

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.c. Please specify:

- i) Provider of solutions for tracking and tracing systems (or parts thereof)
- ii) Provider of solutions for security features (or parts thereof)
- iii) Data Management Providers (or parts thereof)

- *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

Bundesdruckerei GmbH
Kommandantenstr. 18
10969 Berlin
Deutschland
Tel.: (0 30) 25 98 - 2596
Fax: (0 30) 25 98 - 61 24
E-Mail: [REDACTED]

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

Yes No

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

• [7aa14b46-f723-43e1-8656-6975bb36b602/Excerpt_Commercial_Register_1.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 type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Ease of operation for users | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input 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 type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| *Administrative/financial burden for economic operators | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input 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 type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Ease of operation for users | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *System integrity (e.g. low risk of manipulation) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Potential of reducing illicit trade | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| *Administrative/financial burden for economic operators | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input 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 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 type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Ease of operation for users | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *System integrity (e.g. low risk of manipulation) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Potential of reducing illicit trade | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| * Administrative/financial burden for economic operators | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input 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 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 checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *System integrity (e.g. low risk of manipulation) | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Potential of reducing illicit trade | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| *Administrative/financial burden for economic operators | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Administrative/financial burden for public authorities | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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

- **d8c78d73-51d0-4d94-a656-fed7a83484b/20150729_QuestionB1_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 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 type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Ease of operation for users | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *System integrity (e.g. low risk of manipulation) | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Potential of reducing illicit trade | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| * Administrative/financial burden for economic operators | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| * Administrative/financial burden for public authorities | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input 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 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 type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Ease of operation for users | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *System integrity (e.g. low risk of manipulation) | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Potential of reducing illicit trade | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| * Administrative/financial burden for economic operators | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| * Administrative/financial burden for public authorities | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input 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 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 checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Potential of reducing illicit trade | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| * Administrative/financial burden for economic operators | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| * Administrative/financial burden for public authorities | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input 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 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 checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Potential of reducing illicit trade | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| *Administrative/financial burden for economic operators | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Administrative/financial burden for public authorities | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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

- [35872308-008e-42dc-bd95-4db81aaefe29/20150730_QuestionB2_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 type="radio"/> | <input checked="" 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 type="radio"/> | <input checked="" 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)

• [1eb476eb-7c82-440a-b8fa-096863d3e846/20150730_QuestionC1_final.pdf](#)

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

ISO/IEC

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)

• [51910d0b-8758-4365-b3b2-49b34f019f73/20150731_QuestionD2_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.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)

• [45ea1879-c2ef-4994-b4a7-e782008104ae/20150731_QuestionD5_final.pdf](#)











*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 checked="" type="radio"/> | <input type="radio"/> |
| *Marking products with serialized unique identifiers on the production line | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Verifying if products are properly marked on the production line | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| *Scanning products upon dispatch from manufacturer's/importer's warehouse | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| *Scanning products upon receipt at distributor's/wholesaler's premises | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| | | | | | |

| | | | | | |
|--|---|---|---|---|---|
| <p>*Scanning products upon dispatch from distributor's/wholesaler's premises</p> |  |  |  |  |  |
| <p>*Aggregation of products</p> |  |  |  |  |  |

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

additional measures described in an separate file (see D17)

*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/puch/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)

*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

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

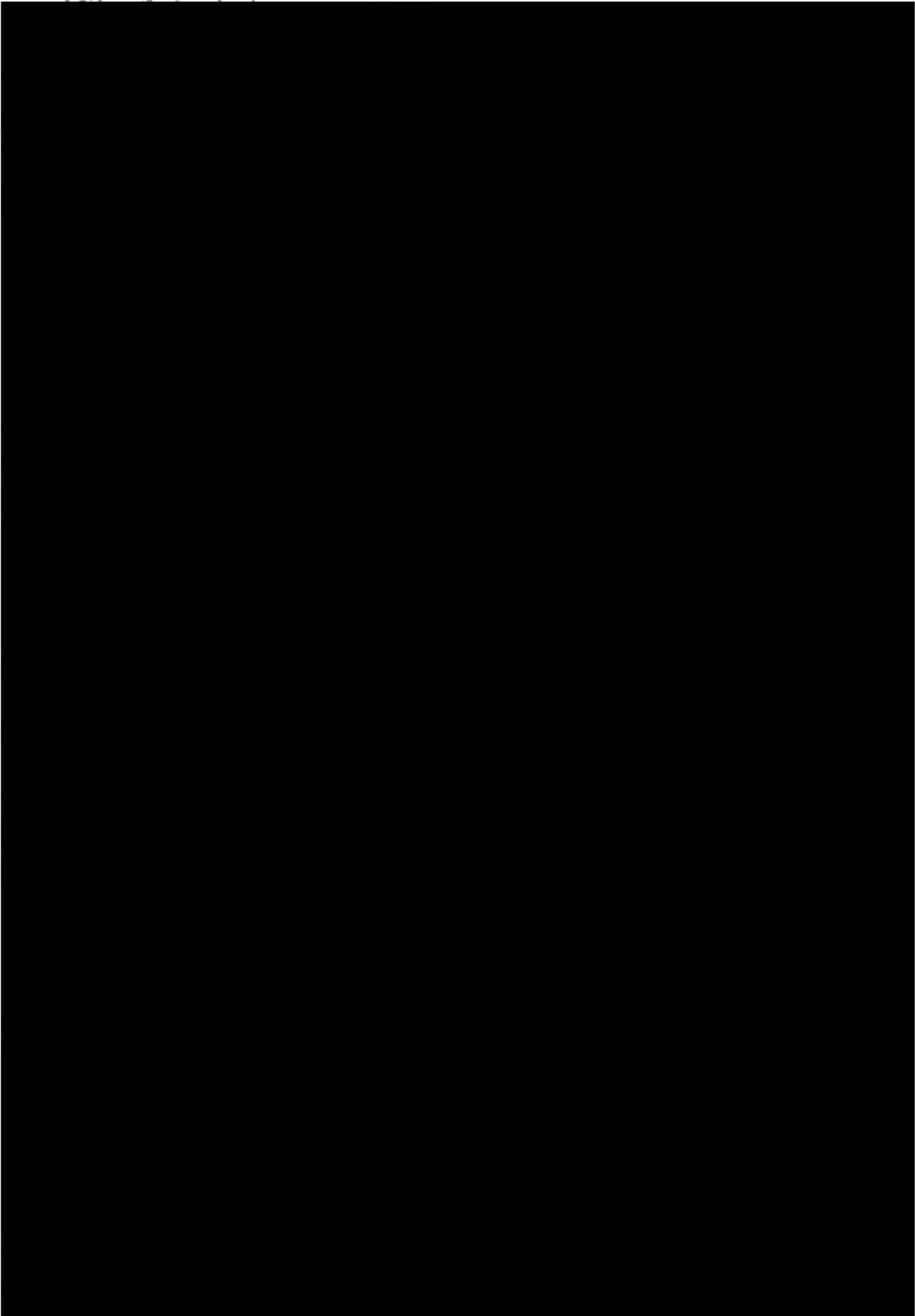
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- [fb65c0c4-693c-41b8-8568-d07b262ba83b/20150802_QuestionD16_final.pdf](#)

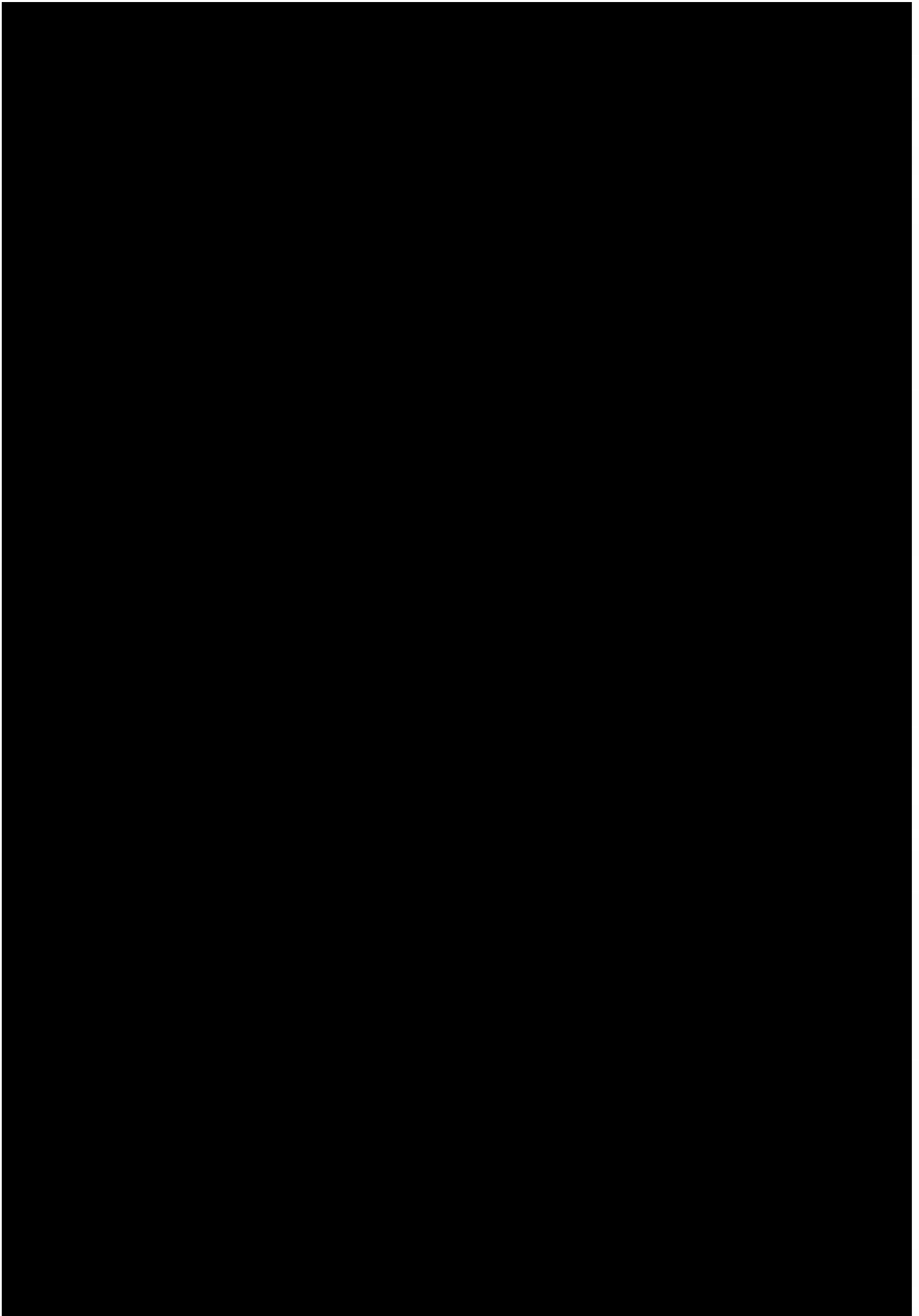
Contact

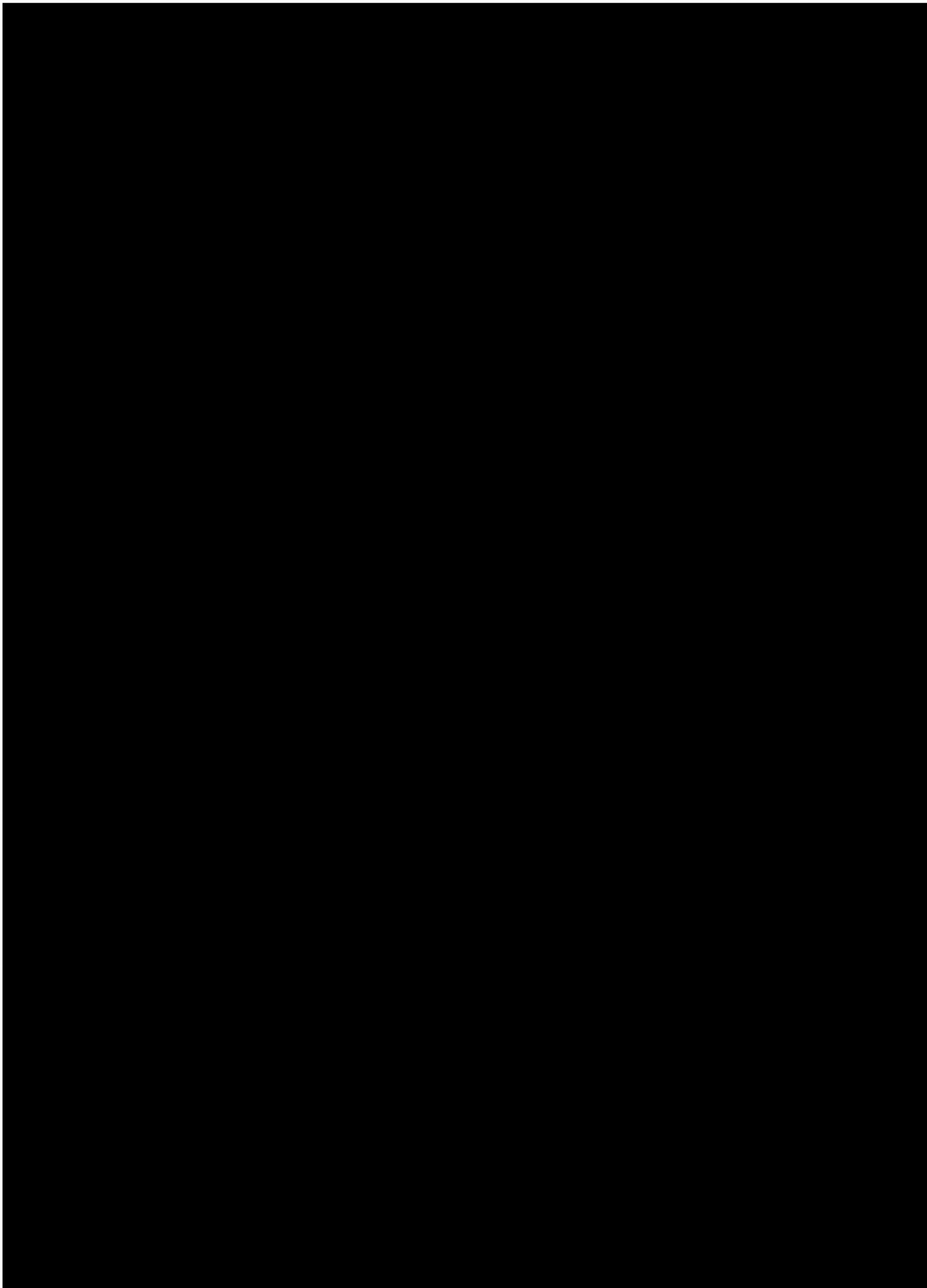
✉ SANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu

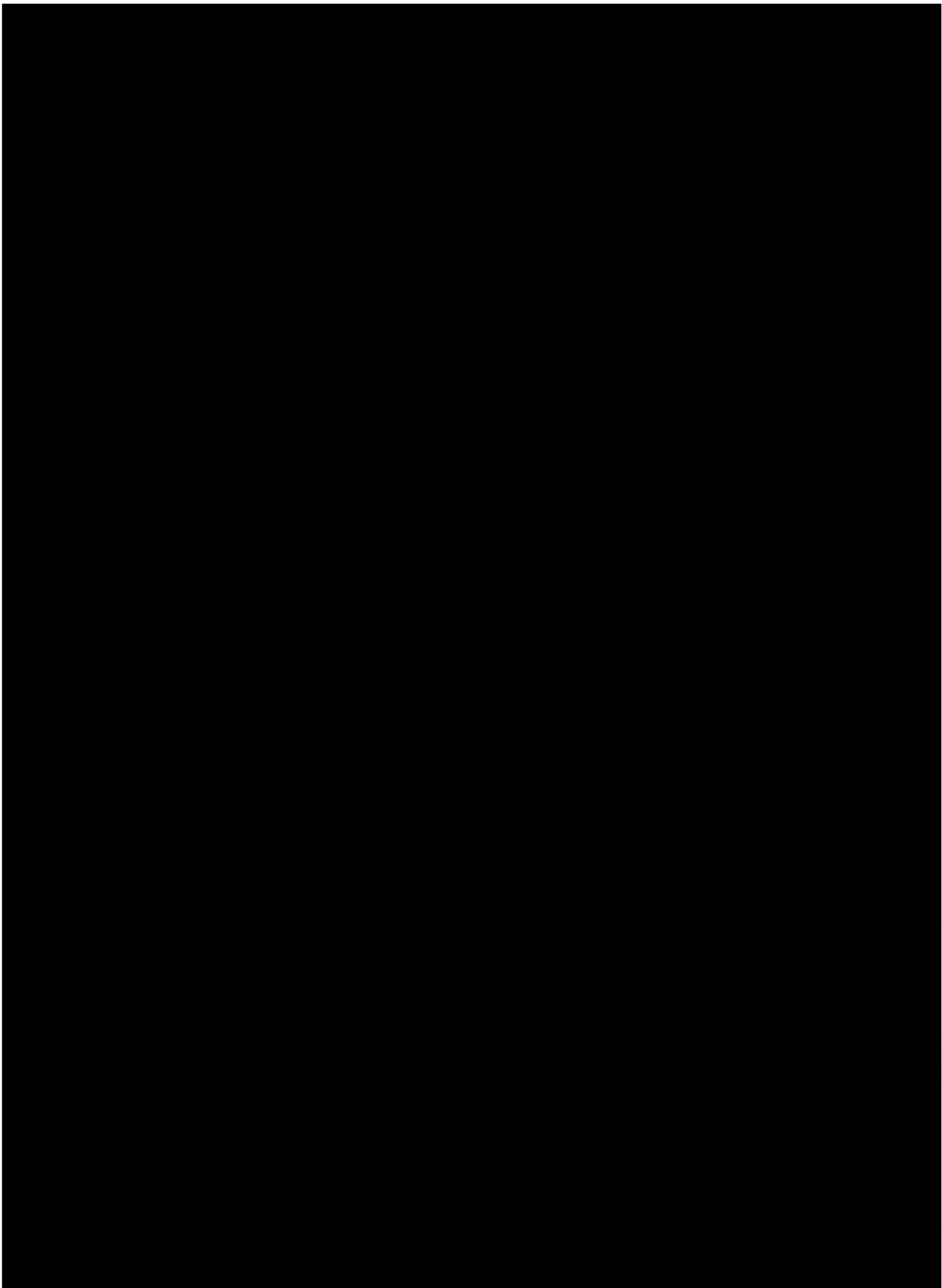
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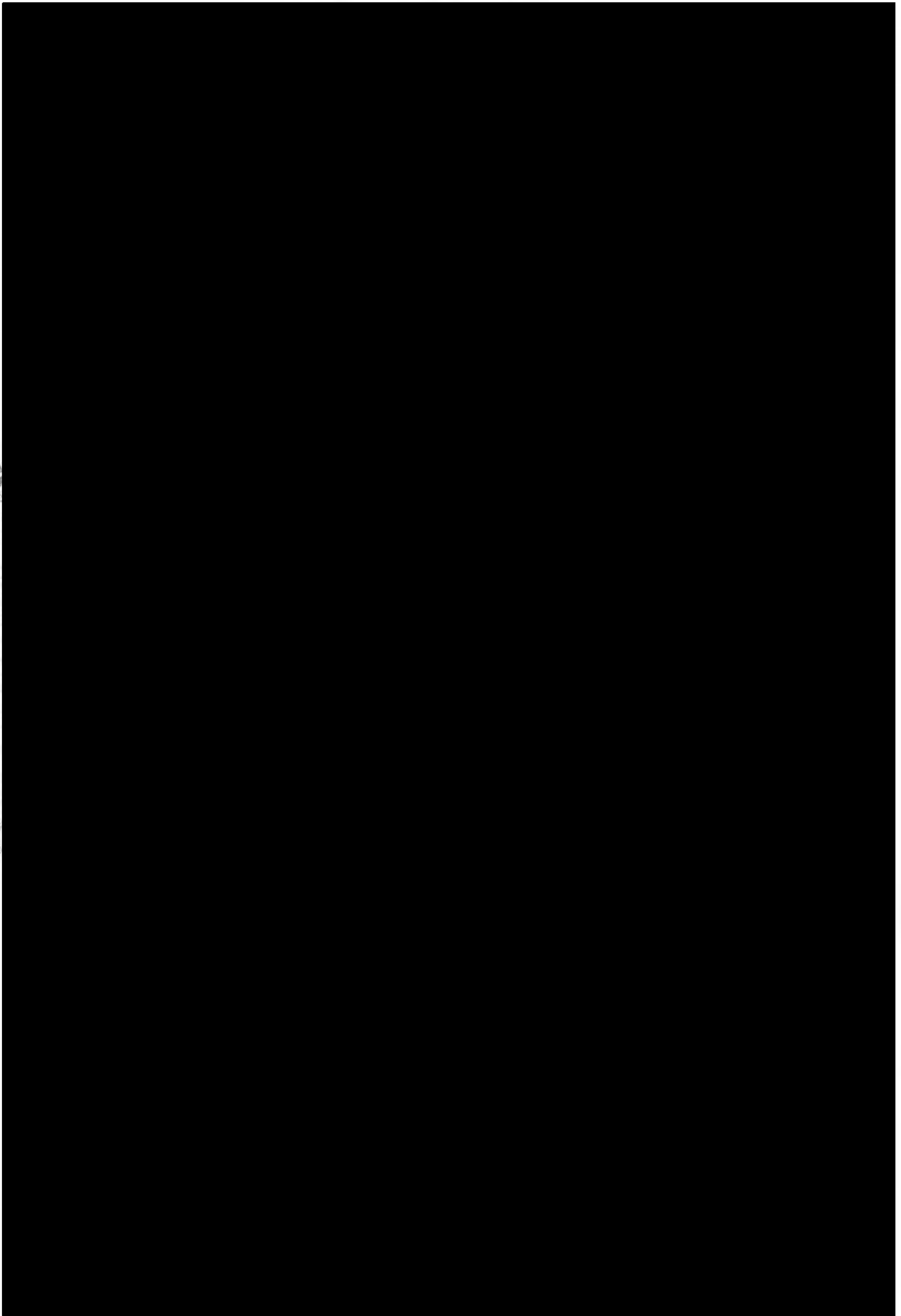
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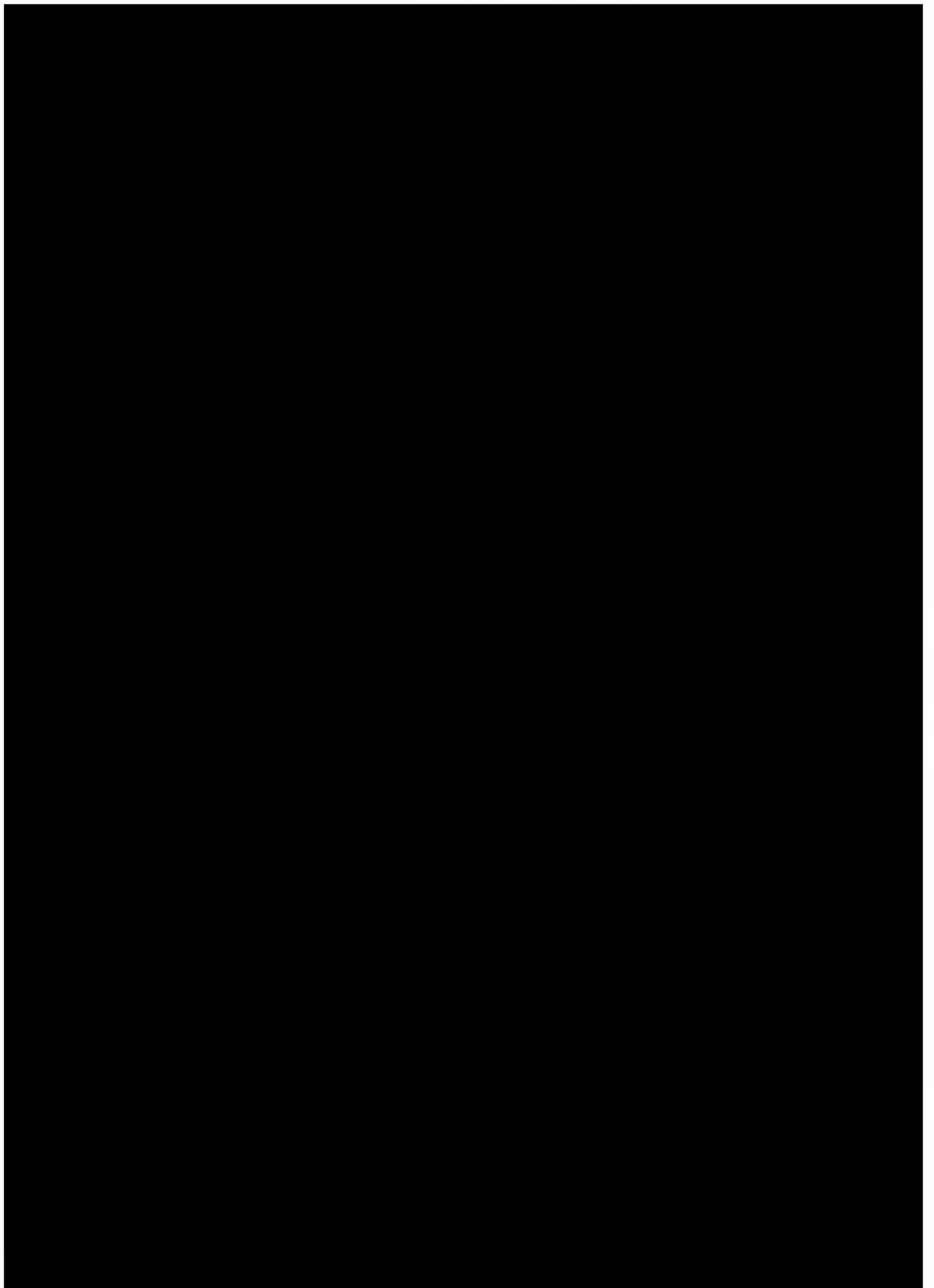


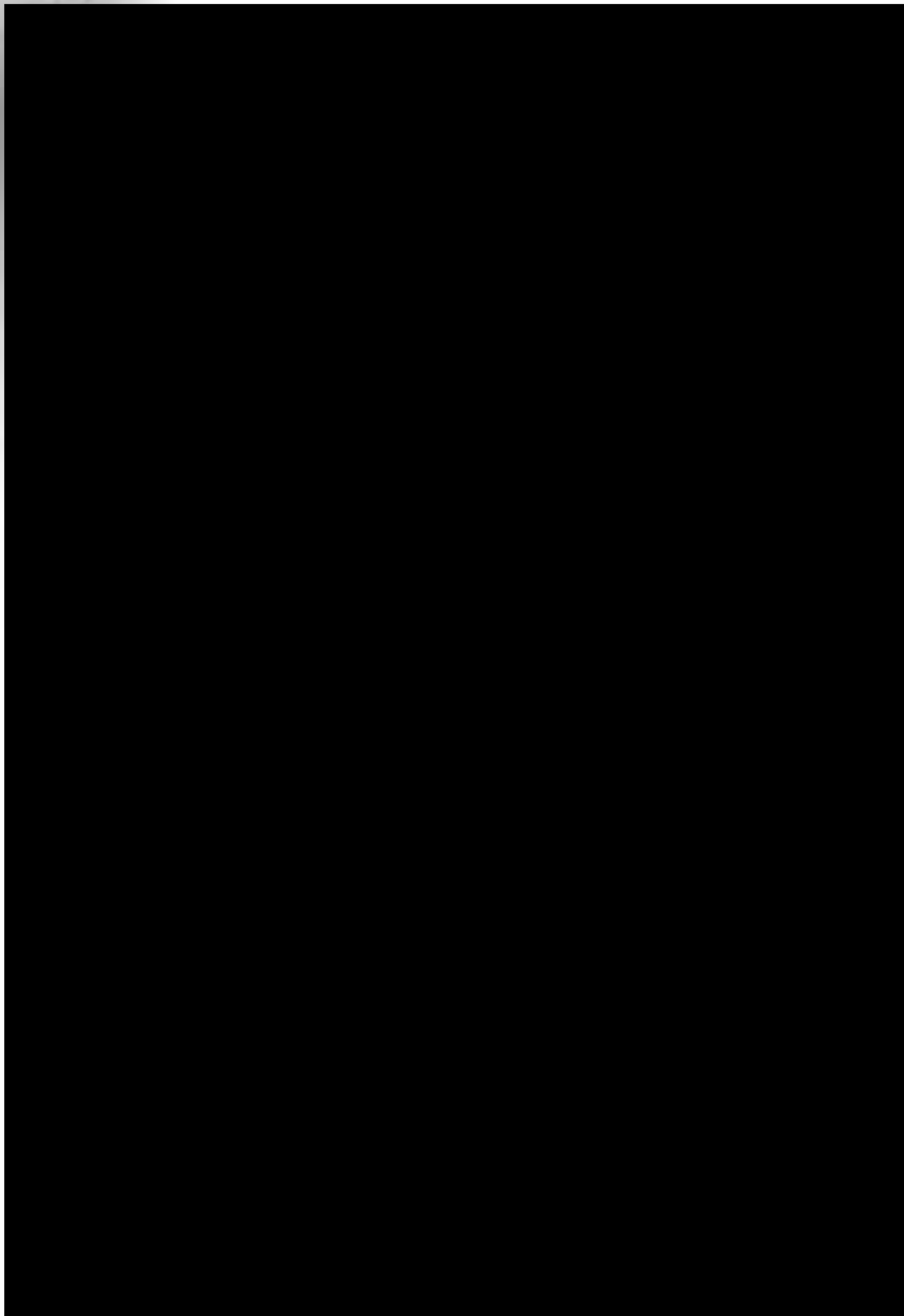












Targeted stakeholder consultation on the implementation of an EU system for traceability and security feature: Additional comments on the options referred to in question B.1

Version 1.0

Date: 2015-08-06

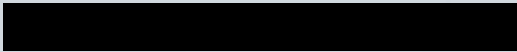


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1 Comments

In our opinion, the four solution variants for a track & trace system discussed in the feasibility study do not take equal consideration of all requirements of the market stakeholders. The smaller tobacco product manufacturers, in particular with a low level of automation and with a high level of product diversification are not adequately represented. Furthermore, the outlined approaches have a more pronounced focus on cigarette manufacturing. We believe that the following distribution processes are not sufficiently taken into account. The same applies to control processes used by the authorities.

We have included these aspects in our ranking of the individual options. This means that the options can be barely differentiated with regard to evaluation of the individual categories. If the application cases had been specified in more detail, we would have been able to make a considerably more distinctive differentiation. We are of the opinion that the specification must take all stakeholders into account – manufacturers, wholesalers, distributors, retailers, consumers and authorities.

1.1 Technical feasibility

In principle, we consider all the described solution variants to be technically feasible. Differentiations can only be made in terms of implementation timescales, initial costs and cost of operation. We have taken this into account in our ranking of the other evaluation categories.

1.2 Interoperability

With regard to interoperability, we have given all solutions based on direct marking on the packages worse rankings than the label-based solutions. The label-based solution is already used for all types of product and is therefore already integrated into the entire tobacco industry. The required extensions and enhancements therefore concentrate on tracking.

This category is a good example for explaining why a totally contrary ranking for the application: "Product type – cigarette with highly-automated production" has been made, since some of the modules for direct marking have already been integrated in keeping with the provisions of the FCTC protocol, and all label solutions are considered to be a hindrance within the production process, also additional advertising area on the packages is lost. In response to these requirements, Bundesdruckerei is, in cooperation with the tobacco industry, developing a solution approach that takes both marking variants into account.

1.3 System integrity

With respect to system integrity, those solution approaches that permit issue of unique identifiers independently of the tobacco industry and enable independent central data storage have been given a higher ranking.

As the outlined solution 4 is strongly geared towards the process already used for collecting revenues by means of tax stamps, we have given this solution the highest ranking. Other

reasons are that the integrity of this process has been tried and tested over many years and adequate active control mechanisms that are also suitable for ensuring the integrity of the track & trace system are already in place.

1.4 Potential of reducing illicit trade

We do not see any potential for the reduction of illicit trade of the kind currently encountered in Germany. This conclusion is based on our long-standing cooperation with law-enforcement and investigation authorities.

1.5 Administrative/financial burden for economic operators

With regard to the financial burden on commercial stakeholders, all solutions based on direct markings on packs have been given worse rankings than label-based solutions. The label-based solution is already used for all types of product and has therefore already been integrated into the entire tobacco industry. The required extensions and enhancements therefore concentrate on tracking.

Similar to the category "Interoperability", a totally different situation arises if focus is placed on the highly-automated cigarette manufacturing industry.

1.6 Administrative/financial burden for public authorities

We are not in a position to estimate the financial and administrative burden on public authorities. We have only given a ranking for option 4, based on the assumption that it would be easy to extend established taxation procedures which use tax stamps.

1.7 Conclusions

As already explained for the feasibility study, it is impossible to find a universal ("one size fits all") solution approach for all cases. On the contrary, it must be possible to devise special solutions for every application case by combining individual solution modules.

In our view, minimum standards that enable free competition of individual solution providers need to be defined in order to ensure the required interoperability.

These minimum standards must be used to define the framework parameters of unique identifiers (data content, data carrier), pack aggregation, data communications and data storage.

2 Pilot project

In 2015, Bundesdruckerei GmbH started a pilot project aimed at evaluating pragmatic solution approaches. In this project, the requirements of all stakeholders were to be taken into account. By way of the respective industry associations, representative manufacturers of all product groups (cigarettes, RYO, cigars) are involved in order to accommodate the needs of the various production technologies. The logistics processes typically used in Germany have also been modelled in order to represent the commercial aspects of both the wholesale and the retail tobacco trade.

The German government is represented by the respective specialist departments of the two ministries directly and indirectly affected by the TPD, namely the Ministry of Finance (BMF)

and the Ministry of Food and Agriculture (BMEL). Here, especially the experience gained by these departments on counter-smuggling measures can be integrated. Furthermore, additional taxation optimisation methods can also be discussed from the viewpoint of the administrations. The directive does not call for any link to tax collection processes. However, linking the two statutory provisions in a single solution approach makes it possible to develop efficient and innovative solutions – particularly with regard to the German Federal Government’s “Digital Agenda”.

2.1 Project targets

1. On the basis of the tax stamp with an unconcealed standardised code, an end-to-end Track&Trace system with central database at Bundesdruckerei is to be developed, with the objective of demonstrating compliance with the requirements of Articles 15 and 16 of the TPD.
2. Development of modules for digitisation of the tax assessment process on the basis of the centrally issued code used for TPD.
3. Development of an approach for countries without tax stamps, so as to ensure that the results are internationally interoperable.

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Attachment B.2.5

Targeted stakeholder consultation on the implementation of an EU system for traceability and security feature: Additional comments on the options referred to in question B.2

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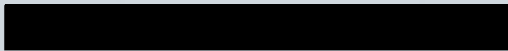


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1 Comments

In our opinion, the four solution variants for a security feature discussed in the feasibility study do not take equal consideration of the requirements of market stakeholders. Cigarette manufacturers, in particular, whose production processes are highly automated and whose product range is characterised by a small diversification, are not adequately represented. In such efficiency-driven high-volume production, every additional label is a very strong cost factor.

This can be avoided if the currently existing tax stamps for options 1 and 4 can be used. This would create direct dependency on the taxation accounting provisions of each individual member state, which, on the one hand, has the disadvantage that additional harmonisation would be required, but has, on the other hand, the advantage that established processes can be used. Furthermore, a link between the tax stamp and the TPD label indicates that current accounting processes based on the physical existence of the label are in place. This would make any move towards the introduction of a digital accounting system unattractive.

Furthermore, the outlined approaches have a more pronounced focus on tobacco manufacturing. We believe that too little consideration has been taken of ensuing distribution processes. The same applies to control processes used by the authorities.

We have included these aspects in our ranking of the individual options and have classified each label as being an additional label to the existing tax stamp label.

1.1 Technical feasibility

In principle, we consider all the solution variants described for options 1, 2 and 4 to be technically feasible. In our ranking of the other evaluation categories, we have taken the technical challenges that would arise if another label has to be integrated in addition to the tax stamp into consideration.

We were not able to submit a ranking for option 3 as we have not actively observed this technology in recent years, although we are essentially familiar with a solution of this kind in other sectors. We are therefore not able to assess the maturity of this technology.

1.2 Interoperability

With regard to interoperability, we have given all solutions based on direct marking on the packages worse rankings than the label-based solution (option 4). The label-based solution provides an opportunity for synergies and the additional possibility of central serial production outside of tobacco production lines using a tried and tested digital printing process that is not only efficient but also achieves high quality output.

1.3 Ease of operation for users

The advantages of option 4 as explained with regard to interoperability also formed the basis for our ranking in this category. Option 3 is ranked as being more complex due to the need to introduce new technology, both in tobacco manufacturing and authentication processes.

1.4 System integrity

System integrity is given a high ranking for all options, since all options are based on concepts that have been well proven in the security industry. Only option 2 has been given a slightly lower ranking since unique identifiers have been used to replace the features of level 2 in the security concept.

1.5 Potential of reducing illicit trade

We do not see any potential for the reduction of illicit trade of the kind currently encountered in Germany. This conclusion is based on our long-standing cooperation with law-enforcement and investigation authorities.

1.6 Administrative/financial burden for economic operators

With regard to the administrative and financial burden on commercial stakeholders, all solutions have been ranked as being bad, since an additional label would have to be affixed in all cases. The additional synergies that might possibly be achieved by using a tax stamp have not been included in the ranking.

Option 3 was given a worse ranking due to the introduction of an additional technology that is also new. Option 4 was ranked as being better, since the above synergies with regard to serial production may have an effect in this case.

1.7 Administrative/financial burden for public authorities

The burden on public authorities has been ranked as being high, since a new element would have to be controlled and an existing stamp is not used.

1.8 Conclusions

As already explained for the feasibility study, it is impossible to find a universal ("one size fits all") solution approach for all cases. On the contrary, it must be possible to devise special solutions for every application case by combining individual solution modules.

In our view, minimum standards that enable free competition of individual solution providers need to be defined in order to ensure the required interoperability.

Minimum standards for security requirements have to be defined. The specification of actual security features such as optically variable ink or optically variable devices is not desirable. On the contrary, tried and tested tax stamp security concepts should be applied. In this context we can state that, at least for Germany, the unbroken further development driven above all by the responsible investigation and enforcement authorities allows the achievement of a very high security level. In this way, it was demonstrably possible to edge forged products out of the market.

The high security level is explicitly not achieved by adding more and more features, but by a sustainable concept that above all takes the requirements of individual control instances into

account. Integrating the retailers and consumers into the active control process for individual security features, as discussed in the feasibility study, would lead to exploding costs which, at least in Germany, would not provide any additional benefits at present.

If the label is established as the medium for the security package and the currently used tax stamps can be used for this purpose as well, the focus must be on standardisation in ensuing measures in order to give the tobacco manufacturers a firm basis for planning while at the same time ensuring cost-efficiency. The same applies to control instances, of course.

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Attachment C.1.1

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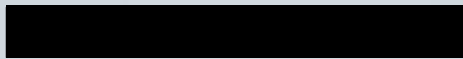


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1 Benefit analysis

We do not agree with the benefit analysis outlined in the feasibility study because it does not differentiate between the effectiveness of the individual options. An even more serious aspect here is that we do not believe that the described solution options will lead to a reduction of the illicit trade in Germany. The situation may be different in other markets, but we have absolutely no information on the illicit trade there.

In our opinion, a completely isolated market segment that works in the same way as a normal market – except that it is not regulated – has developed on the black market. As long as the alliance between suppliers and consumers is not broken down, additional regulation will not contribute to a reduction of illicit trading. On the contrary, past experience has shown that strict regulatory interference resulting in rising prices will lead to an increased demand on the illegal market.

We are assuming that all measures arising due to Articles 15 and 16 of the TPD will lead to increased costs and, as a result, to rising product prices. This therefore puts a question mark on the reduction of illicit trading as discussed in the study.

2 Cost analysis

We are not able to agree with the cost study outlined in the feasibility study since the underlying basic data for estimating the costs are not enough transparent. Furthermore, the study points out the uncertainty of the basic data, making ranking of the cost aspect impossible. We also believe that one cannot assume the costs for the distribution channels to be equal.

Another issue is that no possible synergies, e. g. as achieved using the existing tax stamps, have been taken into consideration. These would be suitable for showing such an option 5 (tax stamp with unique identifier) to be the lowest-cost option as opposed to option 4; the same applies to the costs at the control instances.

Currently we do not consider it possible to improve cost analysis by means of a tendering process since, in our opinion, "a single" solution would have to be specified, thus preventing competition between various providers and various solution variants. On the contrary, a framework should be specified for individual solution components and then fair competition between all business stakeholders should permit the development of an ideal solution package for every application case.

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Attachment D.2

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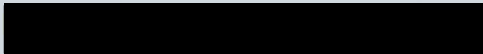


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1 Unique identifier3

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1 Unique identifier

Stakeholders on the manufacturer side have varying requirements on the unique identifier. This not only applies to the form of application, but also and especially to the information which is to be included as part of the unique identifier.

For instance, particularly manufacturers with low production volumes and manufacturers with low automation and low-developed IT infrastructure in production processes demand that the unique identifier can be generated independently of the actual production process and, if at all possible, be purchased in the form of a comprehensive solution with a secure label as supplied by a service provider, the existing tax stamp being the method of choice. Of course, this does not mean that all information required in accordance with Art. 15 would be available at the time the unique identifier is generated. Therefore, in our opinion, it is necessary to separate the mandatory data that make up part of the unique identifier from the data which are linked to the identifier by a relation in the database on a case to case basis with high flexibility.

Complete liberalisation of the rules right up to the concept that unique identifiers simply represent a link to the central database is to be recommended. As an additional advantage, this measure would considerably reduce the complexity of the standardisation process.

To prevent the unique identifier being predictable and to achieve effective protection against unauthorised issuing of identifiers, cryptographic mechanisms that are under the sovereign control of the respective member state should be deployed when generating unique identifiers. This is particularly necessary if the unique identifiers are also to be used in support of taxation accounting processes. Cryptographic mechanisms have the additional advantage that the unique identifiers can then be authenticated offline by the controlling authorities.

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Attachment D.5

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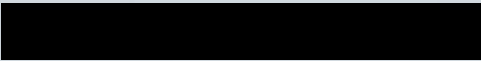


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1 Data carrier

With regard to interoperability, defining a single data carrier would offer the best solution. However, after studying the requirements of stakeholders from the producer side and those of stakeholders along the entire distribution chain more closely, Bundesdruckerei has come to the conclusion that obstacles to enforcing such an approach are too great. On the contrary, it seems more sensible to use the system solutions already in place to some extent for logistics processes and to integrate these in a suitable manner. This means that the complete system would have to be able to handle several data carrier types, which would have to be centrally standardised, of course.

In our opinion, a human-readable version of the unique identifier must always be implemented together with and parallel to a machine-readable version. Apart from ensuring greater system robustness, this offers the added advantage that technical obstacles for using the system in control processes would be very low and this would therefore contribute towards greater acceptance and distinct usage affinity. Another important benefit would be the possibility of being able to countercheck the two implementation modes against each other and to integrate this countercheck into the authentication solutions.

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Attachment D.9

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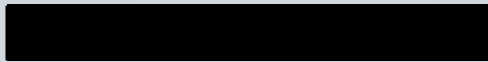


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1 Additional measures for control.....3

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1 Additional measures for control

In our opinion, the security of the overall system which is to be introduced is based on two pillars: tracking & tracing and the security feature. In order to ensure that both of these remain secure, efficient control mechanisms have to be put in place.

As far as security features are concerned, modelling a solution on standards already applied in the security industry (e. g. ISO14298:2013(E) Management of Security Printing Processes), as discussed in the feasibility study, is a sensible and recommendable measure. In addition, both system integrity and conformity of the processes to the specifications have to be monitored using regular control measures. We believe that this has to be done by the competent authorities. Commissioning a third party to conduct these control measures under the supervision of the authorities is also possible.

Similar procedures must apply to tracking and tracing products. For instance, these could be based on the standards ISO 27001:2013 – Information Security Management and ISO 27002:2013 – Information technology –Security techniques – Code of practice for information security controls. As we see it, it must be ensured here that different specifications for the mandatory security measures also apply for different individual stakeholder groups.

In our opinion, the process of generating the unique identifiers has particularly high security requirements. We consider that the responsibility lies here in particular with the authorities of each member state. This especially applies in cases where the unique identifiers are to serve as a basis for taxation accounting processes.

In Bundesdruckerei's opinion, the FAR (false acceptance rate) to be achieved must be specified for the use case: "verifying if products are properly marked on the production line". We assume that machine-readable data carriers will be predominantly used on high-volume production lines. This means that even if a "no-read" event occurs for a pack/tin/pouch/item, identification by means of the human-readable data carrier will still be possible. All kinds of "re-run" processes should be avoided, particularly in the cigarette industry's highly-automated production lines. Due to the high throughput speed, the information required in accordance with Art. 15 will be identical for a large number of packs. Therefore we consider it to be acceptable to allow n packs per carton to be involved in no-read events. In the ensuing process steps and above all in the entire distribution chain, only the unique identifier of the respective aggregation package (carton, master case, pallet) is used.

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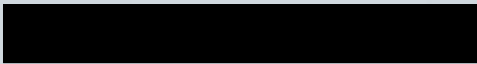


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1 Method of putting the security feature on the pack

In the feasibility study, the label is essentially the carrier of choice for the security package. The advantages of this method, especially in the run-up to introduction, cannot be dismissed. After all, the respective manufacturer can order a label solution of this kind from a security printing company and then simply apply the labels using existing components.

We do not consider it necessary to stipulate that this must be the security feature carrier, as other conformant solution approaches can also be deduced from the TPD. We at Bundesdruckerei are of the opinion that in order to allow comparison between these approaches, a minimum standard is required, similar to the minimum standards for identification and travel documents as specified by the ICAO.

This procedure would also allow renewed discussion of other methods in which the security feature is integrated during the production of the packaging material. The disadvantages of using commercial printing processes as mentioned in the study can be counteracted by specific additional equipment and materials. This variant would mean a further concentration of competition between packaging material producers. Some of these production processes are already part of the production chains of tobacco manufacturers, however. A development similar to that for the "brand protection" aspect and which leads to a security package might be necessary. If this is the case, this variant offers desirable synergetic effects.

In the above discussions, more focus is placed on the manufacturers' requirements. If the control authority requirements are the primary requirements, a standardised security package would be a better choice. In this context, the established tax stamps already offer high security along with the advantage that the security features, especially the covert feature, are only known to the authorities.

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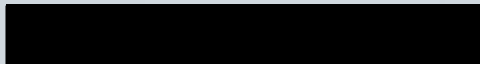


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1 Comments on consumer check3

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1 Comments on consumer check

The participation of consumers in the control processes has two major advantages.

On the one hand, the consumer is made a part of the system by means of an active component. As a result, this element can also contribute towards preventing at least any further increase in the consumer's readiness to purchase illegal products. To promote this, the entire system should be opened to additional user-relevant data content in order to achieve additional benefits more easily.

On the other hand, this would turn the user into an active control instance and in this way might increase the frequency of checks considerably, thus backing up established control processes implemented by the authorities. Considering the vast number of data records, the overall system must be able to check the plausibility of the data holdings intelligently. "Read events" reported from the field are best suited for this. The number of "read events" reported from the field could even be increased by introducing a reward system (e. g. a lottery).

From the field queries thus received, for instance if unique identifier are received more frequently, it would be possible for the authorities to initiate specific investigations of suspect products.

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