-tobacco and non-nicotine products, as these are outside the scope of the FCTC, which deals with tobacco products only. Parties should remain vigilant about scope creep unless and until the Parties agree to extend the FCTC to cover non-tobacco products such as ENDS, ENNDS, nicotine pouches, etc.</p>
<p>6.3 Novel and emerging tobacco products: reports by the Convention Secretariat and by WHO</p>	
<p>Documents: <a href="#">FCTC/COP/10/9</a> and <a href="#">FCTC/COP/10/10</a></p>	<ul style="list-style-type: none"> <li>• <a href="#">FCTC/COP/10/9</a> Challenges posed by and classification of novel and emerging tobacco products (Convention Secretariat)</li> <li>• <a href="#">FCTC/COP/10/10</a> Comprehensive report on research and evidence on novel and emerging tobacco products, in particular heated tobacco products (WHO)</li> </ul> <p><b>In summary</b>, the basic purpose of these two papers is to argue that heated tobacco products are smoking products (10/9), do not offer harm reduction benefits, and, therefore, should be regulated in the same way as cigarettes (10/10). However, this narrative is false and dangerous. These products are, beyond any reasonable doubt, far less harmful than cigarettes and, in some countries, have triggered a dramatic decline</p>

	<p>in smoking. E.g. see Cummings et al. (2020) <a href="#">What Is Accounting for the Rapid Decline in Cigarette Sales in Japan?</a> MDPI</p>
<p>In accordance with decision FCTC/COP9(2), document FCTC/COP/10/9 is an updated version of document FCTC/COP/9/10. The document examines the challenges that novel and emerging tobacco products are posing for the comprehensive application of the WHO FCTC and provides information on the adequate classification of such products to support regulatory efforts, as requested in decision FCTC/COP8(22). The COP is invited to note document FCTC/COP/10/9 and provide further guidance.</p> <p>In accordance with decision FCTC/COP9(2), document FCTC/COP/10/10 is an updated version of document FCTC/COP/9/9. It contains a report that summarizes <i>Technical Report Series 1029</i>, which was the eighth report of the WHO Study Group on Tobacco Product Regulation, and the outcomes of the Heated Tobacco Product (HTP) Expert meeting held in February 2020, both of which respond to paragraphs 2(a)–(d) of decision FCTC/COP8(22). It also reports on changes to the 2022 World Customs Organization Harmonized System codes for nicotine and tobacco products. The report also includes updated evidence, market developments and some recent updates related to HTPs, including policy measures adopted up to 31 December 2022. The COP is invited to note document FCTC/COP/10/10 and provide further guidance.</p>	<p><b>The first paper, <a href="#">FCTC/COP/10/9</a></b>, attempts to distort tobacco policy by using a false definition to misclassify <u>heated</u> tobacco products as <u>smoked</u> tobacco products by classifying the heated tobacco aerosol as “smoke”. <i>Smoke is a product of combustion, and heated tobacco products do not involve combustion when operating as intended and are chemically qualitatively and quantitatively different.</i> (see <a href="#">Sussman et al. 2023</a>)</p> <p><i>In general, HTP emissions contain far fewer compounds than tobacco smoke and exhibit, on average, a 90% reduction in HPHCs. The TPM of HTPs is dominated by water and has a high volatile content, whereas the TPM of tobacco smoke is mostly composed of low-volatile droplets and solid particles.</i></p> <p>In addition, an investigation of heated tobacco function found no products of combustion (e.g. CO, NOx, NO) were formed when comparing regular operation in an oxidising environment compared to a non-oxidising environment (<a href="#">Cozzani et al. 2020</a>)</p> <p>Where the issue has been examined in court, the courts have determined that heated tobacco products <u>cannot</u> be classified as smoking products (<a href="#">Germany, 2021</a> and <a href="#">Sweden, 2022</a>).</p> <p><i>The court explained that the distinction between a “smoking tobacco product” and a “smokeless tobacco product” is based solely on whether a tobacco product is consumed with or without a combustion process; and it is irrelevant whether smoke occurs when the tobacco product is consumed. The court found that the plaintiff’s tobacco product was heated in a controlled manner without the tobacco igniting and thus there was no combustion process. The court ruled that a tobacco product consumed in this way is then to be classified as a “smokeless tobacco product.”</i> [<a href="#">Campaign for Tobacco-Free Kids summary of German case</a>]</p> <p>The Secretariat paper does not mention these cases and the technical and legal reasoning behind the rulings. The Secretariat paper aims to suggest a false and misleading equivalence between HTP aerosol and tobacco smoke, presumably to bolster its argument against tobacco harm reduction and to support regulation of these products as if they were as dangerous as cigarettes, which is far from the case. There really is no doubt here, and the only “challenge” is the challenge justifying the misclassification of reduced-risk products to misapply policies and taxation that should be applied only to the most dangerous products. Delegates should reject this analysis and treat Convention Secretariat statements regarding heated tobacco products as unreliable.</p> <p>The second paper, <a href="#">FCTC/COP/10/10</a>, a report by WHO, suffers from multiple defects.</p>

	<p>For example:</p> <p><i>“28. As summarized in paragraphs 18–22, the existing evidence is insufficient to support the reduced exposure claims for HTPs. While it is true that the level of some HPHCs in the aerosols from HTPs is lower than in CC smoke, the level of others has not been reported or is actually higher.”</i></p> <p>This is a misrepresentation of the balance of the evidence. There is no doubt that toxic exposures are much lower. The reduced exposure is of such a magnitude that it is highly likely that switching from smoking to an HTP would significantly reduce health risks. This is the basis for US FDA <a href="#">authorisation of marketing</a> and <a href="#">reduced risk claims</a> in the United States of the world’s most popular heated tobacco product. WHO fails to mention the two-million-page application and in-depth analysis by the FDA in reaching its authorising decisions.</p> <p>WHO deals with the evidence mainly by dismissing it because most of the studies have been done by the companies that make the products.</p> <p><i>Industry-published studies generally show reduced toxicity for cells and genetic material and lower levels of a range of toxicological and inflammatory biomarkers after exposure in vitro to HTP aerosols, compared with CC smoke.</i></p> <p>However, simply dismissing this evidence is unscientific and naïve or cynical. The industry produces this science to support regulatory applications assessed by sceptical regulators and to support its own product stewardship. In other words, they have incentives to produce high-quality science and a challenge to their science that is typically far stronger than the peer review in scientific journals.</p>
6.4 Forward-looking tobacco control measures (in relation to Article 2.1 of the WHO FCTC) (item proposed by a Party)	
Document <a href="#">FCTC/COP/10/11</a>	<p><b>In summary</b>, this agenda item aims to bring new policies into the discussion at the COP, and it is seen as a way of developing “endgame” ideas. The idea of the FCTC is to promote evidence-based policies, not to encourage the uptake of speculative policies for which there is no evidence or experience.</p>
Document FCTC/COP/10/11 provides context for work that could be undertaken to strengthen the implementation of the WHO FCTC, taking into account Article 2.1 of the WHO FCTC. This agenda item was proposed by a Party. The COP is invited to note document FCTC/COP/10/11 and provide further guidance.	<p><a href="#">FCTC Article 2.1</a> is primarily a clarification that Parties are not limited in the action they can take beyond the scope of the FCTC:</p> <p><i>“In order to better protect human health, Parties are encouraged to implement measures beyond those required by this Convention and its protocols, and nothing</i></p>

	<p><i>in these instruments shall prevent a Party from imposing stricter requirements that are consistent with their provisions and are in accordance with international law.”</i></p> <p>It is not the basis for developing new measures in the FCTC. The priority for COP should be implementing the existing FCTC articles and evaluating tobacco control policies, especially the prohibition of low-risk products favoured by WHO. The Foreword to the FCTC, the text correctly asserts the expectation that:</p> <p><i>The WHO FCTC is an evidence-based treaty that reaffirms the right of all people to the highest standard of health.</i></p> <p>It follows that the FCTC is a vehicle for promoting evidence-based policy measures that lead to higher standards of health. When there is persuasive evidence that “endgame” measures do, in fact, lead to higher standards of health rather than a range of foreseeable negative unintended consequences, then a Party is free to propose such measures as a Treaty amendment through Article 28.</p> <p>Paragraph 9 of <a href="#">FCTC/COP/10/11</a> states:</p> <p><i>9. To date, the Conference of the Parties (COP) to the WHO FCTC has not adopted a decision focused on implementation of Article 2.1, nor has the COP considered a dedicated report that summarizes or analyses the experience of Parties in relation to implementation of this article.</i></p> <p>Article 2.1 does not need an “implementating decision” – it is a self-standing clause and applies <i>only</i> to activity outside the remit of the FCTC. Ultimately, the proposal is to gather information about what policies exist.</p> <p><i>This might include, but not be limited to, an overview of the experience of Parties and a literature review of relevant tobacco control practices. A better understanding of the landscape of forward-looking measures to advance tobacco control would assist Parties in continuing their progress in reducing continually and substantially the prevalence of tobacco use and exposure to tobacco smoke.</i></p> <p>It may seem unreasonable to object to lists of policies, but care is essential. WHO has promoted policies that fall outside the scope of the FCTC, such as the prohibition of ENDS, yet has never evaluated the effects to ensure these prohibitions are “evidence-based”. The COP needs to be a guardian of evidence-based policy and not a forum for advancing untried and speculative ideas for which no supporting evidence exists.</p>
6.5 Implementation of Article 19 of the WHO FCTC: Liability (item proposed by Parties)	There is very little to see on liability – not much progress and no credible theory for how to operationalise a liability regime, what purpose it would serve, or who would ultimately pay the costs.

**Original FCTC/COP/10/1(annotated)**

**Commentary**

<p>Document <a href="#">FCTC/COP/10/12</a></p>	<p>Liability is a matter for the courts and domestic law, and money can be raised through taxation.</p>
<p>Document FCTC/COP/10/12 provides an overview of the work undertaken by the COP in relation to Article 19 (Liability) of the WHO FCTC and provides considerations for potentially expanding that work. This agenda item was proposed by Parties. The COP is invited to note document FCTC/COP/10/12 and provide further guidance.</p>	<p>Governments can extract money from the tobacco sector through taxation. People harmed by tobacco use can bring legal actions as individuals or groups and make a case that the harm is attributable in part to improper conduct by tobacco companies. There have been such cases, and several have been successful, but the courts carefully consider which parties and what conduct creates the liability. It is impossible to generalise about liability and natural justice demands such claims are tested in a neutral court.</p> <p><b>Who pays?</b> The ultimate burden of both taxation and liability would likely fall on current tobacco consumers through increased costs passed on through product prices (depending on the impact on competition). This has been the main effect of the \$206 billion US Master Settlement Agreement (MSA) of 2000. See <a href="#">Sloan et al. 2003</a></p> <p><i>Conclusion: The experience during the post-MSA period demonstrates that the MSA did no major harm to the companies. Some features of the MSA appear to have increased company value and profitability.</i></p> <p>It is unclear what the FCTC Article 19 can add to the established taxation and legal systems, and there has been little advancement in the ten years since the report of an expert group on liability (<a href="#">FCTC/COP6/8</a>). This paper essentially reiterates and refers to that.</p> <p>That probably accounts for the vagueness of the proposals since Article 19 was conceived more than 20 years ago. There is little to be done here, and it is a largely pointless discussion regarding either the objectives of the FCTC or public health.</p>
<p><b>7 Reporting, implementation assistance and international cooperation</b></p>	
<p>7.1 Improving the reporting system of the WHO FCTC</p>	
<p>Document <a href="#">FCTC/COP/10/13</a></p>	<p>This is a reasonable attempt to streamline and modernise reporting requirements.</p>
<p>Document FCTC/COP/10/13 describes the work carried out under the guidance of the Bureau to improve the reporting system of the WHO FCTC. The report contains a proposal to improve the reporting system, including in relation to the reporting instrument of the WHO FCTC. The COP is invited to note document</p>	<p>Parties should focus on synthesising and making available the extensive information collected.</p>

**Original FCTC/COP/10/1(annotated)**

**Commentary**

<p>FCTC/COP/10/13, consider the proposed revised reporting instrument for the WHO FCTC contained in Annex 2 and adopt the draft decision contained in Annex 3 of the report.</p>	
<p>7.2 Implementation Review Mechanism</p>	<p>This aims to develop the review mechanism for a sample of 25 Parties. It is voluntary and should not be controversial.</p>
<p>Document <a href="#">FCTC/COP/10/14</a></p>	
<p>In accordance with decision FCTC/COP9(2), document FCTC/COP/10/14 is resubmitted to the COP without change from document FCTC/COP/9/11. The document describes the pilot project exercise for an Implementation Review Mechanism for the WHO FCTC carried out in accordance with decision FCTC/COP8(16) and Specific Objective 3.1.2 of the <i>Global Strategy to Accelerate Tobacco Control: Advancing Sustainable Development through the Implementation of the WHO FCTC 2019–2025</i>. The COP is invited to note document FCTC/COP/10/14 and consider adopting the draft decision contained in Annex 3 of the report.</p>	
<p>7.3 Contribution of the WHO FCTC to the promotion and fulfilment of human rights (item proposed by a Party)</p>	<p>This paper looks for overlaps between FCTC and human rights concepts and treaties but without any clarity about how this would lead to anything concretely useful rather than just a larger mesh of bureaucratic connections.</p>
<p>Document <a href="#">FCTC/COP/10/15</a></p>	<p>Accepting that there is “the right to the enjoyment of the highest attainable standard of health”, the question is who or what entities are responsible for that – including tobacco companies, regulators and individuals – and by what means can this be achieved—the opposition to tobacco harm reduction conflicts with the objective of attaining a high standard of health.</p>
<p>Document FCTC/COP/10/15 highlights the mutually supportive nature of the WHO FCTC and human rights, provides additional considerations on the nexus between tobacco control and human rights, and outlines the work of the Convention Secretariat on human rights. This agenda item was proposed by a Party. The COP is invited to note document FCTC/COP/10/15 and provide further guidance.</p>	<p>WHO and tobacco control activists have been instrumental in denying millions of smokers access to life-saving, low-risk alternatives to cigarettes – this has occurred through prohibition, regulation and misinformation – for which there is no scientific or ethical basis. Any discussion of human rights must address the abuse of people who smoke (and those who will take up smoking in the absence of alternatives) by nominal health agencies and activists that purposefully deny them safer alternatives and help to make cigarettes the most prominent and dangerous way to consume the relatively innocuous drug nicotine.</p> <p>For an extended discussion, see Ruth Goldsmith (2020) <a href="#">Tobacco Harm Reduction and</a></p>

	<a href="#">the Right to Health</a> , Global Status of Tobacco Harm Reduction
<b>8 Budgetary and institutional matters</b>	There is a very poor assessment of “value for money” and what the expenditure is buying regarding the <i>outcomes</i> expected from the FCTC.
8.1 Performance and progress reports	The Parties should insist on greater scrutiny of the finances and accountability of the finances of the FCTC Secretariat.
Document <a href="#">FCTC/COP/10/16</a>	<p>Most revenues came from extra-budgetary contributions (\$10.5m) rather than assessed contributions (\$8.8m). Extra-budgetary contributions create potential distortions and conflicts of interest. For transparency, the sources of these funds should be fully disclosed, and any conditions attached to the funding should be declared.</p> <p>Parties should take an active interest in how these funds are spent. After staff (\$8.8m), the second and third largest expenditures are on Contractors (\$4.9m) and Transfers and grants (\$2.9m). <i>Who are the beneficiaries of these contracts, transfers and grants, and how are they chosen?</i></p>
a) Performance report for the 2020–2021 Workplan and Budget	
b) Interim performance report for the 2022–2023 Workplan and Budget	
c) Global Strategy to Accelerate Tobacco Control: Advancing Sustainable Development through the Implementation of the WHO FCTC 2019–2025	The success of the FCTC should be measured by the rate of decline of <i>smoking</i> globally and, therefore, the FCTC’s contribution to reducing non-communicable diseases and <a href="#">SDG Target 3.4</a> : to reduce four NCDs by one-third by 2030 compared to 2015.
The COP is invited to note the performance and progress reports for the reported periods contained in document FCTC/COP/10/16. Further, the COP is invited to consider adopting the draft decision contained in Annex 5 of document FCTC/COP/10/16 to adopt an extension to 2030 of the <i>Global Strategy to Accelerate Tobacco Control: Advancing Sustainable Development through the Implementation of the WHO FCTC 2019–2025</i> , as recommended by the Bureau.	
8.2 Proposed Workplan and Budget for the financial period 2024–	

2025	
Documents <a href="#">FCTC/COP/10/17</a> and <a href="#">FCTC/COP/10/INF.DOC./1 Rev.1</a>	To follow
The COP is invited to consider the report and adopt the Workplan and Budget for the financial period 2024–2025 contained in Annexes 1, 2 and 3 of document FCTC/COP/10/17, and to note the additional information contained in the Explanatory note FCTC/COP/10/INF.DOC./1.	
8.3 WHO FCTC Investment Fund	The main problem here is a weak underlying rationale for an investment fund – offering loans that have to be repaid with interest – for spending on tobacco control.
Document <a href="#">FCTC/COP/10/18</a>	
Document FCTC/COP/10/18 describes the arrangements made to launch the WHO FCTC Investment Fund, in accordance with decision FCTC/COP9(13). The report proposes the establishment of a single Oversight Committee, which would serve the WHO FCTC Investment Fund and the Investment Fund to support implementation of the Protocol to Eliminate Illicit Trade in Tobacco Products, under the direction of the separate governing bodies of the treaties. The COP is invited to note document FCTC/COP/10/18, to consider the terms of reference for a single Oversight Committee contained in Annex 1 and to adopt the draft decision contained in Annex 2 of the report.	<p>The paper provides generalities but does not give precise or useful information on the status of the Fund. Why a verbal update and not a written report?</p> <p><i>The Convention Secretariat remains engaged in outreach efforts to potential investors to the Fund and is undertaking a mapping of potential investors to the Fund. Investor outreach has been limited to Parties. <b>The Convention Secretariat will provide a verbal update at the Tenth session of the COP (COP10) on the status of investment for the Fund.</b></i></p> <p>The Secretariat must be candid and transparent, even when aspects of the FCTC or COP initiative are not performing to expectation. Here is the objective:</p> <p><i>Objective: To establish an Investment Fund (with projected initial capital of US\$ 50 million and an estimated annual return of investment of US\$ 2 million) to provide sustainable funding to the COP to implement the WHO FCTC in alignment with COP-adopted decisions, workplans and budgets.[FCTC/COP9(13)]</i></p> <p>The fundamental problem here is the rationale for an “investment fund”. <i>Investments have to be paid back with interest.</i> It is not apparent that tobacco control expenditure is a good reason for countries to add to their debt burden, compared to investment in water and sanitation or economic infrastructure. Alternatively, there is the option to fund tobacco control from the regular budget generated by taxation if this is a sufficiently high priority compared to other calls on the budget. The Fund cannot provide “free money” for tobacco control. That would need to be justified as “overseas development assistance” and compared with other calls on aid budgets.</p>



**Original FCTC/COP/10/1(annotated)**

**Commentary**

<p>8.4 Payment of Assessed Contributions and measures to reduce Parties in arrears</p>	<p>It would be better if the Secretariat were funded at the level that could be met by assessed contributions (and that these are paid) rather than drawing on the potentially distorting and conflicting reliance on extra-budgetary contributions.</p>
<p>Document <a href="#">FCTC/COP/10/19 Rev1</a></p>	
<p>The COP is invited to note the report providing information on the progress made on the payment of Assessed Contributions and the current status of Parties in arrears, contained in document FCTC/COP/10/19, and consider adopting the draft decision annexed to it, as recommended by the Bureau.</p>	<p>The proposed sanctions would bar countries in significant arrears from holding certain official positions related to FCTC proceedings. A possibly more effective way to address arrears would be to suspend support for delegates' travel and subsistence, which would then become the responsibility of the Party in arrears.</p>
<p>8.5 Review of accreditation of nongovernmental organizations with the status of observer to the Conference of the Parties</p>	<p>The selection and cultivation of compliant and sycophantic NGOs should embarrass the Parties, Secretariat and WHO. It represents a deliberate attempt to create a bubble and foster groupthink. A major rethink is necessary.</p>
<p>Document <a href="#">FCTC/COP/10/20</a></p>	
<p>The COP is invited to note the report reviewing the accreditation of nongovernmental organizations (NGOs) with the status of observers to the COP, contained in document FCTC/COP/10/20, and to consider adopting the draft decision annexed to it to maintain the observer status of the reviewed NGOs.</p>	<p>This process is a failure to create a genuinely diverse and open process in which the Parties have access to a full range of perspectives and stakeholders, including consumers (those most directly affected), genuine grassroots civil society organisations, and public health experts who take a different perspective to WHO and the complex of billionaire-funded interest groups and astroturf organisations who are admitted.</p> <p>As I set out in my advice to COP-10 delegates, <a href="#">Eyes on the ball</a>:</p> <p><i>[...] recognize that the so-called civil society representatives with observer status at the COP are not necessarily neutral guardians of the public interest. They are carefully selected activists, chosen for their allegiance to the WHO and almost always funded by foreign interests. Unlike other conventions, such as the United Nations Framework Convention on Climate Change, the FCTC is highly restrictive on which nongovernmental organizations (NGOs) are permitted as observers to the COP. Only 26 NGOs are currently accredited, and participating NGOs must be approved by the COP, provide evidence that they support the FCTC and show that they are working toward its implementation. A single NGO, now known as the Global Alliance for Tobacco Control, acts as an umbrella for smaller NGOs, but only if they meet its <a href="#">membership criteria</a>. The Secretariat <a href="#">assesses their suitability</a> and reports to the COP.</i></p> <p>The WHO FCTC is a poor shadow of the UNFCCC (climate treaty). For a more detailed analysis of the way the FCTC fails basic principles of openness and transparency:</p>

**Original FCTC/COP/10/1(annotated)**

**Commentary**

	<i><a href="#">The WHO tobacco control treaty meetings are closed bubbles of cultivated groupthink – a comparison with the UN climate change treaty</a>, 2021</i>
8.6 Possible amendments to the Rules of Procedure of the Conference of the Parties	No comment
Document <a href="#">FCTC/COP/10/21</a>	
The COP is invited to consider possible amendments to the Rules of Procedures of the COP, as recommended by the Bureau, contained in Annex 1 of document FCTC/COP/10/21, and to adopt the draft decision contained in Annex 2 of the document.	
8.7 Strengthening synergies between the Conference of the Parties and the World Health Assembly: report by the WHO Director-General on resolutions and decisions of the World Health Assembly	No comment
Document <a href="#">FCTC/COP/10/22</a>	
The COP is invited to note the report by the Director-General of WHO on the outcomes of the Seventy-fifth and Seventy-sixth World Health Assembly and the WHO regional committees relevant to the implementation of the WHO FCTC, as presented in document FCTC/COP/10/22.	
8.8 Appointment of the Head of the Convention Secretariat: report by the Bureau	No comment
Document <a href="#">FCTC/COP/10/23</a>	
Document FCTC/COP/10/23 contains the joint recommendations of the Bureau elected by COP9 and the Bureau elected by the Second session of the Meeting of the Parties to the Protocol to improve the process of appointment of the Head of the Convention Secretariat, in accordance with decisions FCTC/COP9(9) and FCTC/MOP2(9). The COP is invited to note document FCTC/COP/10/23 and consider adopting the draft decision annexed to it.	

<b>9 Date and place of the Eleventh session of the Conference of the Parties*</b>	No comment
Document <a href="#">FCTC/COP/10/24</a>	
<p>In accordance with Rules 3 and 4 of the Rules of Procedure of the COP, the COP shall decide on the date and duration of its next regular session. The report contained in document FCTC/COP/10/24 proposes a date and place for the conduct of the Eleventh session of the COP (COP11). It also makes reference to the requirements for Parties to host future sessions of the COP and the Meeting of the Parties to the Protocol. The COP is invited to note document FCTC/COP/10/24 and consider adopting the draft decision annexed to it to decide the date and place of COP11.</p>	
<b>10 Election of the President and Vice-Presidents of the Conference of the Parties*</b>	No comment
Document <a href="#">FCTC/COP/10/25</a>	
<p>The election of officers of the COP is governed by Rule 21 of the Rules of Procedure of the COP. Each regional group of Parties is invited to put forward a candidate for membership of the Bureau and to inform its respective current Bureau Member and the Convention Secretariat of its nomination, if possible before the opening of the session. The procedure is described in document FCTC/COP/10/25. The COP is invited to note document FCTC/COP/10/25 and elect the officers that constitute the Bureau of the COP.</p>	
<b>11 Provisional report of the Tenth session of the Conference of the Parties*</b>	
Document <a href="#">FCTC/COP/10/26</a>	
<p>The COP is invited to adopt the provisional report of the Tenth session of the COP contained in document FCTC/COP/10/26.</p>	To follow
<b>12 Closure of the session*</b>	