

**From:** SANTE B2 TOBACCO CONTROL  
**Sent:** 31 January 2019 10:38  
**To:** [REDACTED]  
**Cc:** SANTE B2 TOBACCO CONTROL  
**Subject:** RE: Track & Trace obligations (importer)

Dear [REDACTED]

Thank you for your e-mail of 16 January. Please find below in red comments to your questions.

Best regards,

Team Track & Trace



**European Commission**  
Directorate-General for Health and Food Safety  
Unit B2 – Cross-border healthcare and tobacco control

B-1049 Brussels/Belgium  
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**From:** [REDACTED]  
**Sent:** Wednesday, January 16, 2019 4:21 PM  
**To:** SANTE B2 TOBACCO CONTROL <[SANTE-B2-TOBACCO-CONTROL@ec.europa.eu](mailto:SANTE-B2-TOBACCO-CONTROL@ec.europa.eu)>  
**Cc:** SANTE TT SW <[SANTE-TT-SW@ec.europa.eu](mailto:SANTE-TT-SW@ec.europa.eu)>  
**Subject:** Track & Trace obligations (importer)

Dear Madam, Dear Sir,

As a European manufacturer and importer of tobacco products ("Landewyck Tobacco"), we allow ourselves to submit some "inquiries" related to our collaboration with [REDACTED]  
[REDACTED]

This collaboration is carried out for [REDACTED] cigarettes production at [REDACTED]; the cigarettes are afterwards imported into the EU by Landewyck Tobacco.

## 1) The context

⇒ 4<sup>th</sup> recital of the Commission implementing regulation 2018/574:

*“In order to combat multiple existing types of fraudulent activities that result in illicit products being made available to consumers, including practices that entail the false declaration of exports, the traceability system provided for under this Regulation is to apply, in accordance with Article 15 of Directive 2014/40/EU, **to all tobacco products manufactured in the Union, as well as to those manufactured outside the Union insofar as they are destined for or placed on the Union market.**”):*

## 2) Our understanding of the approach

- We register █████ as a facility located outside the EU (art. 16 (4) Commission Implementing Regulation 2018/574);  
**Correct.**
- We register █████ machines used for █████ cigarettes (art. 18 (3) Commission Implementing Regulation 2018/574);  
**Correct.**
- As Unit level Unique Identifiers (UI) need to be applied on packs before the import into the EU (art.6 (2) Commission Implementing Regulation 2018/574):
  - We will send via our primary repository request for UIs █████ (art.9 (1) Commission Implementing Regulation 2018/574);  
**The request would be sent directly to the competent ID issuer.**
  - We will send those UIs received to █████ (who probably needs to equip properly in order to be able to receive and further handle them for printing, application, etc.);  
**Correct.**
  - Further █████ will produce and apply UIs on products, as they should communicate to us some messages like:
    - application of unit level UI's on unit packets;
    - application of aggregated level UI on aggregated packaging;
    - dispatch of tobacco products, etc.

as once validated, we would communicate these information via our Primary Repository (article 32 Commission Implementing Regulation 2018/574).

In principle, this is correct for the application of UIs, but not for dispatches. Information on the latter will come from the entity who handles the imported tobacco products in question after they entered the Union territory and were released for free circulation (i.e. presumably the Union importer). The first message after reporting on the application of UIs would be an arrival message. On the latter aspect, please see the comment under point 3b.

### 3) **The tricky points on which we need a clarification**

- a) **Are there any special “time frames” for the transmission “of required information”** (article 34 of Commission Implementing Regulation 2018/574) **for products manufactured outside the EU?**

Article 34 applies to all economic operators alike, including importers located in the EU and subject to the derogations in paragraphs 4 and 5.

- b) **What is the starting point of the “time frames” referred to in point (a): “the occurrence of the event”** ? In the light of article 8 (5) of the Protocol to Eliminate Illicit Trade in Tobacco Products, could we consider that the “occurrence of the events” for tobacco products manufactured outside the EU is their (products) import onto the EU territory?

In the case of imports, the occurrence of the event on product movements equals the point in time when a product is imported into the Union. Where a product is placed under a special procedure upon its entry into the territory of the Union (see Art. 210 UCC), the product shall be considered imported at the point in time when it is released for free circulation (see Art. 201 UCC). At this point in time, the unit level unique identifier must have been applied to the packet (see Art. 6(2) Implementing Regulation 2018/574). The application of the unique identifier must be recorded to the traceability system within the prescribed timeframe. The first reporting event on product movements as such normally will take the form of a message to the traceability system concerning the arrival of the product (‘arrival message’) to the facility at which the product is released for free circulation.

- c) **Are there any exceptions foreseen for anti-tampering device installation** (article 7 Commission Implementing

Regulation 2018/574) for manufacturers situated outside the EU territory?

If the answer to Question 1 is in the negative, in our understanding [REDACTED] would need to be equipped with an anti-tampering device, but only starting as of May 20<sup>th</sup> 2020 (as they handle the production of [REDACTED])

No further derogations are foreseen for anti-tampering devices beyond those set out in Article 7 (a) – (c). If the legal entity in question – or, where applicable, the group of undertakings to which it belongs – will handle less than 120 million unit level UIs at Union level during the year 2019, the obligation to install an anti-tampering device shall apply as of 20 May 2020.

Thank you a lot for your feedback, as we remain at your disposal in case of any questions,

Best regards,

[REDACTED]



Landewyck Tobacco S.A.

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T: [REDACTED]  
F: [REDACTED]

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