



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Health systems, medical products and innovation
The Director

Brussels
SANTE.DDG1.B/[REDACTED]/(2019)8515359

To whom it may concern,

Subject: Follow-up to letter of 27 November 2019 on the notification of proposed external auditors / audit firms (Article 15(8) of Directive 2014/40/EU)

I am writing to you in follow-up to my letter of 27 November 2019 concerning the notification of proposed audit firms, as required under Article 15(8) of Directive 2014/40/EU.

Several manufacturers have responded to advise that an adequate internal selection and bidding process requires more time. I furthermore understand from the comments received that the absence of complete information on the scope of the annual audit reports poses additional difficulties to the selection process.

In light of these concerns, we have decided to amend the notification procedure for the proposed audit firms. I refer you to the new notification procedure outlined below.

Notification procedure:

Article 15(8), second subparagraph, of Directive 2014/40/EU stipulates that an external auditor, who is proposed and paid by the tobacco manufacturer, shall monitor the activities of each notified and approved primary repository. As such, manufacturers are invited to propose to the Commission, for approval, an audit firm responsible for auditing their primary repository.

The approved audit firms shall submit annual reports on the audits of the primary repositories to the competent authorities and to the Commission. The Commission undertakes to publish guidelines on the scope of the audit reports. The publication is foreseen for early 2020.

Manufacturers are invited to notify the Commission of the audit firms that they propose to monitor the activities of their respective primary repository.

Note: Two or more manufacturers may also decide to submit a joint notification proposing one audit firm.

Each manufacturer should submit the information listed in Annex A (signed by the manufacturer), as well as copies of the required declaration forms B and C (signed by the proposed audit firm), in electronic format, to SANTE-TT-SW@ec.europa.eu.

The notification of the proposed audit firm should be submitted within **45 calendar days** from the date of publication of the guidelines document referred to above.

The Commission will carry out the assessment of the proposed audit firm as quickly as possible and will seek to issue a decision within three months of the date of receiving the notification. A list of approved audit firms will be made publicly available on the Commission website.

Your sincerely,

(e-signed)

Andrzej RYS

Enclosed: Annexes A, B, C

ANNEX A
- Notification of proposed audit firm -

Pursuant to Article 26(1) of Commission Implementing Regulation (EU) 2018/574, each manufacturer of tobacco products shall contract an independent third-party provider for the purpose of establishing a repository, which stores data relating to the tobacco products of the individual manufacturer (hereafter "primary repository"). The activities of the primary repository and its provider shall be monitored on an annual basis by an independent external auditor. The auditor shall be proposed and paid by the tobacco manufacturers.

I, the undersigned *[insert name and surname]*, being *[insert name of position held]* of *[insert company name]*, (hereafter "the company"), located at *[insert full address]* and with the VAT identification number *[insert VAT number]*, acting as a legal representative of the aforementioned company, hereby propose **the audit firm** indicated below to be responsible for the annual audits of the primary repository contracted by the company.

Name of audit firm: *[please insert]*

Full address (legal seat): *[please insert]*

Legal representative(s) of audit firm: *[please insert]*

VAT identification number: *[please insert]*

Place and date:

Signature:

ANNEX B
- Declaration form: independence of audit firm and auditors -

Pursuant to Article 26(1) of Commission Implementing Regulation (EU) 2018/574, each manufacturer of tobacco products shall contract an independent third-party provider for the purpose of establishing a repository, which stores data relating to the tobacco products of the individual manufacturer (hereafter "primary repository"). The activities of the primary repository and its provider shall be monitored on an annual basis by an independent external auditor. The auditor shall be proposed and paid by the tobacco manufacturers.

I, the undersigned [insert name and surname], being [insert name of position held] of [insert name of audit firm], (hereafter "the audit firm"), located at [insert full address] and with the VAT identification number [insert VAT number], acting as a legal representative of the aforementioned audit firm, hereby solemnly declare that:

- the audit firm complies with the requirements on legal independence, financial independence, and absence of conflict of interest, as defined in Article 35(2) (a) – (c) of Commission Implementing Regulation (EU) 2018/574;
- the audit firm has not been contracted in the last four calendar years to carry out non-audit services in the fields of tobacco traceability or the fight against illicit trade of tobacco products;
- the auditors carrying out the audit of the primary repository on behalf of the audit firm have not been employed in the tobacco industry, nor have they had any professional involvement in any project related to tobacco, in the last four calendar years;
- the auditors carrying out the audit of the primary repository on behalf of the audit firm are free from any pecuniary or non-pecuniary interest linked to the tobacco industry, including possession of stocks, participation in private pension scheme or interest held by their partners, spouses or direct relatives in the ascending or descending line.

Place and date:

Signature:

ANNEX C

- Declaration form: professional suitability of audit firm and auditors -

Pursuant to Article 26(1) of Commission Implementing Regulation (EU) 2018/574, each manufacturer of tobacco products shall contract an independent third-party provider for the purpose of establishing a repository, which stores data relating to the tobacco products of the individual manufacturer (hereafter "primary repository"). The activities of the primary repository and its provider shall be monitored on an annual basis by an independent external auditor. The auditor shall be proposed and paid by the tobacco manufacturers.

I, the undersigned [*insert name and surname*], being [*insert name of position held*] of [*insert name of audit firm*], (hereafter "the audit firm"), located at [*insert full address*] and with the VAT identification number [*insert VAT number*], acting as a legal representative of the aforementioned audit firm, hereby solemnly declare that:

- the audit firm has at least seven years of experience in carrying out audits of medium-sized and/or large-sized enterprises, and at least five years of experience in offering services of IT Audit and Information System Security, including expertise in assessing organisational and physical security, operations security, access control, communications security, business continuity mechanisms, and assets and data integrity;
- the Lead Auditor with responsibility for the audit of the primary repository must be certified as an ISO/IEC 27001 Lead Auditor;
- any other auditor(s) who may be involved in the audit have at least two years of professional experience in carrying out audits in the area of information security management (ISMS).

Place and date:

Signature: