

Targeted stakeholder 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.

This is a targeted stakeholder consultation. The purpose of this consultation is to seek comments from stakeholders:

- directly affected by the upcoming implementation of an EU system for traceability and security features pursuant to Articles 15 and 16 of the new Tobacco Products Directive (Directive 2014/40/EU), or
- considering to have special expertise in the relevant areas.

In the Commission's assessment, the following stakeholders, including their respective associations, are expected to be directly affected:

1. manufacturers of finished tobacco products,
2. wholesalers and distributors of finished tobacco products,
3. providers of solutions for operating traceability and security features systems,
4. governmental and non-governmental organisations active in the area of tobacco control and fight against illicit trade.

Not directly affected are retailers and upstream suppliers of tobacco manufacturers (except the solution providers mentioned in point 3 above).

The basis for the consultation is the Final Report to the European Commission's Consumers, Health and Food Executive Agency (CHAFAEA) in response to tender n° EAHC/2013/Health/11 concerning the provision of an analysis and feasibility assessment regarding EU systems for tracking and tracing of tobacco products and for security features (hereafter the Feasibility Study). The Feasibility Study was published on 7 May 2015 and is available at http://ec.europa.eu/health/tobacco/docs/2015_tpd_tracking_tracing_frep_en.pdf. The interested stakeholders are advised to review the Feasibility Study before responding to this consultation.

The comments received in the course of this consultation will be an input to the further implementation work on a future EU system for traceability and security features. In particular, the comments will be taken into account in a follow-up study.

Stakeholders are invited to submit their comments on this consultation at the following web-address <https://ec.europa.eu/eusurvey/runner/trace> until 31 July 2015. The web-based survey 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 or to upload (a) separate document(s) in PDF format up to the limit of total number of standard A4 pages (an average of 400 words per page) indicated in the question. Submissions should be - where possible - in English. For a corporate group one single reply should be prepared. For responses from governmental organisations, which are not representing a national position, it should be explained 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 consult the [privacy statement](#)). Participants in the consultation are asked not to upload personal data of individuals.

The replies to the consultation will be published on the Commission's website. In this light no confidential information should be provided. If there is a need to provide certain information on a confidential basis, contact should be made with the Commission at the following email address: SANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu with a reference in the email title: "Confidential information concerning targeted stakeholder consultation on the implementation of an EU system for traceability and security features". A meaningful non-confidential version of the confidential information should be submitted at the web-address.

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

A. Respondent details

*A.1. Stakeholder's main activity:

- a) Manufacturer of tobacco products destined for consumers (finished tobacco products)
- b) Operator involved in the supply chain of finished tobacco products (excluding retail)
- c) Provider of solutions
- d) Governmental organisation
- e) NGO
- f) Other

*A.1.e. Please specify:

- i) NGO active in the area of fight against illicit trade of tobacco products
- ii) Other

***A.1.e.ii. If other, please specify**

Text of 1 to 800 characters will be accepted

GS1 develops open standards enabling traceability throughout industry supply chains.
GS1 standards are the most commonly used in the FMCG sector and have already been implemented by a vast majority of the operators impacted by the new traceability requirements of the Tobacco Products Directive.

***A.2. Contact details (organisation's name, address, email, telephone number, 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

GS1 in Europe
Rue Royale 76, mailbox 1
Brussels 1000
Belgium
www.gs1.eu

***A.3. Please indicate if your organisation is registered in the Transparency Register of the European Commission (unless 1d):**

Yes No

***A.3.1. Please enter your registration number in the Transparency Register**

324248318335-69

***A.4. Extract from the trade or other relevant registry confirming the activity listed under 1 and where necessary an English translation thereof.**

• **efda9b1a-a9ae-4126-baba-bf5c0e434834/C ENG-Memorandum of Agreement GS1 in Europe January 2014 - suggested modifications (3).pdf**

B. Options proposed in the Feasibility Study

B.1. Please rate the appropriateness of each option for tracking and tracing system set out in the Feasibility Study in terms of the criteria listed in the tables below

B.1.1. Option 1: an industry-operated solution, with direct marking on the production lines carried out by tobacco manufacturers (for further details on this option, please consult section 8.2 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

B.1.2. Option 2: a third party operated solution, with direct marking on the production lines carried out by a solution or service provider (for further details on this option, please consult section 8.3 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

B.1.3. Option 3: each Member State decides between Option 1 and 2 as to an entity responsible for direct marking (manufacture or third party) (for further details on this option, please consult section 8.4 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

B.1.4. Option 4: a unique identifier is integrated into the security feature and affixed in the same production process (for further details on this option, please consult section 8.5 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

B.1.5. Please upload any additional comments on the options referred to in question B.1 (max. 5 pages)

- **e24212db-7f4f-48a0-8828-600510a24163/Tobacco - GS1 comments on B1 FINAL.pdf**

B.2. Please rate the appropriateness of each option for security features set out in the Feasibility Study in terms of the criteria listed in the tables below

B.2.1. Option 1: a security feature using authentication technologies similar to a modern tax stamp
 (for further details on this option, please consult section 9.2 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

B.2.2. Option 2: reduced semi-covert elements as compared to Option 1 (for further details on this option, please consult section 9.3 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

B.2.3. Option 3: the fingerprinting technology is used for the semi-covert and covert levels of protection (for further details on this option, please consult section 9.4 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

B.2.4. Option 4: security feature is integrated with unique identifier (see Option 4 for traceability)
 (for further details on this option, please consult section 9.5 of the Feasibility Study)

	Appropriate	Somewhat appropriate	Neutral	Somewhat inappropriate	Inappropriate	No opinion
*Technical feasibility	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Interoperability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Ease of operation for users	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*System integrity (e.g. low risk of manipulation)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*Potential of reducing illicit trade	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Administrative/financial burden for economic operators	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Administrative/financial burden for public authorities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

B.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)

- [2c247f1d-be9e-4b8f-94b0-deb25d05aaab/Tobacco - GS1 comments on B2 FINAL.pdf](#)

C. Cost-benefit analysis

C.1. Do you agree with?

	Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Disagree	No opinion
*The benefit analysis presented in section 11.3.1 of the Feasibility Study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*The cost analysis presented in section 11.3.2 of the Feasibility Study	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

*C.1.1. If you selected option "Disagree" or "Somewhat disagree" in the previous question, please upload your main reasons for disagreement (max. 5 pages)

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D. Additional questions

The questions in this section relate to different possible building blocks and modalities of the envisaged system (questions D.1, D.3, D.4, D.6, D.8, D.10, D.12, D.14 and D.16). When replying please take into account the overall appropriateness of individual solutions in terms of the criteria of technical feasibility, interoperability, ease of operation, system integrity, potential of reducing illicit trade, administrative/financial burden for economic stakeholders and administrative/financial burden for public authorities.

*D.1. Regarding the generation of a serialized unique identifier (for definition of a unique identifier, see Glossary in the Feasibility Study), which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) A single standard provided by a relevant standardization body
- b) A public accreditation or similar system based on the minimum technical and interoperability requirements that allow for the parallel use of several standards;
- c) Another solution
- d) No opinion

*D.1.a. Please indicate your preferred standardization body

Text of 1 to 400 characters will be accepted

GS1 standards are the most appropriate standards:

- already implemented and used by the vast majority of operators in the FMCG supply chain and in the tobacco supply chain.
- developed through a transparent and open process whereby any operators can participate to the standardisation body.
- proven and easy to adopt with an approach to introduce a serialised unique identifier.

D.2. Please upload any additional comments relating to the rules for generation of a serialized unique identifier referred to in question D.1. above (max. 2 pages)

• 34974e8e-7122-455e-8942-88e7a5a50b13/Tobacco - GS1 comments on D2 FINAL.pdf

*D.3. Regarding (a) data carrier(s) for a serialized unique identifier, which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) Solution based on a single data carrier (e.g. 1D or 2D data carriers)
- b) Solution based on the minimum technical requirements that allow for the use of multiple data carriers;
- c) Another solution;
- d) No opinion

*D.3.a. Please indicate your preferred data carrier and explain why

Text of 1 to 400 characters will be accepted

An appropriate solution that is consistent along the entire supply chain must have the following attributes:

- Easy to implement
- Compatible with existing hardware and software (ERP, Scanners, checkout)
- Low printing costs

The existing GS1 data carriers (1D and 2D) fulfil the identification requirements.

*D.3.c. Please explain your other solution

Text of 1 to 800 characters will be accepted

There can be more than one data carrier on a product.

1D and 2D data carriers are intended to be used for specific purposes defined in the General specifications. Therefore, they are not interchangeable, nor can one be used to replace the other.

Moreover, in the future, there will be more data carriers than only the 1D and 2D barcode (ex. RFID). Innovation would therefore be hindered by prescriptive provision on data carriers.

*D.4. Regarding (a) data carrier(s) for a serialized unique identifier, which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) System only operating with machine readable codes;
- b) System operating both with machine and human readable codes;
- c) No opinion

D.5. Please upload any additional comments relating to the options for (a) data carrier(s) for a serialized unique identifier referred to in questions D.3 and D.4 above (max. 2 pages)











*D.6. Regarding the physical placement of a serialized unique identifier, when should it happen (multiple answers possible)?

- a) Before a pack/tin/pouch/item is folded/assembled and filled with products;
- b) After a pack/tin/pouch/item is folded/assembled and filled with products;
- c) No opinion

D.7. Please upload any additional comments relating to the placement of a serialized unique identifier referred to in question D.6. above (max. 2 pages)

D.8. Which entity should be responsible for?

	Economic operator involved in the tobacco trade without specific supervision	Economic operator involved in the tobacco trade supervised by the third party auditor	Economic operator involved in the tobacco trade supervised by the authorities	Independent third party	No opinion
*Generating serialized unique identifiers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Marking products with serialized unique identifiers on the production line	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Verifying if products are properly marked on the production line	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Scanning products upon dispatch from manufacturer's/importer's warehouse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*Scanning products upon receipt at distributor's/wholesaler's premises	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

*Scanning products upon dispatch from distributor's/wholesaler's premises					
*Aggregation of products					

D.9. In relation to question D.8. above, please specify any other measures that your organisation considers relevant

Text of 1 to 1200 characters will be accepted

As it relates to the above question, it is important to keep in mind that GS1 provides only a prefix portion of the trade item key (GTIN) and GS1 members assign the Trade item reference number and any sub-identifiers such as batch or serial numbers.

Moreover, GS1 provides rules and guidance for the users to accurately allocate the identifiers to their products.

This solution enables a consistent use of GS1 standards, but with flexibility and fluidity in the implementation of our standards.

*D.10. Regarding the method of putting the security feature on the pack/tin/pouch/item, which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) A security feature is affixed;
- b) A security feature is affixed and integrated with the tax stamps or national identification marks;
- c) A security feature is printed;
- d) A security feature is put on the pack/tin/pouch/item through a different method;
- e) No opinion

D.11. Please upload any additional comments relating to the method of putting the security feature on the pack referred to in question D.10 above (max. 2 pages)

*D.12. Regarding the independent data storage as envisaged in Article 15(8) of the TPD, which of the following solutions do you consider as appropriate (multiple answers possible)?

- a) A single centralised storage for all operators;
- b) An accreditation or similar system for multiple interoperable storages (e.g. organised per manufacturer or territory);
- c) Another solution
- d) No opinion

D.13. Please upload any additional comments relating to the independent data storage referred to in question D.12. above (max. 2 pages)

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*D.14. In your opinion which entity(ies) is/are well placed to develop reporting and query tools (multiple answers possible)?

- a) Provider of solutions to collect the data from the manufacturing and distribution chain;
- b) Provider of data storage services;
- c) Another entity
- d) No opinion

D.15. Please upload any additional comments relating to the development of reporting and query tools referred to in question D.14. above (max. 2 pages)

*D.16. Do you consider that the overall integrity of a system for tracking and tracing would be improved if individual consumers were empowered to decode and verify a serialized unique identifier with mobile devices (e.g. smartphones)?

- a) Yes
- b) No
- c) No opinion

D.16.a. If yes, please explain your considerations

Text of 1 to 800 characters will be accepted

Enabling the consumers to have access to some T&T information would be beneficial for the consumer and the authorities:

- It would empower the consumer and build trust to buy authentic products.
- It would include a soft final check of the efficiency of the supply chain.

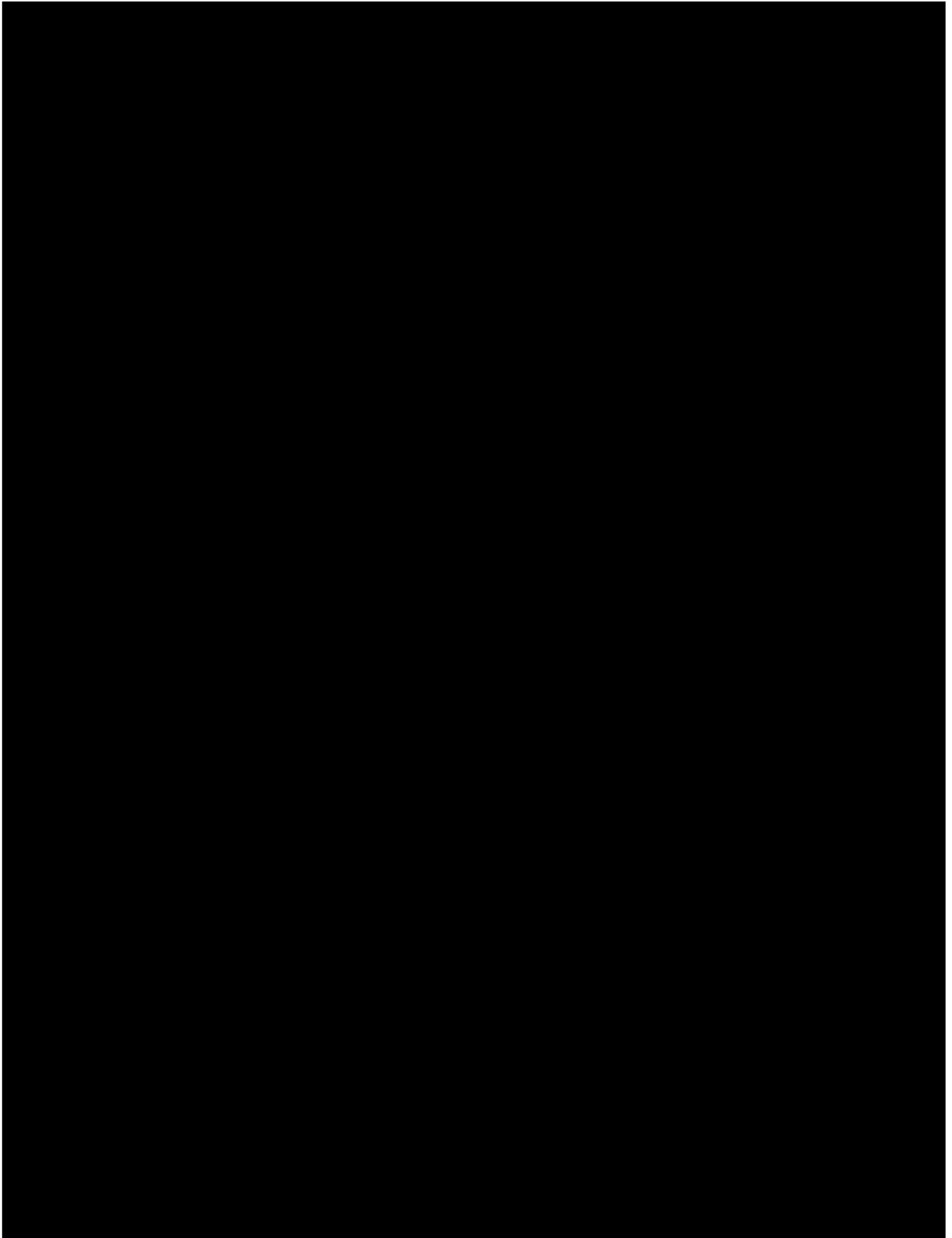
However, before enforcing such a possibility, a technical feasibility assessment and a cost-impact evaluation should be run to ensure that operators can offer this option to their consumers.

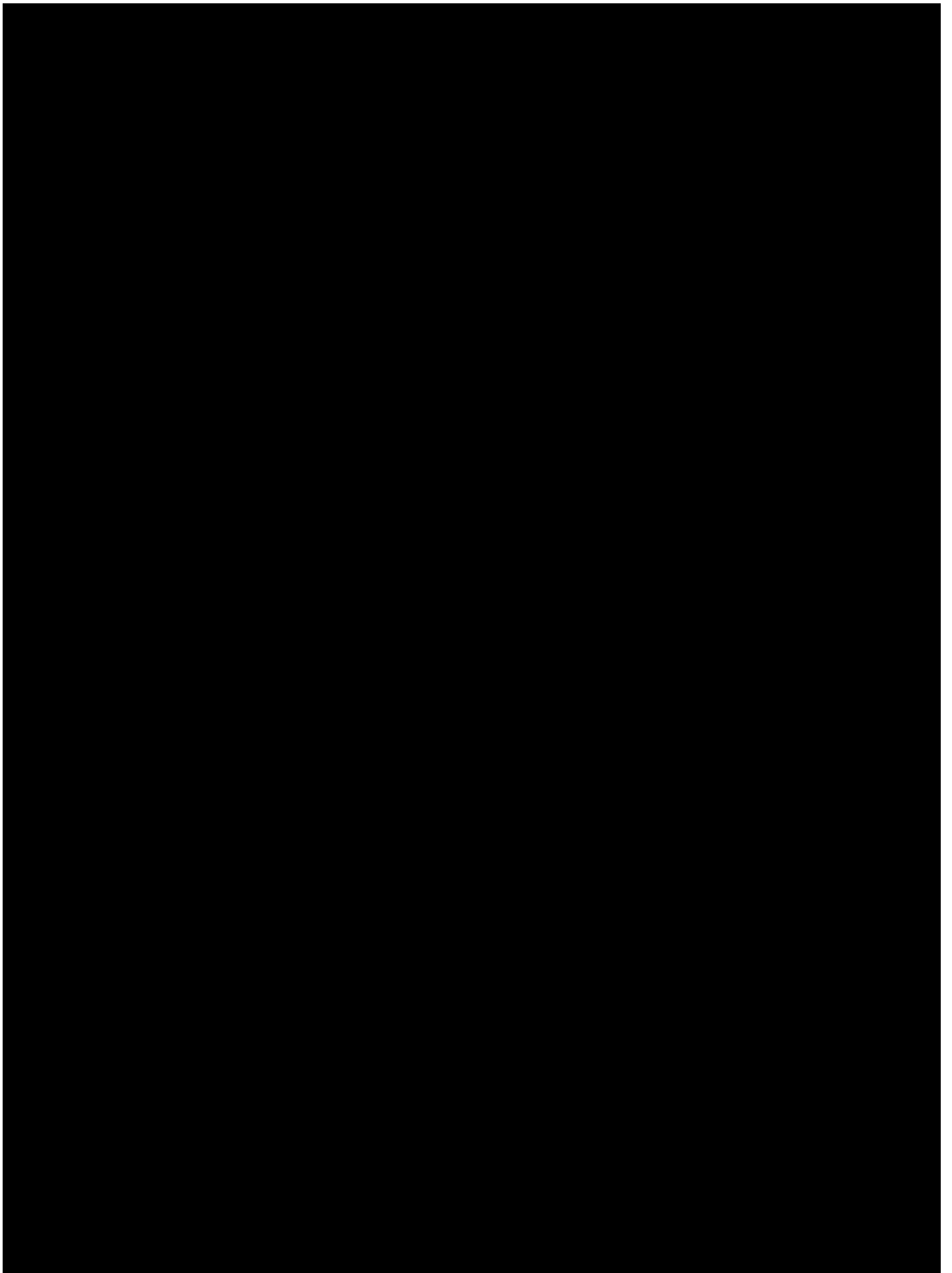
D.17. Please upload any additional comments on the subject of this consultation (max. 10 pages)

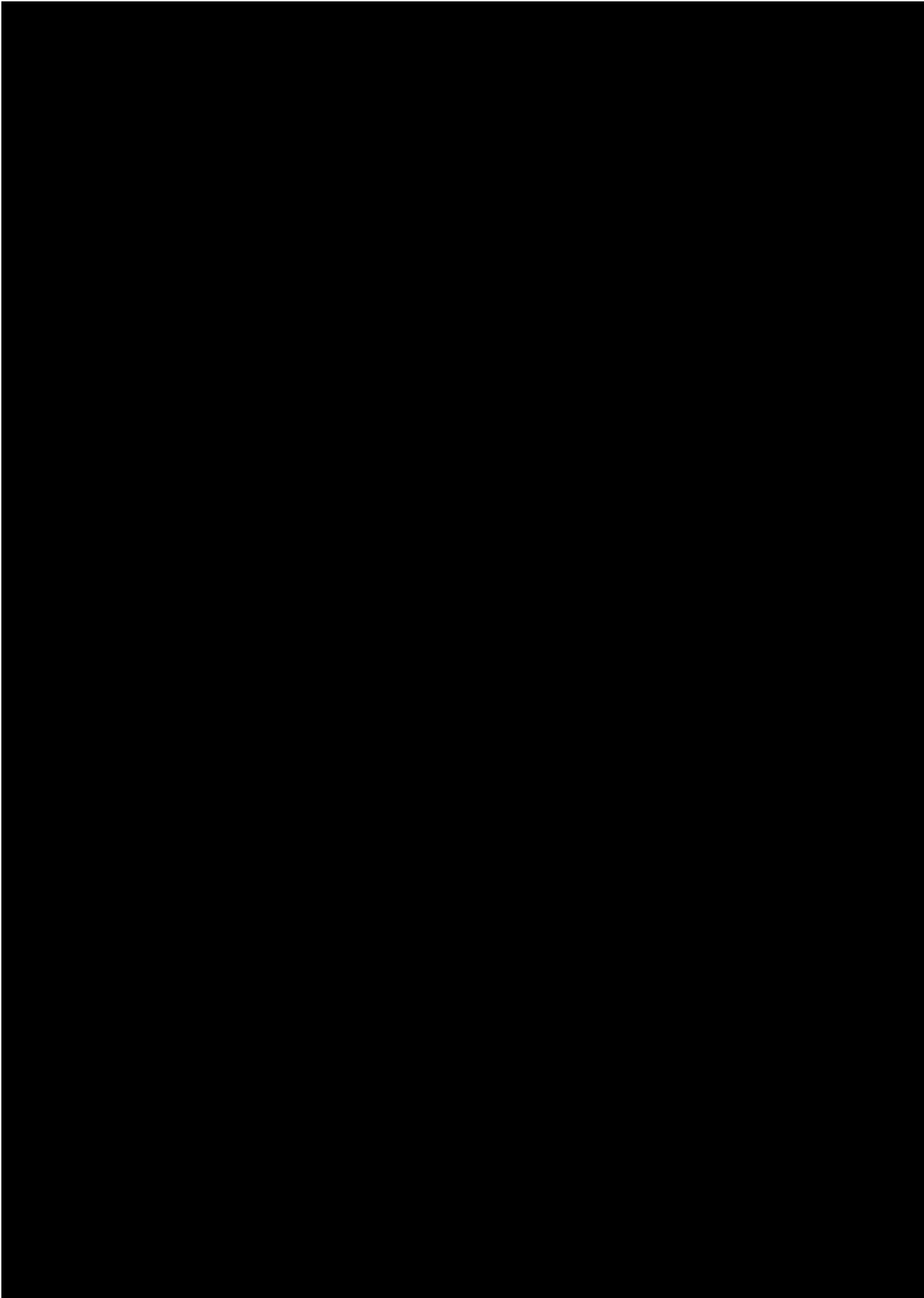
• [a436abca-8f3f-4458-8293-a150e6872f37/Tobacco - GS1 comments on D17 FINAL.pdf](#)

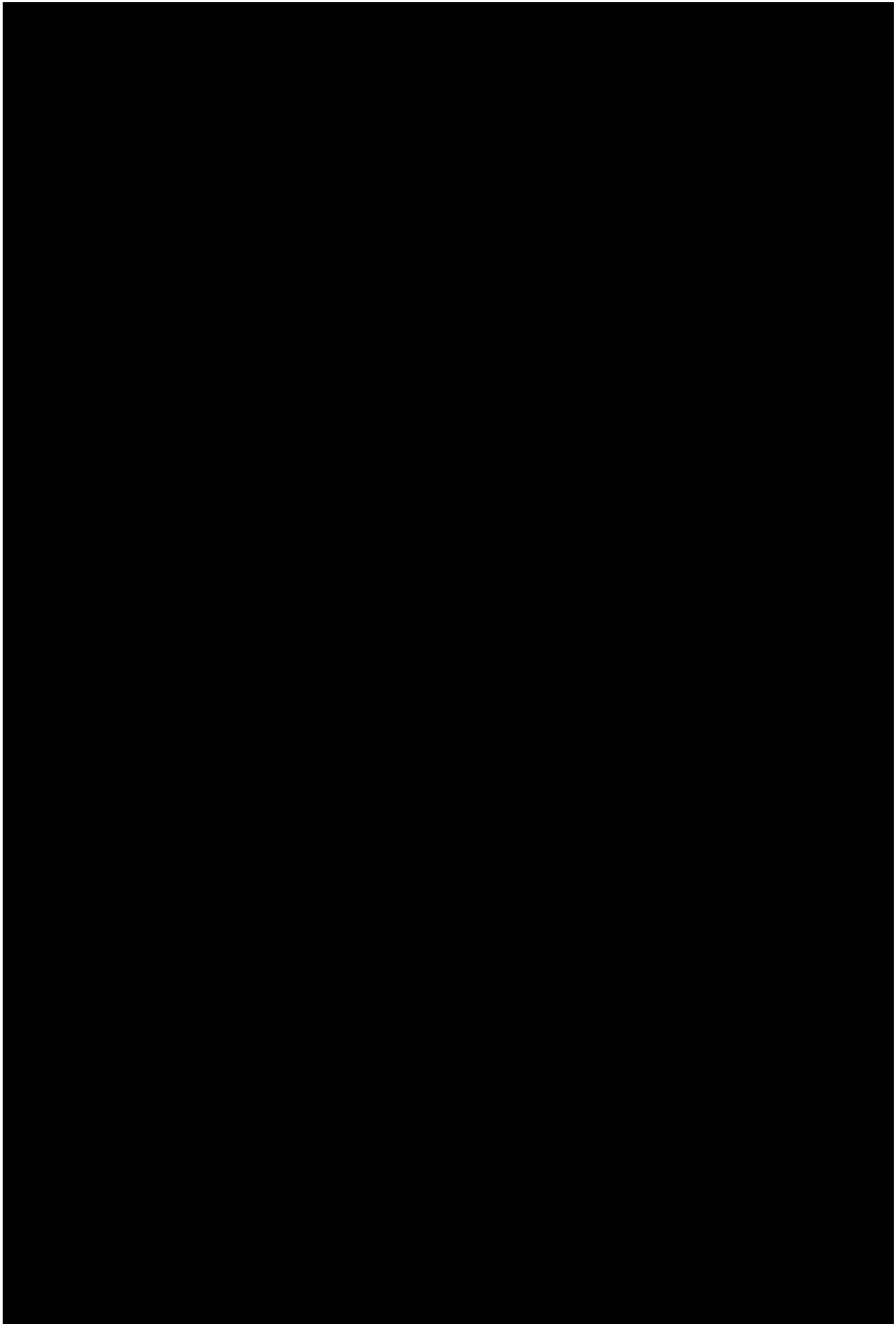
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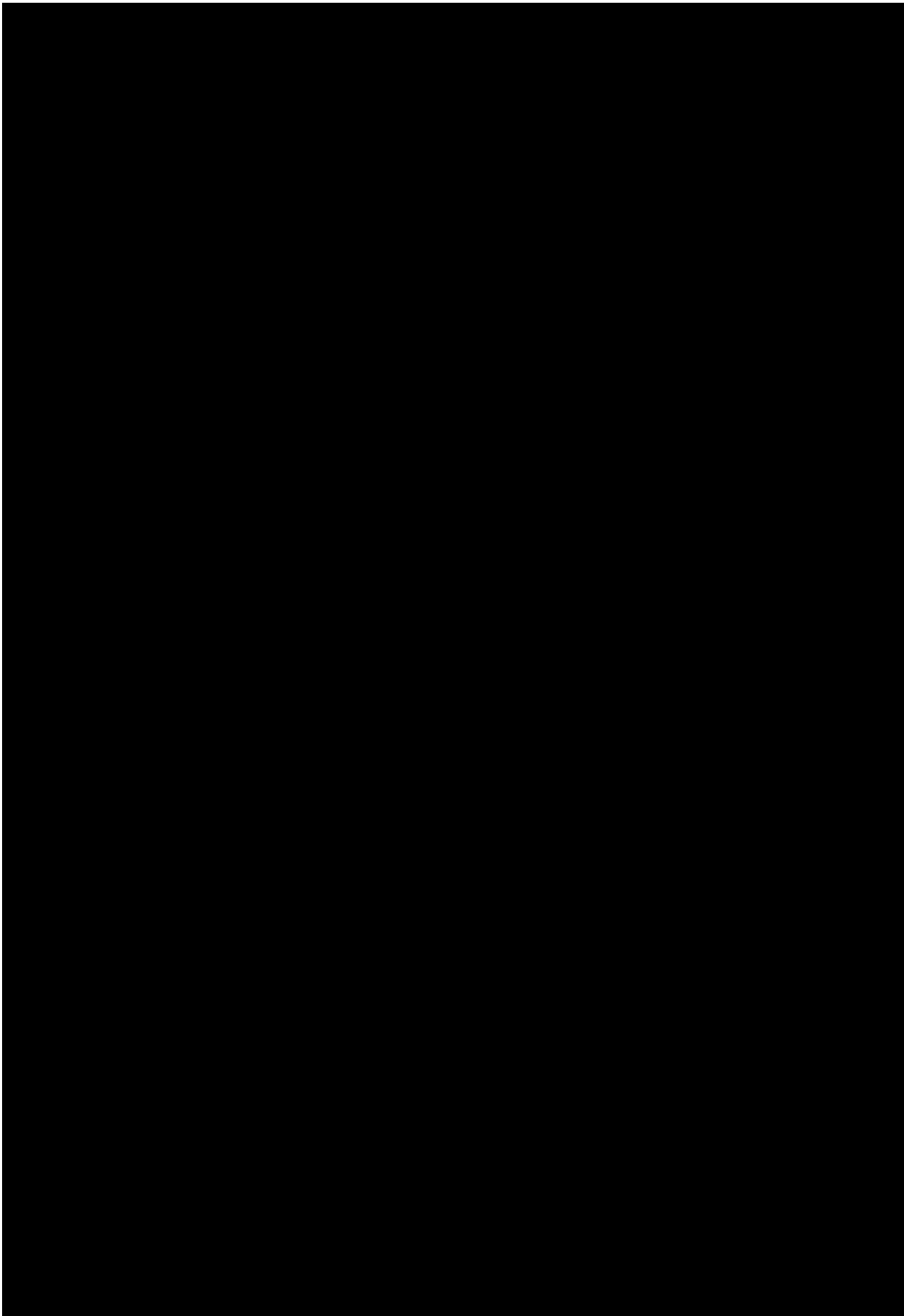
✉ SANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu

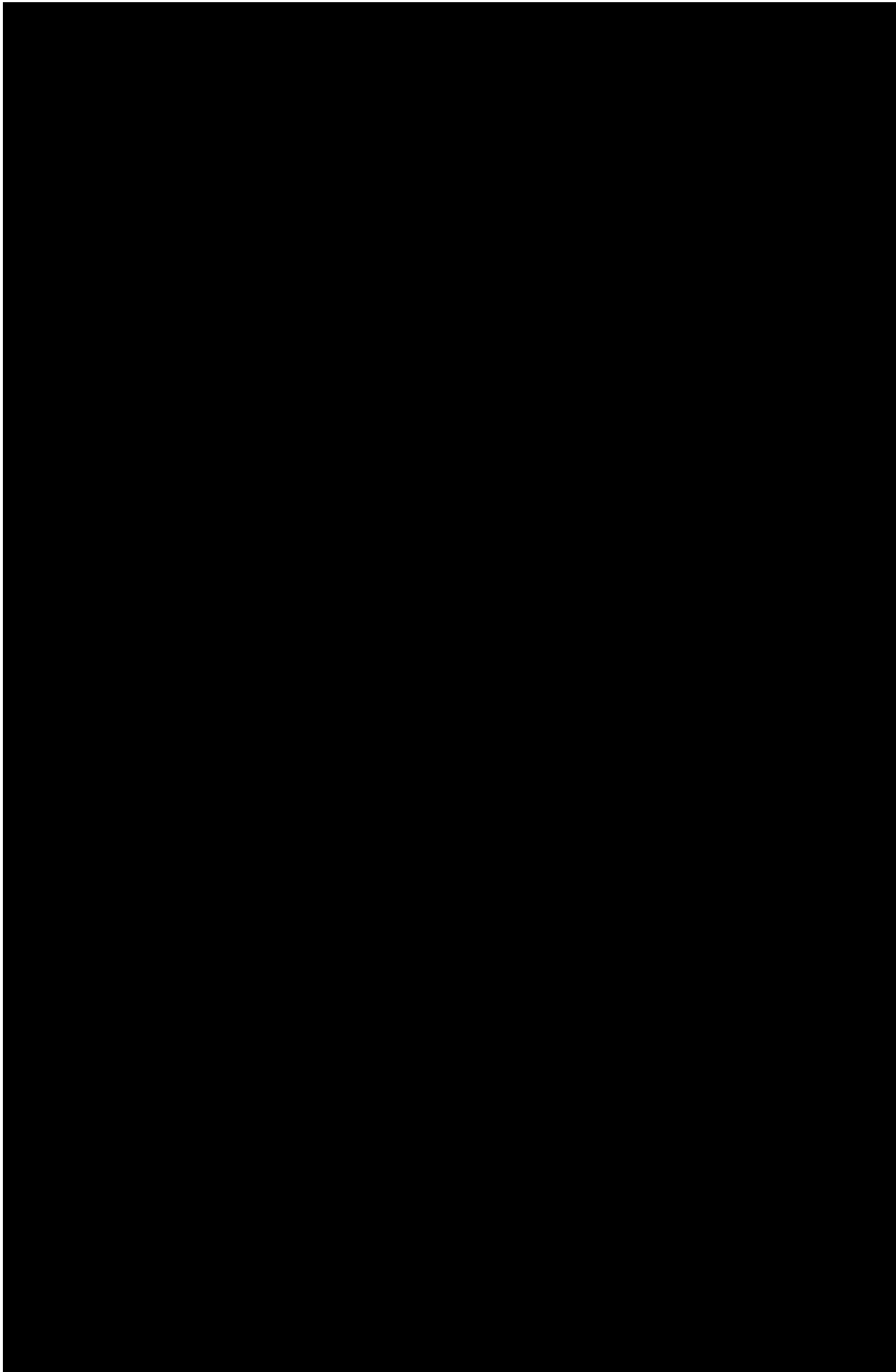


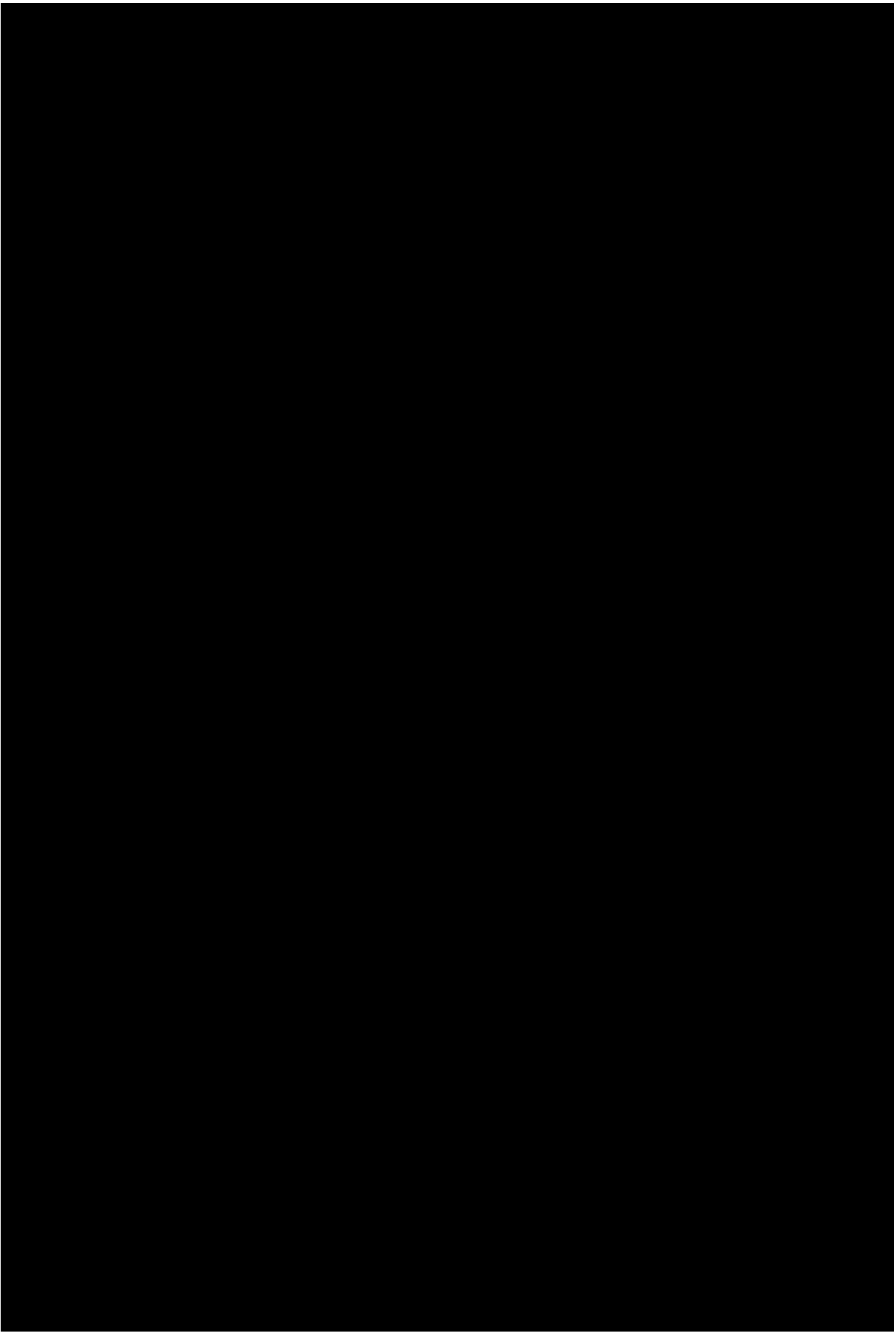


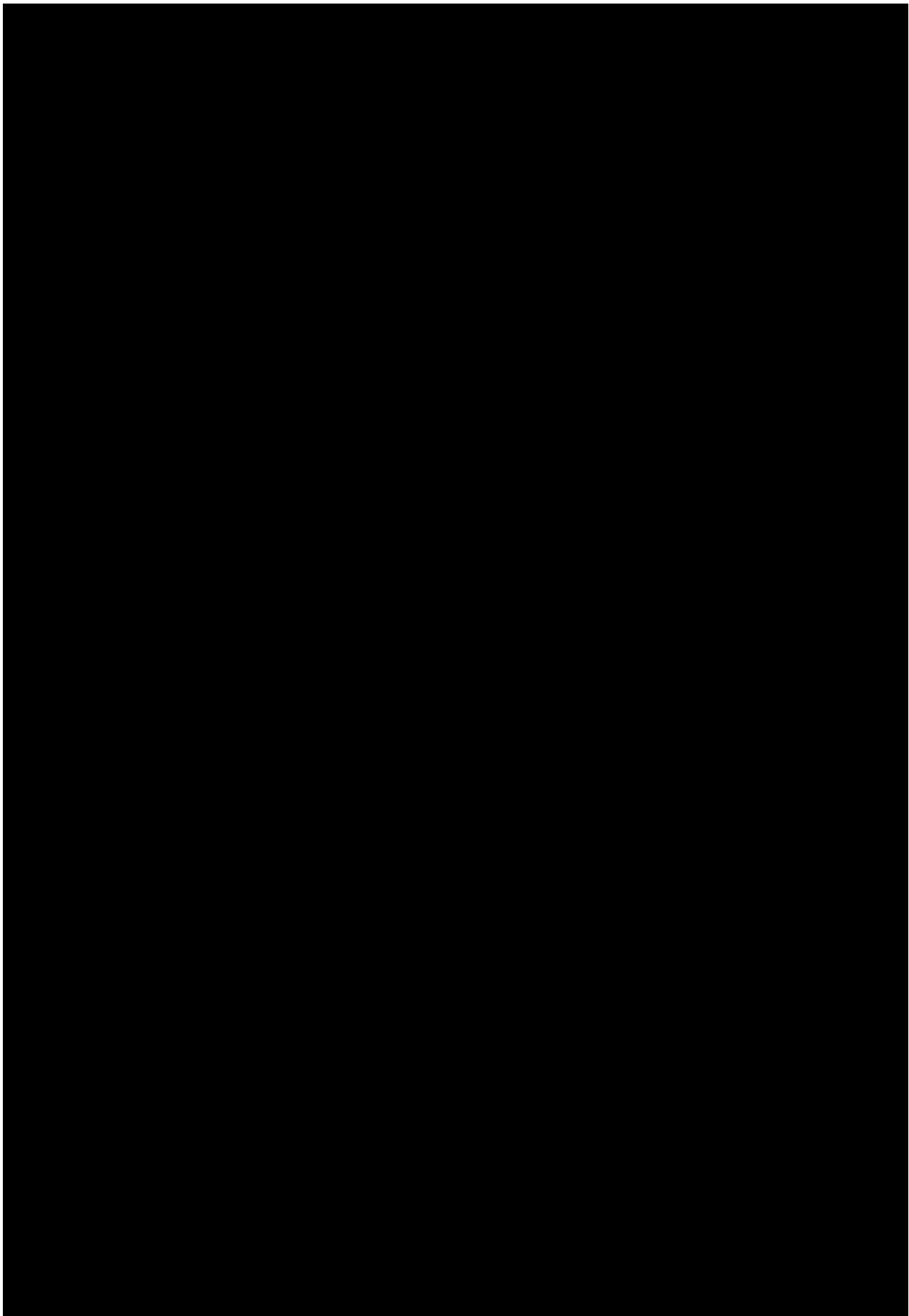


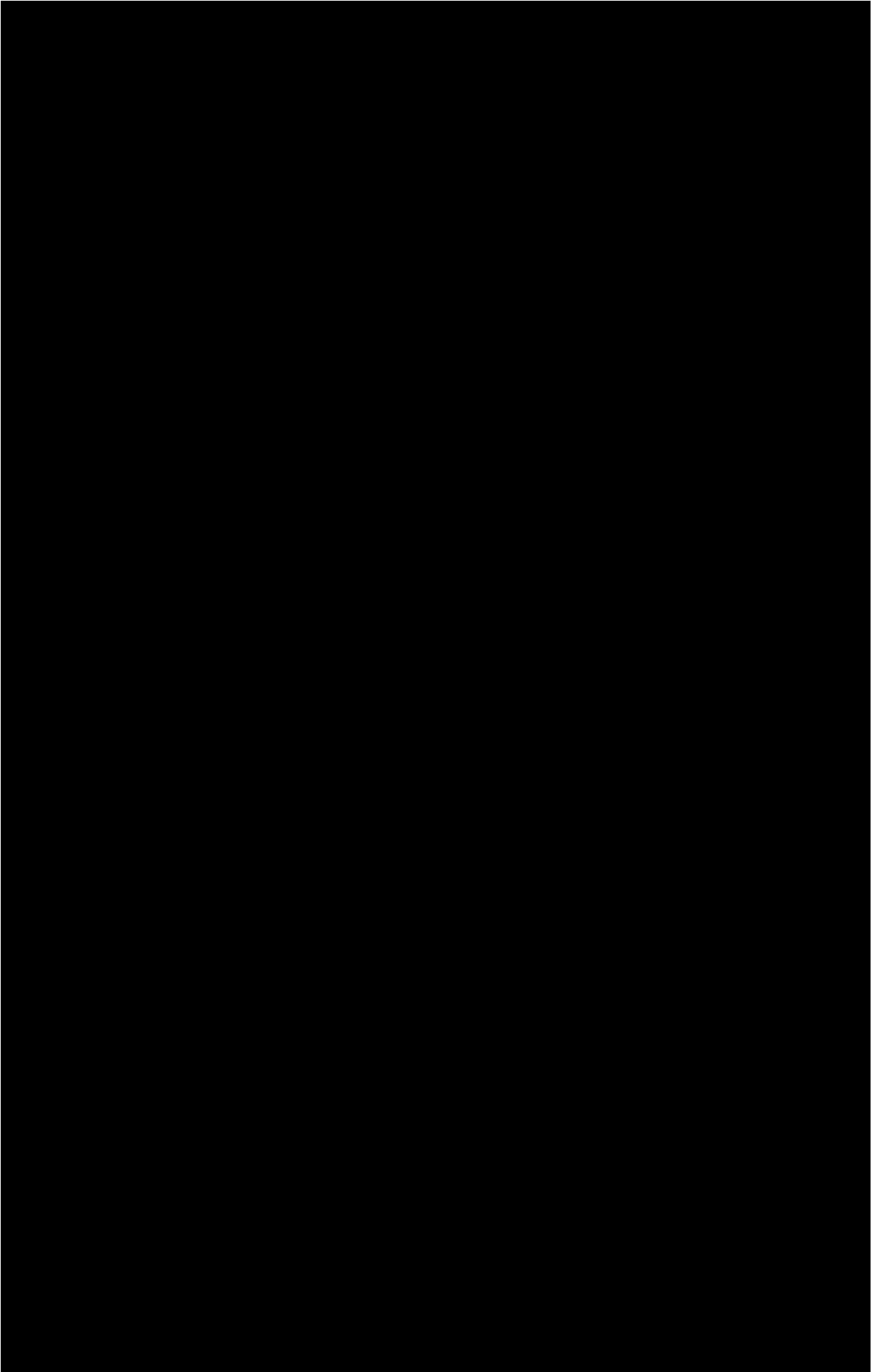


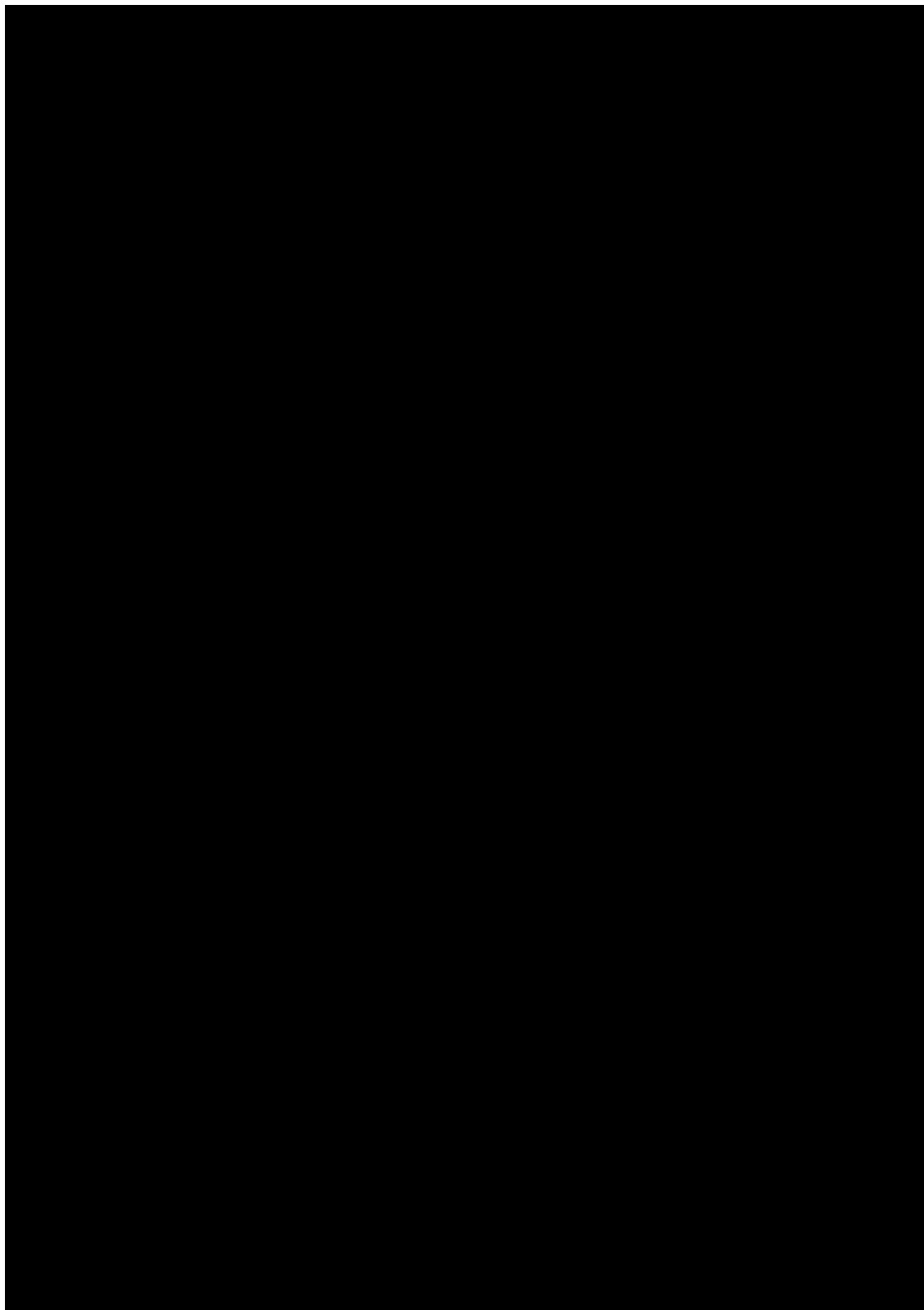














B.1.5. Please upload any additional comments on the options referred to in question B.1 (max. 5 pages)

Preliminary remarks

We hope that Tobacco traceability requirements will seek to leverage existing standards and systems in order to maximise efficiency and fluidity of those systems. The ideology behind the GS1 system of standards is that the flow of information in the supply chain should be fluid, and the system should be open, flexible, decentralised and adaptable. In that sense, the 4 options are not completely factoring in the full potential of using GS1 standards for an efficient T&T systems, and particularly EPCIS.

Option 1

As a standardisation organisation, we have particular expertise in providing technical standards enabling a T&T system. As such, we have assessed the technical feasibility as appropriate. Our assessment is based on the fact that the feasibility study requires the use of GS1 standards. It is also a realistic scenario, as GS1 standards are already used by the entire supply chain.

Regarding the interoperability criteria, we would like to underscore the importance of having a flexible, scalable system that supports T&T for products beyond tobacco. Operators using traceability systems for other products might not be able to transfer the systems in place to the Tobacco products. It would therefore prevent operators from having a full and horizontal T&T interoperable system for all their activities.

Option 2

From our perspective, as a technical standard organisation, the second option described in the feasibility study is appropriate on the technical feasibility aspects, so long as there is only one third party that would be neutral and endorsed by all stakeholders. Having several service providers would absolutely bring complexity to the system, even if the standards set are very strictly defined.

Concrete questions come into play if there are various solution providers. First, the issue of governance should be tackled to ensure smooth transmission of data. Another concern is around the speed of exchange of the data: the more operators handling the data, the slower the exchange will be. Then, it would be up to each participant in the supply chain to know which participant wants what data, versus one third party responsible for establishing the data communications standards. In addition, with too many solution providers in the mix, there would be questions and confusion around how to handle data that is already stored, and how that data would be transmitted from one Member state to another. Finally, there is significant risk of manipulation of data from one solution provider to another when exporting data from one operator to another, affecting data quality and integrity. For these reasons, we prefer to remain neutral in our assessment of the other criteria.

Option 3

In regards to our experience as a standardisation organisation, we observe that option 3 would raise important interoperability concerns, as one cannot ensure that the different options chosen by each Member State would be compatible – even though standards are set at EU level.

The option of Marking by a third party makes this option even more complex as it would divide the manufacturing / packaging process in two parts. Currently, cigarettes are produced and packaged in one production line, and they are produced upon order. If a third party is introduced, the manufacturers would be dependent on the solution provider that would interfere in the production / packaging process. It increases the complexity of the Supply chain by including another player in the chain, as it would cut one segment of the chain into two.

Option 4

As regards option 4, we understand why in theory integrating a global unique identifier into a security feature is desired.

The feasibility study mentions that one of the advantages foreseen would be for Member states to create synergies with what they have already implemented, meaning processes and procedures that produce the tax stamp. With this in mind, we have to highlight that this solution does not address the high risk of losing the data carrier in case of alteration of the stamp – and therefore losing the unique identifier. Therefore, the unique identifier would need to also be marked somewhere else on the packaging to ensure full availability of the data.

As it would create a double unique identifier marking, we do not see any advantage of this option as it is described. It would become appropriate only if the security feature is permanently affixed (not removable) on the pack, which is not a condition set in the feasibility study.

Furthermore, under this option, the data has to be shared on several databases that would need to exchange these data. This would trigger interoperability and integrity problems.



B.2.5. Please upload any additional comments on the options referred to in question B.2 (max. 5 pages)

GS1 does not have any direct interest in the discussion of security features. However, as option 4 merges the unique identifier and the security features, we have some comments to make on this option.

In our view, it raises 2 main questions:

- Renationalisation of identifiers in case of synergies of existing national tax stamp with option 4 would completely diminish the idea of having unique identifiers at the global level.
- The optimisation of the supply chain would be hindered by this option. GS1 standards support our users in gaining efficiency in the supply chain. However, the fact that the responsible person would be the printer would actually mean that the security features would have to be pre-printed. This, combined with the fact that the data needs to be recorded on the production line, means that the security features need to be scanned during the production/packaging process. In GS1's perspective, this goes against the optimisation of the supply chain management.

In addition, we would like to underscore that the feasibility study is not exploring the possibility of using RFID tags, which would address some of the concerns we raised. RFID tags ensure that identification numbers remain global, unique and serialised and provide options for high security features as the EPC GEN2v2¹ supports now cryptographic authentication of tags and readers, to verify identity and provenance, as well as reduce the risk of counterfeiting and unauthorized access.

¹ GS1 EPCglobal standards are designed to facilitate the flow of products and related business data across the supply chain and they define how that data is communicated between supply chain stakeholders. With EPCglobal, new technologies are added to the GS1 suite of standards, namely Radio Frequency Identification (RFID). They make use of the Electronic Product Code (EPC), which is a universal identifier that provides for unique identification for every physical object anywhere in the world. The EPC can be used at the level of item, logistics unit or as an asset identifier. The GS1 identification keys for item instances can be used as EPC's.



C.1.1. If you selected option "Disagree" or "Somewhat disagree" in the previous question, please upload your main reasons for disagreement (max. 5 pages)

The cost analysis is not taking into account that operators already use some standards that answer traceability requirements. The implementation cost of a T&T system based on these standards would then be negligible – and therefore limit cost impact.



D.2. Please upload any additional comments relating to the rules for generation of a serialized unique identifier referred to in question D.1. above (max. 2 pages)

GS1 global identification standards enable a more granular level of product identification and product tracing by adding a batch/lot number, best by / use by date or a serial number (sGTIN) to identify individual units. For example, 2 cases of Product 'X' can be easily distinguished in the supply chain even though they share the same GTIN, because each has its own serial number (serialised GTIN). The serialised GTIN creates the ability to distinguish each individual case from another as its assigned identity is globally unique.

Therefore the rule is to use an already existing GTIN on a product which is sold in the supply chain and add a serialised number. Both should be encoded on a second symbol.

Anyone already having a GTIN can have a serialised GTIN, without any additional cost implicated.



D.13. Please upload any additional comments relating to the independent data storage referred to in question D.12. above (max. 2 pages)

Although EPCIS, our standard for data sharing that would fit with the traceability requirement of the Tobacco Products directive, is a distributed data sharing standard by default in the B2B process, it is mainly for IP rights concerns, as Business partners should not share potential sensitive data with their counterparts.

In the question tabled by the European Commission, we are in a Business – to – Government (B2G) environment. In this context, data shared with authorities do not have the same sensitivity as business-related data. Therefore data sharing should be centralised to make easier the process of data storage and sharing.



D.17. Please upload any additional comments on the subject of this consultation (max. 10 pages)

GS1 is an international not-for-profit organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply chains globally and across sectors. GS1 has local member organisations in 112 countries.

The GS1 System is an integrated system of global open standards, processes and enabling technologies that provide for accurate identification and communication of information regarding products, assets, services and locations. It is driven by 2 million companies executing billions of transactions every day in 150 countries and is the most widely used supply chain standard in the world.

In the past four decades, the use of GS1 standards has spread from retailers and manufacturers in fast-moving consumer goods to other sectors such as healthcare, defence, and consumer electronics and is now increasingly used in transport and logistics. Benefits for these companies include improved speed of operations, increased visibility of the flow of shipments, more efficient handling and inventory management, more efficient recall, and increased security of distribution. GS1 standards are already in use by a vast majority of tobacco supply chain's stakeholders. Enabling GS1 standards in answering traceability requirements would come as a complement to what is already operating in the supply chain.

GS1 standards are the most appropriate standards to be used in the area of tobacco traceability, and here are the main reasons sustaining this statement:

- GS1 standards are already implemented and used by the vast majority of operators in the FMCG supply chain and in the tobacco products supply chain.
- GS1 standards are developed through a transparent and open process whereby any operators can participate to the standardisation body.
- GS1 is an NGO recognised by the UNECE, and many of the standards, including the GTIN and EPCIS are recognised by ISO.
- GS1 standards are global and universal, and GS1 is a neutral organisation.
- GS1 standards are based on an Identify – Capture - Share architecture, enabling operators in the supply chain to run full traceability and visibility in their supply chain based on our standards.
- The usage of GS1 standards for traceability purposes is a proven and easy option to adopt with an approach to introduce a serialised unique identifier
- Inside the GS1 system, the appropriate auto identifiers (AI) are already in place and in use by several systems. In addition to that, the GS1 identifiers for traceability are embedded in the entire GS1 system. For this reason, implementing GS1 standards is cost-efficient and simpler than most other systems.
- GS1 standards are forming the basis of tracking and traceability efforts in various industry supply chains (including healthcare sector) and by other governments around the world,

- GS1 standards are proven to work. We have many use cases proving implementation is possible and successful for T&T purposes, among participants in various supply chains globally.

The GS1 identification standards, such as the Global Trade Item Number (GTIN), are the cornerstone of GS1, enabling our users to take the full benefit of the other available standards. To obtain GTIN, any user is invited to become a member.

Any operator can apply for membership with any GS1 local offices or to Global office if no local office exists. To become a member of GS1, an operator will have to contribute to:

- An entrance fee.
- A yearly membership fee.

In the particular case of Tobacco products, the vast majority of the operators are already members of GS1, therefore using our standards will not create any additional costs.

Here are the guiding principles of the determination of our fee for new members:

- The fees are based on the numbering capacity required by the operator and the turnover of the company.
- The GS1 local offices define their fees based on their local markets.
- All fees are transparent and available on the GS1 local offices' websites.
- Many local offices have developed special prices for SMEs and farmers.

The fees allow the community to ensure the integrity of the system, ensuring maintenance and update. This requires resources funded by users through these fees.

For these reasons, it is impossible to estimate an average fee as so many parameters must be taken into account. In any case, and this applies to all industry players, the economic impact of the membership fee on our users is very limited. In addition, distributors do not need identifiers so depending on the country where they get their GLN, the membership fee can or cannot apply – and in any case is limited.