Public consultation on the implementation of an EU system for traceability and security features pursuant to Articles 15 and 16 of the Tobacco Products Directive 2014/40/EU

Fields marked with * are mandatory.

Introduction

This is a public consultation on the implementation of an EU system for traceability and security features for tobacco products, as required under Articles 15 and 16 of the Tobacco Products Directive 2014/40 /EU (TPD). The purpose of this consultation is to seek comments from the general public and interested parties, such as consumers, retailers of finished tobacco products, manufacturers of finished tobacco products, wholesalers and distributers of finished tobacco products, providers of solutions for operating traceability, security feature or data storage systems, and governmental and non-governmental organisations active in the area of tobacco control and the fight against illicit trade.

The basis for the consultation is the Commission's Inception Impact Assessment. This document develops the main policy options currently under consideration for implementing the system for traceability and security features provided for under Articles 15 and 16 TPD. These policy options are outlined in Table 4 of the Inception Impact Assessment (page 8).

As the objective of this public consultation is, among others, to gain confirmation or otherwise of the assumptions made regarding the policy options mentioned above, **those participating are strongly advised to review the Inception Impact Assessment before responding**. The comments received in the course of this consultation will provide input for the ongoing implementation work on the future EU system.

Stakeholders are invited to submit their responses to this consultation via the survey form below until **4 November 2016**.

The survey form consists of closed and open questions. For open questions stakeholders will be asked to provide comments up to the limit of characters indicated in the question. Submissions

should - where possible - be in English.

In the case of corporate groups, one single reply should be prepared. For responses from governmental organisations not representing a national position, the reply should explain why the responding body is directly affected by the envisaged measures.

The information received will be treated in accordance with Regulation 45/2001 on the protection of individuals with regard to the processing of personal data by the Community (please see here for information on rules governing personal data protection and consult the privacy statement provided on the consultation webpage). In the case of submissions by corporate groups, respondents are asked not to upload personal data of individuals.

Please note that organisations falling under the following respondent groups should register in the Transparency Register before they begin to answer the questions:

- Manufacturers of tobacco products destined for consumers (finished tobacco products)
- Operators involved in the supply chain of finished tobacco products (excluding retail)
- Providers of solutions for operating traceability, security features or data storage
- Non-Governmental Organisations

The submissions of non-registered organisations will be published separately from those of registered ones and considered as the input of individuals.

The Commission reserves the right to contact you to request further explanation and/or justification of your calculations and/or the reasoning on which your responses rely. You may also be requested to provide further evidence for your detailed replies.

Answers that do not comply with the overall specifications outlined above cannot be considered.

A. Respondent details

*A1. Please identify which respondent group you fall under:

- ☐ a) Consumer/member of the general public
- ☐ b) Retailer of finished tobacco products
- ☐ c) Manufacturer of tobacco products destined for consumers (finished tobacco products)
- ☑ d) Operator involved in the supply chain of finished tobacco products (excluding retail)
- ☐ e) Provider of solutions for traceability, security features or data storage
- ☐ f) Governmental organisation
- ☐ g) NGO
- ☐ h) Other organisation

If you fall under groups **b)**, **c)**, **d)** or **e)** above, please indicate if you are a small or medium sized enterprise as defined in [Commission Recommendation 2003/361/EC](#) (i.e. an enterprise which employs fewer than 250 persons and which has an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.)

- ○ Yes
- ⦿ No

If other, please specify

Text of 1 to 800 characters will be accepted

If other, please specify

Text of 1 to 800 characters will be accepted

A5. If you fall under respondent group **d)** above, please indicate your main area(s) of activity:

- ☑ Importer
- ☑ Distributor
- ☑ Wholesaler
- ☑ Warehouse operator
- ☐ Other

B. Respondant contact details

B2. In the case of organisations, please provide the organisation's name, address, email, telephone number and, if applicable, name of the ultimate parent company or organisation (if possible, please do not include personal data)

Text of 1 to 800 characters will be accepted

```
COMPAÑÍA DE DISTRIBUCIÓN INTEGRAL LOGISTA HOLDINGS, S.A.
Adress:C/ Trigo, 39. Polígono Industrial Polvoranca
C.P. 28914 (Leganés), Madrid
```

B3. Please indicate if your organisation is registered in the Transparency Register of the European Commission* (unless you fall under respondent groups **a)**, **b)** or **f)** of Question 1A above):
(**Please note that organisations falling under the relevant respondent groups should register in the Transparency Register before they begin to answer the questions. The submissions of non-registered organisations will be published separately from those of registered ones and considered as the input of individuals.*)

- ◉ Yes
- ○ No

If you indicated yes, please enter your Transparency Register registration number:

Text of 1 to 20 characters will be accepted

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462081624095-48
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Where applicable please upload extract from the trade or other relevant registry confirming the activity indicated under Question A1 (English translation where possible)

* B4. Please state your preference with regard to the publication of your contribution
(*Please note that regardless of the option chosen,your contribution may be subject to a request for access to documents under Regulation 1049/2001. In such cases, the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules.*)

- ◉ My contribution may be published under the name indicated; I declare that none of it is subject to copyright restrictions that prevent publication
- ○ My contribution may be published but should be kept anonymous; I declare that none of it is subject to copyright restrictions that prevent publication
- ○ I do not agree that my contribution will be published at all.

C. Consultation questions

Please carefully read the Inception Impact Assessment document before answering the questionnaire   5

Questions on the governance model

* C1. Out of the three governance models outlined in the Inception Impact Assessment for the traceability system for tobacco products, which one do you consider most suitable for operating the traceability system from your perspective:

- ● Option A1: industry operated solution
- ○ Option A2: third party operated solution
- ○ Option A3: mixed solution (industry and third party)
- ○ No opinion

* C2. Do you agree that the industry operated model (option A1) will require, on the part of the public authorities, additional control measures to ensure traceability of tobacco products?

- ○ Yes
- ● No
- ○ No opinion

* C3. Do you consider that traceability of tobacco products can only be achieved on condition that the supply chain is controlled by a third party independent from the tobacco industry?

- ○ Yes
- ● No
- ○ No opinion

* C4. If options A1 and A2 are to be compared in terms of their overall impact on cost per pack of product (excluding potential additional costs for the public authorities related to monitoring and enforcement in option A1), do you consider*

- ● Option A1 to be cheaper than option A2
- ○ Both options to have the same cost impact
- ○ Option A1 to be more expensive that option A2
- ○ No opinion

Subquestion a) to question C4: What is your estimate of the average likely increase in the cost of a pack of product that would be incurred in establishing and operating the traceability system under option A1 (in Euro, ex-factory level, before taxes. If relevant please indicate an exchange rate)?
Please outline your justifications/reasoning for this estimate including a clear indication of your sources of information. If needed please indicate how your estimate may differ for different categories of products

Text of 1 to 1500 characters will be accepted

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As many critical issues are still pending to be defined, it is not just
impossible but absolutely not prudent to provide any estimation in the
proposed terms. Among these issues it is mandatory to univocally define the
role and liability of the distributors and transport companies.

Although these pending clarifications from final implementing acts, Logista
has already a high level estimation of the impacts of the implementation of
traceability.

Our cost estimation includes:

1.       Depreciation of investments in IT and Installations, including a T&T
data base to store and communicate T&T events, accounting for around 20% of
annual T&T running costs.
2.       Operating costs. Accounting for some 80% of the additional annual
costs. It is important to mention that operating costs resulting of
productivity downgrade (which according to our first estimations could
represent 30% downgrade in manual process) amounts to 60-70% of annual costs

Logista is willing to share its knowledge and its estimations in the frame of
Stakeholders workshops to be organized by EU. As there are a large set of
open points pending to be clarified by EU and directly impacting future T&T
cost base, Logista is not providing any detailed figure in response to this
consultation because we believe that it is absolutely mandatory to have these
topics cleared and understand first Logista complexity and the major
hypothesis assumed to built up our estimation.
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Subquestion b) to question C4: What is your estimate of the average likely increase in the cost of a pack of product incurred in establishing and operating the traceability system under option A2 (in Euro, ex-factory level, before taxes. If relevant please indicate an exchange rate)?

Please outline your justifications/reasoning for this estimate including a clear indication of your sources of information. If needed please indicate how your estimate may differ for different categories of products

Text of 1 to 1500 characters will be accepted

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Considering our preference for cheaper A1 solution, not only will the cost of
proprietary solutions operated by a single player always be higher than an
open standard solution (ensuring a competitive environment), but that such A2
solution will be practically unfeasible as Logista supply chain is managed by
highly complex systems and any ad-hoc traceability system would not be able
to trace the items accordingly.
Needless to mention potential discretionary royalties for the use of licenses
for that proprietary solution would add burden to the system.
This complexity requires full integration between new T&T components and
existing systems within Logista, and the only way is the use of open
standards which allow their seamless implementation in the existing systems.
On top of that, there will be a need of huge investments to adapt all EU
sites, and regarding implementation of this 3rd party solution, there will be
a need of maintenance staff on every site throughout EU sites to avoid
downtimes, and we foresee great difficulties in signing Service Level
Agreements between operators and T&T solution provider, as this 3rd party
will have to ensure no disruption will be caused by the T&T solution.
Finally if the EU commission will is to respect the EUTPD deadlines,  the
unique possible System alternative  is the System already used by major
players of Tobacco industry and tested in 3 major markets. Any other solution
will necessarily require of significant additional delays.
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* C5. Do you agree that a mixed model of governance, in which the choice of governance is separately made with respect to each distinct technological block/process (e.g. generation, printing/affixing and visual control of a unique identifier) can both provide for full traceability of tobacco products and mitigate the overall public-private cost of establishing and operating the system?

- ○ Yes
- ● No
- ○ No opinion

C6. Would you like to add any comments or suggestions on the choice of the governance model?

Text of 1 to 1500 characters will be accepted

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Only when the whole supply chain is gone through, we may have all T&T data
required in the EUTPD data base, such as identification of final retail
customer, invoicing and payment terms. Thus, only one entity should be
responsible for all information in the system (unique Ids, aggregation and
all downstream data to be added) according to EUTPD requirements, as this
information may include very sensitive information of supply chain operators
(distributors, wholesalers)
In our opinion, 3 different factors must be balanced to make the right choice:
-        Cost of the solution
-        Timing (not only considering the deadline of May 2019)
-        Final Reliability (according to the required supervision procedures).
While the two first ones are clearly covered by an industry operated solution
which is already operative and tested, the last one will be ensured with
proper control tools and procedures for regulatory bodies.
Additionally, beyond the simple comparison we really doubt of the feasibility
of a 3rd party solution for large distributors and manufacturers as explained
in previous questions.
The FCTC protocol just requires control of T&T systems by Governments, and
therefore, there is no need to go beyond, so considering this very relevant
point, and the huge difference between implementing a new, not-tested
solution and an already running and tested one in terms of cost and
effectivenes, there is no doubt that a industry operated solution is the best
choice for the governance model.
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Questions on the data storage location

* C7. Out of the two data storage locations outlined in the Inception Impact Assessment, which option
do you consider most suitable from your perspective:

- ○ Option B1: centralised data storage
- ● Option B2: decentralised data storage
- ○ No opinion

* C8. Do you agree with the assumption made in the Inception Impact Assessment (p. 12) that
centralised data storage can provide for important economies of scale (construed as savings in costs
gained by an increased level of centralisation), in particular given the related costs of interconnectivity
and interoperability present in the option of decentralised data storage?*

- ○ Yes
- ● No
- ○ No opinion

Subquestion to question C8: Please provide the reasoning for your response

Text of 1 to 1500 characters will be accepted

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On one hand, while a single destination repository clearly simplifies the
data handling at the source, as not splitting/filtering of events is
required, it's also true that the burden is transferred to the central
repository arising doubts about the feasibility and/or operability of such a
huge system (in terms of proper response times or any potential downtimes).
On the other hand, a decentralised model will bring the complexity to the
event sender party due to the higher processing and more complex management
to filter/split the captured information to different destinations.
This complexity generated by the decentralisation could be mostly offset with
the creation/use of a HUB-dispatcher where all the economic actors of the
supply chain (mostly distributors – wholesalers) could deliver T&T
information of all Products /Tobacco manufacturers to be split and diverted
based on product Master data to the decentralised data storage. This HUB
could also operate as a Master Data validating tool for the whole system.
Therefore, these volume and performance indicators must be balanced between
sender and recipient parties to obtain the most suitable solution in terms of
cost and efficiency.
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* C9. Which type of data storage represents higher risks in terms of time required to access data and/or potential downtimes?*

- ● Centralised data storage
- ○ Decentralised data storage
- ○ No opinion

Subquestion to question C9: Please provide the reasoning for your response

Text of 1 to 1500 characters will be accepted

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Larger data bases do always imply worse response times, as they need to dig
into a larger amount of data, and consequently also a higher likelihood of
potential downtimes, meaning probably higher hidden costs for the overall T&T
solution, as downtimes would surely affect all economic agents involved in
the tobacco supply chain (manufacturing premises, distributors,
wholesalers...).
We should bear in mind that the T&T data base should cope with around 20.000
tobacco SKUs, 200 tobacco manufacturers and importers , over 10.000 supply
chain operators, which represent a very ambitious scope and an enormous
amount of data and responsibility.
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* C10. In the case of a decentralised data storage, how should data be split among individual data storages:

- ◯ Geographic decentralisation with regional/national data storages
- ⦿ Product decentralisation with all the data on a single product stored in one place
- ◯ Other option
- ◯ No opinion

* C11. If the option of geographic decentralisation of data storages is considered, the relevant data on a given product should be placed

- ◯ In the storage of the region/country of product origin
- ⦿ In the storage of the region/country of intended retail market
- ◯ In all the regional/national data storages of a given product's presence, incl. transit countries
- ◯ No opinion

*Subquestion to question C11: Please provide the reasoning for your response

Text of 1 to 1500 characters will be accepted

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Geographically decentralised data bases also raises in all cases some doubts
as it may leave some products out of data bases in initial phases if
decentralisation is performed according to manufacturing country or intended
market of sale (if intended sales market is still unknown as in product to be
exported outside EU, or products manufactured outside EU), or throughout
international transits crossing several EU countries for product presence
decentralisation.
There are also some special sales market, such as Duty Free shops throughout
the EU, which may become quite difficult regarding how to be traced as same
product may be directed to different Member States Duty Free retails without
been known at the moment when the product is manufactured.
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C12. Would you like to add any comments or suggestions on the choice of the data storage location?

Text of 1 to 1500 characters will be accepted

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The EU centralised data base raises some technical issues, including its
feasibility, regarding responses times and potential downtimes.
Geographically decentralised alternative also raises some black areas for
certain products and/or situations of the products throughout the supply
chain.
We suggest tackling data storage decentralisation in a manufacturer and/or
importer based alternative, as manufacturer/importer of a single product
remains the same at any stage of the product lifecycle.
Furthermore, based on the experience the technology providers and the
industry, there is a third option which combines both options B1 and B2.
This option will be based on decentralized data storage but with central
component which will receive all the events and dispatch only the information
corresponding to each repository.
Additionally it should also hold a central registry of all products, ensuring
the interoperability of all data storages.
This component under supervision of the EU authorities would also be an
efficient and powerful tool to control all the system without the huge cost
of a single repository.  This component could keep the events for a limited
period of time, allowing the required supervision while the historical data
(which in fact represents most of data storage cost) will be kept in the data
storages.
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Questions on the allowed data carriers

* C13. Out of the three options for data carriers outlined in the Inception Impact Assessment which one do you consider most suitable for operating the traceability system from your perspective

- ○ Option C1: system with a single data carrier
- ● Option C2: system with a limited variety of data carriers
- ○ Option C3: free system allowing any exisiting data carrier
- ○ No opinion

* C14. Do you agree with the assumption made in the Inception Impact Assessment (p. 12) that a system with a single data carrier may offer insufficient flexibility in view of different requirements of various economic operators, including small and medium enterprises?

- ● Yes
- ○ No
- ○ No opinion

* C15. Do you agree with the assumption made in the Inception Impact Assessment (p. 12) that a free system (allowing any existing data carrier) introduces a risk that certain data carriers will not be readable by all the scanners installed in the system and that its functioning would require frequent updates of the scanners, which may not be technically feasible and/or economically viable?

- ● Yes
- ○ No
- ○ No opinion

Subquestion to question C15: Please provide the reasoning for your response

Text of 1 to 1500 characters will be accepted

> There is not just a risk but drastic productivity downgrade in data acquisition (scanning) all along the supply chain, and therefore enormous additional costs and huge complexity in distribution operations. Not standardized qualities, sizes and/or positioning will lead to potential errors (in both manual and automated operations) and longer operation times for every single manual scanning operation.

C16. Would you like to add any comments or suggestions on the choice of the allowed data carriers?

Text of 1 to 1500 characters will be accepted

> Selected data carriers should be based on international standards (GS1). A limited short list should be defined to mitigate the impact in some activities throughout the tobacco supply chain, where there are a wide variety of reading condition in terms of time or space/distance for printing and scanning of products.
> Logista recommends a set of unique GS1 data carriers for every packing level, based on the real-life pilot tests currently running in 3 of the major EU markets: Spain, France and Italy.
> According to these tests and the work done by Logista during the last years, the proposed carriers per packing level are:
> •   Cartons: 2D data matrix due to the limited packing surface available.
> •   Mastercases: Both GS1-128 (1D) and Data Matrix (2D) together to cover all conditions and readings to be performed. 1D for long distance readings in the warehouse, and 2D for manual handling (truck/vans)
> •   Pallets: Both GS1-128 (1D) and Data Matrix (2D) together to cover all conditions and readings.
> •   Regarding packs, which are not very commonly read/scanned throughout the supply chain (mostly in reverse logistics and special flows) we have successfully tested ISS Dotcode as it supports high speed printing in current Tobacco manufacturing processes. ISS Dotcode is immersed in a process to become become a GS1 standard data carrier for products requiring of high speed manufacturing processes.

Questions on the allowed delays in reporting events

* C17. Out of the three options for the allowed delays in reporting events outlined in the Inception Impact Assessment, which one do you consider most suitable for operating the traceability system from your perspective:

- ○ Option D1: real-time (or limited delay – max. several minutes – reports)
- ● Option D2: once daily reports
- ○ Option D3: once weekly reports
- ○ No opinion

* C18. Do you agree with the assumption made in the Inception Impact Assessment (p. 12) that option D1, which envisages real-time reporting (or limited delays of maximum several minutes), would be particularly efficient to track products in transit as it would avoid duplicating scanning operations (e.g. by both a dispatcher/recipient and a transport operator?

- ● Yes
- ○ No
- ○ No opinion

* C19. Do you agree with the assumption made in the Inception Impact Assessment (p. 12) that option D1 (real-time or limited delays of maximum several minutes) would support effective realtime risk analysis so that controls by competent authorities can be better targeted on illicit trade?

- ○ Yes
- ● No
- ○ No opinion

* C20. Do you agree with the assumption made in the Inception Impact Assessment (p. 13) that the once-daily frequency of data uploads provides for important cost savings for the economic operators as compared to the option of real-time reporting (or limited delays of maximum several minutes)?

- ● Yes
- ○ No
- ○ No opinion

Subquestion a) to question C20: What is your estimate of the average likely increase in the cost of a pack of product that would be incurred in operating the traceability system with the option of real-time (or limited delay of maximum several minutes) reporting (in Euro, ex-factory level, before taxes. If relevant please indicate an exchange rate)?

Please outline your justifications/reasoning for this estimate including a clear indication of your sources of information. If needed please indicate how your estimate may differ for different categories of products

Text of 1 to 1500 characters will be accepted

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First of all, feasibility of real time raises certain doubts as certain
operations throughout the supply chain, may not be able to be transmitted on
a real time basis, like for example warehouses or geographical areas with
limited or no coverage for mobile devices which will surely delay
transmission and therefore does not meet real time requirements.
Cost-wise, we cannot nowadays estimate the increase of the cost of real time
reporting, as per example we cannot estimate the need of additional IT
resources, and the huge change in our day-to-day business operations.
Real time itself is a quite complex definition as Logista, as many other
distributors, tend to scan products within its premises taking advantage of
current processes and procedures, and it should be made clear what real time
refers to.
For example, as Logista usually works through highly automated operations,
when we prepare an order in a central warehouse, we scan the products
throughout order preparation, but we may only ship them sometimes even the
day after. Should we therefore read at the moment of preparing or wait until
the moment we are shipping, which would add an enormous complexity and
therefore additional costs to the whole T&T system?
Therefore, as we do not see any significant added value to the system of the
real time transmission, we strongly suggest abandoning this alternative.
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Subquestion b) to question C20: What is your estimate of the average likely increase in the cost of a pack of product that would be incurred in operating the traceability system with the option of once-daily reporting (in Euro, ex-factory level, before taxes. If relevant please indicate an exchange rate)?

Please outline your justifications/reasoning for this estimate including a clear indication of your sources of information. If needed please indicate how your estimate may differ for different categories of products

Text of 1 to 1500 characters will be accepted

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As suggested in the previous answer, we find it very difficult to estimate in
terms of IT additional resources and technical developments to be carried out.
Anyhow, we think our day-to-day business operations would be much less
impacted if compared to the Real Time reporting alternative, despite no doubt
will our business operations be impacted and need significant changes. In
addition, one daily reporting could also make the transport pending issue
irrelevant.
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* C21. Do you agree with the assumption made in the Inception Impact Assessment (p. 13) that the once-weekly frequency of data uploads provides for important cost savings for the economic operators as compared to the option of once-daily reporting?

○ Yes
○ No
◉ No opinion

C22. Would you like to add any comments or suggestions on the choice of the allowed delays in reporting events?

Text of 1 to 1500 characters will be accepted

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We think events should be reported by economic operators in a way which may
affect as less as possible their daily operations, and some self-governance
should be given to economic operators to report all registered movements,
rather than fixed times, which may not adapt to real time operations, which
do vary sensitively depending on external, and impossible to control or even
predict, factors, such as seasonality, product out of stocks, or facilities
incidences.
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Questions on the method of adding a security feature

* C23. Out of the three options for the method of adding a security feature that are outlined in the Inception Impact Assessment which one do you consider most suitable for securing the product from your perspective?

○ Option S1: affixing
◉ Option S2: printing or integrating through a different method
○ Option S3: any method
○ No opinion

* C24. Do you agree with the assumption made in the Inception Impact Assessment (p. 13) that by broadening the range of available methods, it will be easier for economic operators (including small and medium enterprises) to obtain the necessary level of security in a cost-efficient manner?

◉ Yes
○ No
○ No opinion

* C25. How do you rate the importance for consumers of having visible security features on unit packs of tobacco products?

- ○ Important
- ○ Rather important
- ○ Neutral
- ○ Rather unimportant
- ○ Unimportant
- ● No opinion

* C26. Do you consider that enabling individual consumers to decode and verify a serialized unique identifier with mobile devices (e.g. smartphones) would bring added value to the effectiveness of the tracking and tracing system?

- ● Yes
- ○ No
- ○ No opinion

C27. Would you like to add any comments or suggestions on the choice of the method of adding a security feature?

Text of 1 to 1500 characters will be accepted

C28. Please upload any additional comments on the subject of this consultation (max. 5 pages)

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Contact

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