Document 07

BRITISH AMERICAN TOBACCO

Aarlenstraat 80 Rue d'Arlon
B-1040 Brussels
Belgium

Tel +32(0)2/627 88 80
Fax +32(0)2/627 88 81

Ms Anne Bucher
Director General for Health and Food Safety
Directorate-General for Health and Food Safety (DG SANTE)
European Commission

Cc:
Mr Martin Selmayr
Secretary-General of the European Commission
Secretariat General
European Commission

[redacted] – Cross Border healthcare and Tobacco Control
Directorate-General for Health and Food Safety (DG SANTE)
European Commission

Brussels, 23rd April 2019

Dear Ms Bucher,

We are writing to you in relation to an urgent matter regarding the EU traceability system for tobacco products.

We are fully committed to do everything within our power to implement a functioning traceability system as soon as possible. Indeed, our internal traceability solution has been tested and is fully operational. However, due to the nature of the system and the supply chain, the EU-wide traceability system will not work without operational ID Issuers in all Member States and a functioning Secondary Repository.

Under the scheme established by Article 15 of the Tobacco Products Directive 2014/40/EU (the "TPD"), together with Commission Implementing Regulation (EU) 2018/574 of December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products (the "IR"), it is clear that the Commission is responsible for ultimately ensuring the establishment of the traceability system by 20 May 2019.

Due to a series of issues (some of which are set out in the Annex to this letter), it is becoming increasingly likely that the system will not be operational on time. As such, it is possible that British American Tobacco ("BAT") and other manufacturers could be prevented from placing their products on the market on the basis that they do not comply with a traceability system – despite the fact that such a system is not yet in place, due to factors that are outside of our control. This would have a severe and detrimental impact on BAT and the tobacco supply chain as a whole, as well as Member States' revenue streams. It is also likely to increase opportunities for illicit trade, which the traceability system was intended to counter. Some background information that you may find useful on the inter-dependencies of the various parts of

BRITISH AMERICAN TOBACCO

the traceability system and the issues that have contributed to the delay, is set out in the Annex.

We have raised these practical issues in our previous correspondence with DG SANTE, copies of which are enclosed for your information. However, [redacted] response of 9 April 2019 does not offer a practical solution. In particular, [redacted] advised that BAT should make use of the transitional provisions of Article 37(1) of the IR, which provide a one-year grace period for non-compliant products manufactured or imported before 20 May 2019. As explained in our response of 11 April 2019, this is not practically or operationally possible. Further, even if it were possible, building up stock in this way, to mitigate issues that are outside of our control, not only places a disproportionate burden on manufacturers with significant financial implications, it also does not resolve the underlying issues in any way.

We continue to be fully committed to do everything we can to implement a functioning traceability system as soon as possible. However, the traceability system requires a functioning Secondary Repository and operational ID Issuers in all Member States, neither of which we are likely to have in time for the 20 May 2019 deadline.
Given that the deadline is less than a month away, quick and decisive action from the Commission provides the only possible solution. We urgently and respectfully request that the Commission either: (i) amends Article 37(1) of the IR and extend the transitional provision to apply to cigarettes imported or manufactured before the date when the traceability system becomes fully functional; or
(ii) issues interpretative guidance to the Member States confirming that, until the traceability system becomes fully operational, there can be no legal obligation for economic operators to comply with the requirements of a traceability system.

We would like to bring to your attention that, unless the Commission takes appropriate action as a matter of urgency, we will face significant losses. We hope that the Commission will appreciate the seriousness of the issue and take the necessary steps to remedy the situation as soon as possible. We request a meeting with you to discuss the problems and possible solutions at your earliest convenience.

Yours sincerely,

[redacted]

[redacted]

Encs.
(1) Letter from BAT [redacted] dated 5 March 2019
(2) Email from [redacted] to BAT dated 9 April 2019
(3) Letter from BAT [redacted] dated 11 April 2019

ANNEX

Additional Information Relating to the Traceability System

(1) The complexity and inter-dependence of the various parts of the traceability system

Article 15 of the Tobacco Products Directive 2014/40/EU (the "TPD") introduced what amounts to the most extensive traceability system for any product in the world. In essence, the traceability system enables the tracking of each individual cigarette pack from its manufacture in, or import into the European Union, all the way through the supply chain to the final retail outlet.

The specific details of the traceability system are set out in Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products (the "IR"). In particular, under the IR, each Member State is required to appoint an "ID Issuer", which is responsible for issuing "unique identifiers" in that Member State for unit packs, as well as identifier codes for all economic operators involved in the supply chain, including their facilities and machines used to manufacture tobacco products. To allow for immediate and full traceability down to the pack-level, each economic operator in the supply chain is required to record virtually every movement of every cigarette pack with reference to the above identifiers, and also the relevant invoices and payment records.

The relevant information is to be collected and made accessible through a two-level repositories system. Manufacturers and importers appoint so-called "Primary Repositories" which host information relating to that particular manufacturer or importer. Data from each Primary Repository is then instantaneously forwarded to a single "Secondary Repository" for the whole of the EU. This Secondary Repository is effectively the gateway through which the Commission and Member States' authorities can access all information relating to the manufacturing and transportation of each pack, essentially in real time.

In short, the EU traceability system is extremely complex and requires the proactive involvement of a vast number of independent actors for it to function. Moreover, the technology used by each individual actor must be interoperable with that used by the others. As such, the traceability system can only work if each and every individual component of the system functions properly on its own, as well as with all other parts. Furthermore, a project of this magnitude requires significant time for a proper implementation, including testing and lead-in periods.

(2) The issues that have arisen in establishing the traceability system

Under Article 15(13) of the TPD, the traceability system is to apply to cigarettes and roll-your-own tobacco from 20 May 2019. To summarise, the traceability system will not be operational on time for the following reasons:

- Delays by the Member States in appointing their ID Issuers, with the result that a significant number of the ID Issuers will not be operational by 6 May 2019 deadline, which will have a knock-on effect on the whole system being ready to "go live" on 20 May 2019.

- Delays relating to the Secondary Repository, both in terms of it issuing final specifications by 21 February 2019 and the Secondary Repository being made available for testing by 20 March 2019, as required by the IR.

Delays in the appointment of ID Issuers

Broadly speaking, ID Issuers have two areas of responsibility. Once an ID Issuer is appointed by a Member State, with respect to each area of responsibility, the following steps need to be completed in order to have a fully operational ID Issuer that can generate and issue the identifier codes required under the traceability system:

Part 1: Registration of economic operators

- ID Issuer develops a system to process, generate, register and issue identifier codes.

- ID Issuer makes available to economic operators a system (e.g. a website) that could be used for registration. The system should be ready to process such registration in the manner and the scale that is required.

- Upon registration, ID Issuer issues identifier codes for each economic operator, including identifier codes for facilities, factories, warehouses, local depots and individual machines.

Part 2: Supply unique identifiers for unit packs

- ID Issuer develops a system which sets out, for example, how the unique identifiers would be ordered / issued and how the payments would be made.

- ID Issuer releases specifications to the manufacturers. All economic operators then have to make adjustments to their own systems to make them compatible with the specifications set out by each of the 28 ID Issuers. The specifications must be clear and sufficiently detailed so that all economic operators interpret the requirements in the same way.

- The systems of the ID Issuer and the manufacturer go through a process of integration and testing to ensure that the interface between all the systems functions correctly. Multiple systems need to be interfaced, including that of the ID Issuer, Router, Primary Repository and Secondary Repository. For example, an ID Issuer transmits the unit level identifier codes via the Router to the Primary Repository of the requesting manufacturer or importer. The ID Issuer also needs to submit the data that they receive to the Secondary Repository. Given the cross-border nature of the supply chain, this process is likely to involve multiple Member States. For example, a pack will have a code issued by the Polish ID Issuer if it was manufactured in Poland. However, authorities in other Member States need to be able to check that the Polish code is valid. This verification can only be done through the Secondary Repository.

There are approximately 900,000 economic operators operating in the EU that need to be registered. Because of the sheer number of registrations that need to be completed, even if all ID Issuers are fully operational by 6 May 2019 (which is the applicable deadline under Article 3(1) of the IR), it would still be extremely difficult, if not impossible, to have all economic operators registered in time for the system to "go live" on 20 May 2019. Further, our experience shows that testing interfaces between the systems and making any necessary adjustments take approximately two months. In light of the above, in practice, in order for the system to "go live" on 20 May 2019, the ID Issuers' user platforms need to be available for registration by economic operators as soon as possible.

Further, we note that there are some discrepancies between the self-reported status of the Member States with respect to the level of their ID Issuer's preparedness and what we have seen in our dealings with the Member States.

- Notwithstanding the urgency in ensuring that the ID Issuers are operational, as of 23 April 2019, only two Member States – Croatia and Germany – have ID Issuers that have been duly appointed and have been confirmed to be fully operational through testing.

- Most Member States have indicated that they have appointed ID Issuers. However, we estimate that only a handful of Member States will have ID Issuers that will be in the position to issue codes by 6 May 2019. For example, we estimate that only the ID Issuers for Belgium, Czech Republic, Denmark, Ireland, Italy, Latvia, Lithuania, Luxembourg and Netherlands may be fully operational by 20 May 2019.

- Some Member States have indicated that they have appointed ID Issuers but, given the progress made to date and the steps that still need to be completed in order to become fully operational, it is unlikely that they will have an ID Issuer that is fully operational by 6 May 2019. Member States that fall into this category are Austria, Bulgaria, Hungary, UK, Malta, Spain, Cyprus, France, Sweden, Greece and Romania.

Failure by the Secondary Repository to issue its specifications on time

The Secondary Repository is responsible for providing: (i) the data dictionary, which sets out the specifications of information describing the contents, format, and structure of a database and the relationship between its elements (which are used to control access to and manipulation of the databases common for all Primary and Secondary Repositories); (ii) the list of specifications required to allow the data exchanges with the Secondary Repository; and (iii) a Router, which is a device established within the Secondary Repository that transfers data between different components of the repositories system. Without a Secondary Repository, the traceability system cannot function, even if all Member State ID Issuers are fully operational.

Once the Secondary Repository publishes the data dictionary and specifications, all manufacturers and economic operators need to adjust their systems to comply with those specifications. Building the solution to the specifications ensures that the entities involved in the supply chain are sending and receiving correct information that is readable and verifiable across the supply chain, in compliance with the specification.

The Secondary Repository published its specifications (version 1) on 21 February 2019. Subsequent updates to its specifications were made on 8 March 2019 (version 1.1) and 29 March 2019 (version 1.2). These updates introduced ambiguities, some of which have still not been clarified. The risk of such ambiguities is that there could be varying interpretations and approaches by different operators that could, in turn, undermine the integrity and effectiveness of the traceability system.

Primary Repositories were notified at the meeting of the Subgroup on Traceability and Security Features on 12 April 2019 that further updates will be released on 28 April 2019. The expectation is that these will clarify existing issues, not introduce new ones. However, that remains to be seen.

In the meantime, DG SANTE's note of 15 April 2019, following the Subgroup meeting of 12 April 2019, introduced a new layer of complications. The result is that the tobacco supply chain is now waiting for the publication of the updated specifications from the Secondary Repository reflecting the latest changes to the unit pack coding structure. These changes will require significant software changes to the economic operators' systems to process the precise format of code. These software updates are unlikely to be achievable in the remaining timeframe.

Under Article 28(1) of the IR, the final specifications should have been issued by 21 February 2019 and the repositories system should have been available for testing purposes by 20 March 2019. As explained above, we are expecting further updates to the specifications on 28 April 2019 and we understand that the Secondary Repository will not be made available for testing until 10 May 2019, only 10 days before the "go live" date.

BRITISH AMERICAN TOBACCO

[redacted] Rue d'Arlo
sels

[redacted] - Cross Border Healthcare and Tobacco Control
Directorate-General for Health and Food Safety (DG SANTE)
European Commission

Dear [redacted]

The Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products placed an obligation on the Member States to appoint entities capable of generating and issuing unique identifiers by 6 May 2019.

We are concerned that some Member States may understand that a decision on which entity could potentially perform these duties is enough to comply with this requirement. You will be aware, however, that the correct reading of this obligation is that those entities must be fully operational by 6 May 2019, so that the traceability system envisaged by the Tobacco Products Directive is ready to go-live shortly thereafter on 20 May 2019.

As part of this, there must be sufficient time for the systems of the ID Issuers to interface with those of the tobacco manufacturers. It is our experience, after the work of integration carried out in Croatia, that a period of two months is required for that interface process. Both the ID Issuers and the manufacturers require this time to carry out detailed design, build and test activities if there is to be an appropriate, efficient interface.

While several Member States have designated ID Issuers, as evidenced in the Annex to the Summary Record of the Meeting of the Expert-Subgroup on Traceability and security Features of 17 January 2019, those have not yet shared their technical specifications, which are critical so that the interface process may be undertaken.

We are engaging with the Member States to expedite this. However, we would request that if the designated ID Issuers have not shared their technical specifications by 20 March 2019, or if some of the Member States still have not designated an ID Issuer, the Commission exercises its right under Article 4(5) of the Implementing Regulation and authorises economic operators to use the services of another ID Issuer for which the interface process has been completed.

BRITISH AMERICAN TOBACCO

In terms of a specific alternative ID Issuer, we would suggest AKD d.o.o. in Croatia, which is fully operational and has made its comprehensive technical specifications available.

We look forward to your assistance in ensuring we can work to support the EU goal of establishing a traceability system for tobacco products.

Yours faithfully,

[redacted]

From: [redacted]
Sent: 09 April 2019 10:40
To: [redacted]
Cc: [redacted] SANTE-B2-TOBACCO-CONTROL@ec.europa.eu
Subject: FW: Track& Trace: UID issuers appointment

[This is an EXTERNAL email]

Dear [redacted]

Thank you for your letter, in which you share your concerns relating to the national appointments of the ID issuers required under the EU system of tobacco traceability.

We note your request to apply the provision stipulated in Article 4(5) of Commission Implementing Regulation 2018/547, by which in the temporary absence of an ID issuer, the Commission may authorise economic operators to use the service of other appointed ID issuers. However, you should be aware that Article 4(5) is subject to several legal limitations which are being currently carefully considered and analysed.

As you have noted, the Commission has been acting in a highly transparent manner and documents the progress achieved by individual Member States, as regards the ID issuers, in the publicly available reports from the regular meeting s of the Expert Subgroup on tobacco traceability and security features.

The next meeting of the Expert Subgroup will take place in the coming days. Based on the information gathered during that meeting, we will be considering eventual further steps. Please rest assured that we will do our utmost to assist Member States in their remaining tasks.

At the same time, we are sure that your company, as a professional operator, is fully aware of Article 37 of the Implementing Regulation, which provides for a certain margin of security in terms of the continuity of supplies to the consumers.

Kind regards,

[redacted]
European Commission

[redacted] – *B2: Cross-border healthcare and tobacco control*
Directorate-General for Health and Food Safety
Office [redacted]
Rue Breydel 4, B-1049 Brussels
[redacted]
Email: [redacted]

From: [redacted]
Sent: Tuesday, March 05, 2019 5:13 PM
To: [redacted] (SANTE)
Cc: SANTE B2 TOBACCO CONTROL; [redacted] (SANTE)
Subject: Track& Trace: UID issuers appointment

Dear [redacted],

I hope this email finds you well.

Please find attached a letter that you will also receive via ordinary mail. It refers to tobacco traceability and the appointment of ID issuers by the Member States. BAT proposes the temporary use of the ID issuer appointed by Croatia (AKD d.o.o.) in those Member States that will not be able to share the technical specifications required for the interfacing with the manufacturers by 20 March 2019. AKD d.o.o. is, at present, the only fully operational ID issuer in the EU.

I remain at your disposal to provide any additional information you may need.

Best regards,

[redacted]
British American Tobacco
Aarlenstraat 80 Rue d'Arlon
B-1040 Brussels
Belgium
Tel +32 (0)2 627 88 83
[redacted]

BRITISH AMERICAN TOBACCO

Aarlenstraat 80 Rue d'Arlon
B-1040 Brussels
Belgium

Tel +32(0)2/627 88 80
Fax +32(0)2/627 88 81

[redacted] – Cross Border Healthcare and Tobacco Control
Directorate-General for Health and Food Safety (DG SANTE)
European Commission

Brussels, 11th April 2019

Dear [redacted]

Thank you for your email dated 9 April responding to our letter of 5 March concerning the lack of national appointments of ID issuers required under the EU traceability system for tobacco products.

Unfortunately, in the meantime, the situation has become more serious and it is now clear that the traceability system will not be operational on time since:

a. Numerous Member States have not yet appointed their ID issuer and it may be that certain Member States will fail to appoint a fully operational ID issuer by the deadline of 6 May;

b. Although many Member States may have technically selected their ID issuer by 6 May, this will not in itself result in a functioning system (or true "appointment" as required by Commission Implementing Regulation 2018/547 ("**IR**")). The tracking and tracing regime can only function from 20 May if all ID issuers are fully operational and manufacturers have had sufficient lead-in time to ensure that their systems can interface with those of the ID issuers (a process that takes approximately two months);

c. It has not been possible for the provider operating the secondary repository to communicate the final specifications for the data exchange and the common data dictionary within the deadline provided for by Article 28 IR (21 February). Subsequent updates to the secondary repository's specifications were made available on 8 March and 28 March. As such, the repository system was not available for testing purposes by 20 March, as required by Article 31 IR;

BRITISH AMERICAN TOBACCO

d. The subsequent updates to the secondary repository's specifications introduced a number of additional uncertainties. Please note that certain ambiguities still exist today and that they could result in varying interpretations and approaches by different operators which could, in turn, undermine the integrity and effectiveness of the system; and

e. ID issuers will need time to ensure that their systems can interface with the secondary repository, once this becomes available for testing.

Due to its nature, manufacturers cannot comply with the requirements of a traceability system that is not fully functioning across all Member States. The fact that the wording of applicable EU and Member State law nevertheless requires compliance from 20 May raises a range of significant practical and legal difficulties for all involved, including the Commission, Member States, manufacturers and the numerous other economic operators in the distribution chain.

In your email dated 9 April, you suggest that we make use of the transitional provision of Article 37(1) IR, providing a one-year grace period for non-compliant product manufactured or imported before 20 May 2019.

Like any other efficient producer of fast-moving consumer goods, BAT does not have the spare manufacturing capacity to produce both its normal volumes and the volumes it would sell between 20 May 2019 and the time that the traceability system becomes operational across the EU. Further, even if BAT did have spare manufacturing capacity, the rotating health warnings required by Article 10(2) of the Tobacco Products Directive (2014/40) make it impossible to produce stock so far in advance. Many Member State authorities choose the rotating health warnings only a few weeks before these must appear on the packs. Indeed, manufacturers cannot produce future stock in advance, without the information on the health warning requirements from the Member States. Finally, BAT always took the view that building up an unusual volume of stock with the aim of exploiting the transitional provision of Article 37 would undermine the effectiveness of the traceability system that was legally required to be fully functional from 20 May 2019 onwards.

BRITISH AMERICAN TOBACCO

In order to avoid the serious disruptions to the supply chain and the legal problems that may arise, it is now essential that the Commission provides guidance on how to proceed with the implementation of the EU traceability system.

BAT cannot ensure compliance on its own since the functioning of the traceability system is the result of many different public and private actors working together. BAT remains committed to do everything within its power to implement a functioning traceability system as soon as possible. That said, we require a minimum level of legal certainty for the coming months.

In light of your response from yesterday, we would like to discuss the issues with you as a matter of urgency.

Yours faithfully,

[redacted]

[redacted]

[redacted]

PRIOR

1000
23.4.19-16

BRUSSEL LIVINGSTONE
BRUXELLES LIVINGSTONE

BELGIQUE
BELGIE
€ 8,81
PRIOR

3

European Commission
[redacted]
DG Health and Food Safety
Office B232[redacted]
Rue Breydel 4 / Breydelstraat 4
B – 1049 Brussels