

Brussels, 27<sup>th</sup> June 2023

Dear Ms O'Reilly,

1. We read with deep attention your letter of 17/04/2023 to the President of the European Commission, referenced "*Strategic inquiry OI/6/2021/KR*", and pertaining to your "*Preliminary findings in the above inquiry on the European Commission's interactions with tobacco interest representatives*".

2. Please let me start by stating clearly that BAT fully supports the principle of transparency of interactions with public institutions, alongside other equally important principles such as participation of all interested parties into the policy elaboration process, non-discrimination and equal treatment, the right to be heard, science-based and fact-based regulation, Better Regulation; and that we execute our engagement activities in full respect of the applicable regulation, including obviously that pertaining to transparency.

3. As the Brussels-based Director for EU Public Affairs of British American Tobacco Group, this gives me the opportunity to raise to you our deep concerns relating to what we perceive as an increasingly faulty and unjustified application of article 5.3 of the FCTC by the Commission's Directorate General for Health and Food Safety. We take advantage therefore of your intervention in this matter and we would like to provide our input to help with your work in shaping an informed, appropriate and legally sound interpretation of this international provision.

*On the Transparency Policy of DG SANTE*

4. You refer in your letter to something you phrase as the "*proactive transparency policy put in place by the Commission's Directorate-General for Health and Food Safety*". As I am not aware of such policy having ever been made public or even simply shared with the most interested parties, including us, I would respectfully ask you to share with us this policy from the Commission, or ask

the Commission to share it with us and all other interested parties. This would definitely advance the cause of transparency.

5. Short of any written policy, we have on the contrary been faced from the Directorate General for Health and Food Safety with a systematic, although never officially admitted, obstructive practice of denying all of our transparent requests for one-to-one meetings – be it in-person or via video-conferencing. Such practice is questionable, for reasons explained below. We have even witnessed recently informal, but repeated, pressures from the Directorate General for Health and Food Safety on well-established business associations and think-tanks, of which we are members, in favor of our exclusion from these structures. This is particularly disturbing in a democratic system.

### *On the interpretation of FCTC article 5.3*

6. **FCTC does not require exclusion but transparency** - Early last year, in Case C-160/20, article 5.3 of the FCTC has been interpreted by the European Court of Justice as follows : “59. *It is clear from the very wording of that provision that it does not prohibit all participation of the tobacco industry in the establishment and implementation of rules on tobacco control, but is intended solely to prevent the tobacco control policies of the parties to the Convention from being influenced by that industry’s interests*”. We would respectfully ask you to help clarify how a practice of systematic exclusion is compatible with the balanced wording and principles laid out by the Court, and also by the clear language of the Framework Convention and its guidelines.

7. **FCTC applies only to tobacco products** - Article 5.3 explicitly refers to “*public health policies with respect to tobacco control*”, and is part of a treaty named “*Framework Convention for Tobacco Control*”. There are strong arguments supporting the view that the Treaty is applicable only to interactions pertaining to tobacco products as defined in it (i.e., tobacco products for smoking, sucking, chewing or snuffing, as per art 1(f) of the FCTC). There can be no doubt that non-tobacco products such as for example e-cigarettes and nicotine pouches are not covered by the FCTC and its Article 5.3. We would respectfully suggest that you ask the Legal Services of the Commission to check the legal basis for the Directorate General for Health and Food Safety’s view of extending its exclusion practice to meetings who expressly pertain to Novel Products such as vaping products and nicotine pouches, although they do not contain tobacco.

8. **FCTC article 5.3 must be applied “in accordance with national laws”** - Still in this judgement, the Court (paragraphs 35 and 36) references Article 1 and Article 10(3) TEU, Article 15(1) and Article 298(1) TFEU and Article 42 of the Charter, noting that such provision “*enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system. In particular, Article 15(1) TFEU provides that, in order to promote good governance and ensure the participation of civil society, the European Union’s institutions, bodies, offices and agencies are to conduct their work as openly as possible*”.

9. We would respectfully ask you to clarify that a practice of systematic exclusion of a legally operating private entity, namely of the economic and social significance such as ours, is not compatible with these fundamental rights as protected by the Treaties.

10. **The necessity criterion is not mandatory under FCTC and would, otherwise be contrary to art. 15(1) TFEU-** The necessity criterion comes from the Guidelines for the implementation of the FCTC in their non-binding recommendation 2.1 that reads *“Parties should interact with the tobacco industry only when and to the extent strictly necessary to enable them to effectively regulate the tobacco industry and tobacco products”*.

11. **The necessity criterion is complex to operationalize** - Pending receiving the policy that the Directorate General for Health and Food Safety may have developed on this aspect, that we will review thoroughly, we would like to stress the difficulty that such a necessity criterion entails intrinsically when it comes to practical implementation. First, it is open to subjective interpretation. As such, it will leave Civil servants of the Commission unsure whether an interaction can take place or not and exposed to subsequent criticism. The likely outcome is a systematic denial of interaction for precaution reasons, which is contrary to both the text and the spirit of the above mentioned texts. Secondly, it can be argued that when an interaction is requested by an economic operator, it is because it is necessary. No economic operator would spend time and efforts in unnecessary tasks. Third, necessity is especially strong when the Commission undertakes a revision of the current regulatory or legislative framework, since this is the moment when the Civil service needs to receive input and expertise from economic operators. The systematic denial of meetings as currently practiced by the Directorate General for Health and Food Safety specially when elaborating new regulations, while at the same time remaining open to opponent interests, is therefore at odds with the very needs of the Civil Service itself.

12. Considering the subjective nature of the criterion, **complexities will inevitably arise in the process itself**, and you rightly allude to them when asking the Commission to clarify its practice: who is going to conduct the check that the “necessity” criterion is required? And, if required, that it is met? How could a homogeneous approach be established? Should an interservice team become the examiner? And, if the request is formally documented, should it be analyzed and formally decided upon? What might be the sufficient documentation? Will the decision be motivated and published in the official gazette?

13. I noted that in your Preliminary Opinion you rightly ask the Commission to *“explain in what situations an assessment of necessity is conducted, how it is conducted and whether it is documented?”*. Save the above-mentioned considerations, we welcome this clarification, as to our knowledge, the Directorate General for Health and Food Safety has not made public any policy or guidelines on this aspect.

*On the existence of an “acquis Communautaire” relating to good governance*

14. **Civil society expertise is needed for good policy-making** - In an ever more complex world, the capacity of political institutions to deliver smart legislation (understood as one that is fit-for-

purpose to deliver its intended results), depends more and more on the capacity of both civil servants and elected officials to remain in touch with new developments, and to garner sufficient expertise in specific technical policy fields to be able to regulate properly the various economic sectors. This is where it is crucial to *“ensure the participation of civil society, in order to promote good governance”* in the wording of art 15TFEU itself.

15. We would respectfully ask you to confirm that a blanket exclusion approach, as currently practiced by the Directorate General for Health and Food Safety, is practically compromising this overarching good governance imperative.

16. **The Treaties have clear provision on this topic** – Without repeating what was written under section 8 above, suffice to remind here that Article 1 and Article 10(3) TEU, Article 15(1) and Article 298(1) TFEU and Article 42 of the Charter, clearly guarantee an inclusive approach to policy-making.

17. **The Commission has already taken a position on this topic** - In an answer made on behalf of the Commission by the then Commissioner for Health Ms. Vassiliou (E-1879/08EN/14.05.2008), to a written question by MEP Florenz (E-i879/08), it reads : *“With regard to consultations with the industry, the Commission would like to recall the Communication on ‘General principles and minimum standards for the consultation of interested parties by the Commission’ adopted on 11 December 2002, which lays down rules in stakeholder consultation processes. The Commission’s instructions are both to conform to those guidelines for internal EU policy discussions, and to respect them in contributing to the FCTC process. According to those principles, the Commission is committed to an inclusive approach when developing and implementing EU policies, which means consulting as widely as possible on major policy initiatives. This applies, in particular, in the context of legislative proposals”*.

18. At the Second Conference of the Parties of the WHO FCTC, in 2007, the Commission intervened (COP/2/2007/CD, summary records of committees, page 52, [Microsoft Word - COP2\\_07\\_CDREC3-en.doc \(who.int\)](#)), to ensure that references to Article 5.3 would not *“have any implications for normal and necessary contacts between national customs authorities and the tobacco industry.”* This right to engage with the tobacco industry was confirmed by the Chair of the negotiations, who clarified that *“the amendment nor Article 5.3 from which it was derived was intended to jeopardize any responsible relationship between Contracting Parties and the tobacco industry.”*

19. . It also runs counter to international recommendations on good regulatory practice agreed by EU Member States, including the Organisation for Economic Cooperation and Development’s (OECD) Recommendation of the Council on OECD Legal Instruments Improving the Quality of Government Regulation (OECD/LEGAL/0278, OECD Council 9th March 1995), which states that *“regulations should be developed in an open and transparent fashion, with appropriate procedures for effective and timely input from interested parties such as affected businesses and trade unions, other interest groups, or other levels of government.”*

*Unintended consequences of an exclusion policy*

20. **A systematic exclusion policy has negative impacts on good policy making that should be assessed before regulating** - Purely formal interactions such as written exchanges and public consultations are not efficient in many instances. It can be wondered how important workstreams led by the Commission itself will be executed effectively without substantial and flexible interactions with economic operators. To name a few examples of concerns : How will systematic exclusion affect the effectiveness of DG GROW and OLAF's work in tackling illicit trade, that is impossible without industry's involvement ? How will systematic exclusion affect DG SANTE's capacity to enact effective and workable technical rules in its responsibility of managing the tobacco products' Traceability System ? How will systematic exclusion affect DG TRADE's work on Customs classification, Customs' Union Code reform, or International Trade aspects such as Rules of Origin ? How will systematic exclusion affect DG SANTE's capacity to define realistic lead times for the adaptation of our manufacturing facilities, following a change of regulation, be it for ingredients or packaging, to name but only those two?

21. Consequently, we would respectfully ask you to confirm to us whether there has been a formal impact assessment of the restriction policy implemented by the Directorate General for Health and Food Safety, on how the public policy objectives can be effectively and cost-reasonably achieved without the industry's involvement.

*On the need for a "whole-of-Commission" policy*

22. **A "whole-of-Commission" policy should require transparency and refuse exclusion** – In the Ombudsman case 852/2014/LP concluded in 2016, it is observed: *"The Commission should ensure that the proactive transparency policy put in place by the Directorate General for Health and Food Safety, requiring the publication online of all the meetings its staff have with tobacco industry representatives and the minutes taken of those meetings, should apply across all of the Commission's services"*. We fully support transparency. Denial of meetings and other interactions would be detrimental and should not be part of this policy.

23. **A "whole-of-Commission" policy should be generic** - To the extent that a transparency policy is elaborated for the "whole-of-commission", it should be generic enough not to unduly hinder legitimate interactions with the industry on public health policies regarding tobacco control, let alone on matters such as in respect of illicit trade or non-tobacco products, in respect of which the interests are aligned or that relate to products not covered by Article 5.3. We would respectfully ask you to consider this suggestion, and we would be happy to elaborate more in details if you are interested.

24. **A "whole-of-Commission" policy should explicitly allow in-person meetings** - Purely formal interactions such as written exchanges and public consultations are not efficient in many instances. Direct, in-person interactions allow a clearer understanding of technical matters, speedier reaction,



increased regulatory clarity – all of which are of importance both to the Civil Service and to the Industry.

*Conclusion*

25. As I mentioned at the beginning of this letter, we are grateful that you have taken an interest in this debate. The purpose of raising the above questions and points is to positively contribute to your work. Indeed, we support clarification and transparency and we wish to terminate a very uncomfortable and discriminatory situation that has been developed because of a biased interpretation of art. 5.3 FCTC.

We remain at your disposal for an in-person exchange at your most convenient time.

Sincerely Yours

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British American Tobacco