



Ref: SANTE.DDG1.B [REDACTED] (2019)8058195

[REDACTED]
Directorate-General for Health and Food Safety
European Commission
1049 Bruxelles/Brussel
Belgium
[REDACTED]

16 December 2019

Re: Notification of proposed external auditor (Article 15(8) of Directive 2014/40/EU)

Dear [REDACTED]

We refer to [REDACTED] letter in relation to the above, which was received by JTI on 2nd December 2019.

[REDACTED] letter invites us to notify the Commission of JTI's proposed audit firm for the purposes of Article 15(8) of Directive 2014/40/EU (the "**Directive**"), and to submit certain specified information in relation to that audit firm, together with copies of declarations of independence and professional suitability signed by the proposed audit firm, by no later than 7 January 2020. [REDACTED] letter also sets out the basis on which the Commission intends to assess the proposed audit firm, and indicates that the Commission intends to publish guidelines on the scope of the required audit reports in early 2020.

JTI is committed to ensuring the integrity and efficacy of the tobacco traceability system, and intends to propose, and appoint, an independent and professionally suitable audit firm for the purposes of Article 15(8) of the Directive. However, neither the deadline, nor any of the other requirements or criteria set out in [REDACTED] letter, are specifically provided for in the Directive, Commission Delegated Regulation (EU) 2018/573 or Commission Implementing Regulation (EU) 2018/574 (the "**Regulations**"). The imposition of a very short deadline for proposing an audit firm, in particular taking into account the upcoming holiday period, is unreasonable and poses significant challenges.

Further, and leaving aside the fact that it is not provided for in the Directive or the Regulations, we do not believe that it is appropriate or reasonable to require us to propose an audit firm, or for that proposed audit firm to be required to sign a declaration of professional suitability, in advance of the publication of the Commission's guidelines in relation to the scope of the required audit report. Such guidelines are clearly important for ensuring that the audit firm that is proposed by JTI is professionally suitable, and that the scope of the audit reports is adequately dealt with in the contract to be entered into with the audit firm.

Although we await the publication of the Commission's guidelines and reserve our position in that regard, it would appear to us that Article 15(8) of the Directive requires the audit report to deal only with the issue of access to the repositories, assessing, in particular, any irregularities in relation to access. It is clear that the proposed guidelines could impact on the suitability of the proposed audit firm and the contractual arrangements to be agreed with that audit firm.

[REDACTED]

[REDACTED]