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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Director

Brussels,
SANTE.DDG1.B2/[redacted](2019)4248417

Subject: Your letters of 10 May 2019

Dear [redacted]

I have been asked to reply to your two letters of 10 May 2019 addressed to Vice-President Katainen and concerning the EU system of tobacco traceability.

First of all, as you are aware, the EU system of tobacco traceability was successfully launched on 20 May 2019. Ahead of the launch, the ID issuers had registered hundreds of thousands of economic operators and facilities in the system's central repository as well as delivered the first batches of unique identifiers required for marking of the products. We have followed very closely the system's functioning since its start. In the weeks after the system's launch, the overall operational statistics indicated no major blocking issues. All the main data flows function and, where needed, adequate actions are being taken to eradicate infancy issues at the level of both primary and secondary repositories.

For the time being, the Commission has been notified of the absence of the ID issuer in only one Member State, i.e. Romania. In this case, Commission Decision (EU) 2019/691, which authorises the economic operators to use the services of another appointed ID issuer in the temporary absence of the competent entity, was effectively applied to the extent that the manufacturing of tobacco products did not have to be interrupted.

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As regards the issue of the fees charged for unique identifiers, in line with Article 3(9) of Commission Implementing Regulation 2018/574, the ID issuer may establish and charge fees to economic operators solely for generating and issuing unique identifiers. These fees are to be non-discriminatory and proportionate to the number of unique identifiers generated and issued to economic operators taking into account the mode of delivery. The actual level of applicable fees is left to the discretion of each ID issuer and may depend on several factors that may differ across Member States and ID issuers, such as a level of general service (e.g. regular or extended working hours), technical aspects of delivery (incl. a level of IT integration with the systems of tobacco manufactures), modes of payment, overall volumes etc. It is also only natural to expect that the costs of establishing the service as well as of providing the identifier codes for economic operators, facilities and machines will be gradually recouped through these fees.

For the avoidance of doubt, the Commission's estimate used in the impact assessment study provided for an average value of the basic service of generating unique identifiers across the entire EU. As such, this estimate can serve as a useful reference point, but in no respect should it be considered as binding on individual ID issuers. The impact assessment study also assumed a margin of error and we note that a large number of the ID issuers priced their services within the range assumed therein. The same remark can be made with respect to the fees adopted by the operator of the secondary repository for its services.

In this context, it is worth noting that the smaller manufactures grouped in your association are protected by the structure of the fees which are required to remain proportionate to the number of unique identifiers. Therefore the smaller manufacturers cannot be penalised for placing smaller orders. The introduction of the proportionate fees for unique identifiers is one of several measures by which Implementing Regulation (EU) 2018/574 minimises the costs for small and medium-sized enterprises.

Insofar as we may understand your frustration with the new EU regulatory rules concerning tobacco traceability and the fact that you perceive them as an additional burden for the businesses of your members, the Commission implements the Tobacco Products Directive 2014/40/EU, which the European Parliament, representing the European people, and the Council, representing 28 EU Member States, adopted in 2014. In fulfilling our duties, we always strive to eliminate unnecessary burdens. This being

said, certain burdens remain unavoidable as parts of the regulatory rules required for protecting adequately the EU citizens' interests, in particular their health and safety.

In our view, all the better regulation rules were adequately observed in the process of preparing the secondary legislation establishing the EU system of tobacco traceability. The sector represented by your association was consulted in the same way as other stakeholders. The consultations were carried out in a fair and transparent manner respecting both the better regulation process and the EU obligations as a Party to the World Health Organisation's Framework Convention on Tobacco Control.

Finally, as regards the launch of the Russian tobacco traceability system as of 1 July 2019, the Commission's services will continue to use their best efforts to address potential barriers to trade – such as notably double-marking issues - due to the measures introduced by the Russian Federation. Such efforts will continue to be undertaken both in bilateral and multilateral contexts. As you recognise in your letter, the Commission's actions have brought positive outcomes in other instances, in particular as regards the adaptations made to the Australian packaging regulations. However, any solutions aimed at avoiding disruption of EU tobacco exports to the Russian Federation will have to be fully compatible with the now established EU system of tobacco traceability.

Yours sincerely,

[electronically signed]

Andrzej Jan RYS