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 (CHAFEA) 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.a. Please specify:

- [x] i) Cigarettes
- [x] ii) RYO
- [x] iii) Cigarillos
- [x] iv) Cigars
- [x] v) Pipe tobacco
- [ ] vi) Water pipe tobacco
- [x] vii) Smokeless tobacco including chewing, oral and nasal tobacco
- [x] viii) Other

*A.1.a.viii. If other, please specify

Text of 1 to 800 characters will be accepted

electronic vapour products ("e-cigarettes")

*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

Imperial Tobacco Limited,
121 Winterstoke Road,
Bristol,
BS3 2LL,
UK.
Tel: +44 117 963 6636
All contact details are available on our website:
http://www.imperial-tobacco.com/index.asp?page=633
Registered UK Company, number 3236483
(https://beta.companieshouse.gov.uk/company/03236483)

*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

62460931291-40
(http://ec.europa.eu/transparencyregister/public/consultation/listlobbyists.do?letter=I&d-7641134-p=2&alphabetName=LatinAlphabet)

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

- **72c38d8e-385c-4880-9fef-d19d55efb2fb/IMPERIAL TOBACCO HALF YEAR RESULTS FOR THE 6 MONTHS ENDED 31 MARCH 2015.pdf**
- **ddac55d4-7259-40f6-988b-2fdbcac6eb1c/Transparency Register - Imperial Tobacco.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	◉	○	○	○	○	○
*Interoperability	◉	○	○	○	○	○
*Ease of operation for users	◉	○	○	○	○	○
*System integrity (e.g. low risk of manipulation)	◉	○	○	○	○	○
*Potential of reducing illicit trade	◉	○	○	○	○	○
* Administrative/financial burden for economic operators	◉	○	○	○	○	○
* Administrative/financial burden for public authorities	◉	○	○	○	○	○

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	○	○	○	○	◉	○
*Interoperability	○	○	○	○	○	◉
*Ease of operation for users	○	○	○	○	◉	○
*System integrity (e.g. low risk of manipulation)	○	○	○	○	○	◉
*Potential of reducing illicit trade	○	◉	○	○	○	○
* Administrative/financial burden for economic operators	○	○	○	○	◉	○
* Administrative/financial burden for public authorities	○	○	○	○	◉	○

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	○	○	○	○	◉	○
*Interoperability	○	○	○	○	◉	○
*Ease of operation for users	○	○	○	○	◉	○
*System integrity (e.g. low risk of manipulation)	○	○	○	○	◉	○
*Potential of reducing illicit trade	○	○	○	○	◉	○
* Administrative/financial burden for economic operators	○	○	○	○	◉	○
* Administrative/financial burden for public authorities	○	○	○	○	◉	○

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	○	○	○	○	◉	○
*Interoperability	○	○	○	○	◉	○
*Ease of operation for users	○	○	○	○	◉	○
*System integrity (e.g. low risk of manipulation)	○	○	○	○	◉	○
*Potential of reducing illicit trade	○	○	○	○	◉	○
* Administrative/financial burden for economic operators	○	○	○	○	◉	○
* Administrative/financial burden for public authorities	○	○	○	○	◉	○

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

- **4f655ebf-7bf0-4525-968e-bbbd598b33c3/B1_ITG_20150730.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	○	○	○	○	◉	○
*Interoperability	○	○	○	○	◉	○
*Ease of operation for users	○	○	○	○	◉	○
*System integrity (e.g. low risk of manipulation)	○	○	○	○	◉	○
*Potential of reducing illicit trade	○	○	○	○	◉	○
* Administrative/financial burden for economic operators	○	○	○	○	◉	○
* Administrative/financial burden for public authorities	○	○	◉	○	○	○

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	○	○	○	○	◉	○
*Interoperability	○	○	○	○	◉	○
*Ease of operation for users	○	○	○	○	◉	○
*System integrity (e.g. low risk of manipulation)	○	○	○	○	◉	○
*Potential of reducing illicit trade	○	○	○	○	◉	○
* Administrative/financial burden for economic operators	○	○	○	◉	○	○
* Administrative/financial burden for public authorities	○	○	◉	○	○	○

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	○	◉	○	○	○	○
*Interoperability	○	◉	○	○	○	○
*Ease of operation for users	○	◉	○	○	○	○
*System integrity (e.g. low risk of manipulation)	◉	○	○	○	○	○
*Potential of reducing illicit trade	○	◉	○	○	○	○
* Administrative/financial burden for economic operators	○	○	○	◉	○	○
* Administrative/financial burden for public authorities	○	○	◉	○	○	○

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	○	○	○	○	◉	○
*Interoperability	○	○	○	○	◉	○
*Ease of operation for users	○	○	○	○	◉	○
*System integrity (e.g. low risk of manipulation)	○	○	○	○	◉	○
*Potential of reducing illicit trade	○	○	○	○	◉	○
* Administrative/financial burden for economic operators	○	○	○	○	◉	○
* Administrative/financial burden for public authorities	○	○	○	○	◉	○

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

- **9a18de12-79de-454f-9476-4de99484d684/B2_ITG_20150730.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	○	○	○	○	◉	○
*The cost analysis presented in section 11.3.2 of the Feasibility Study	○	○	○	○	◉	○

*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)

- **381aaa5a-73ea-4ce0-8d84-2778ddbbeb67/C1_ITG_20150730.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)?

- [x] 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;
- [x] 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 standardization body for using IDs and data carriers:
- pack: sGTIN (GTIN + serial number)
- carton: sGTIN - DataMatrix
- master case / pallet: sGTIN - GS1-128

*D.1.c. Please explain your other solution

Text of 1 to 800 characters will be accepted

Codentify is an operational solution for combatting illicit trade, combining Product Authentication and Track&Trace technologies, by generating a unique number to serialise the consumer unit. It is based on advanced, highly secure digital coding technology and offers visibility and control over global supply chains. The information that is embedded in the code can be retrieved from the system and includes a variety of information. A machine-readable version of the code, that contains the same information, is also printed on the pack for scanning: the DotCode.

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)

- **cbe8ceb3-cfba-497b-95dd-8e389c8a4945/D2_ITG_20150730.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)
- [x] b) Solution based on the minimum technical requirements that allow for the use of multiple data carriers;
- [x] c) Another solution;
- [ ] d) No opinion

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

Text of 1 to 800 characters will be accepted

```
There is not only one single data carrier that may cover different
packaging hierarchies and be compliant with EUTPD.
For the lowest packaging unit (e.g. pack of cigarettes, pouch) the (AIM)
ISS DotCode is the only available symbology that allows to apply human
and machine-readable codes during high-speed production.
At the next level (outers/cartons) the GS1 DataMatrix is printed.
Both on Master Cases and Pallets the GS1-128 barcode is applied.
According to the 'Analysis and Feasibility Assessment', GS1 data
carriers are the most widely used ones in the supply chain.
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*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;
- [x] 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)

- **84880b98-2aba-4d59-8601-80210f19220b/D5_ITG_20150730.pdf**

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

- [x] a) Before a pack/tin/pouch/item is folded/assembled and filled with products;
- [x] 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)

- **9d0701a0-b9b1-4070-8323-5fc83bc88055/D7_ITG_20150730.pdf**

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	◉	○	○	○	○
*Marking products with serialized unique identifiers on the production line	◉	○	○	○	○
*Verifying if products are properly marked on the production line	◉	○	○	○	○
*Scanning products upon dispatch from manufacturer's/importer's warehouse	◉	○	○	○	○
*Scanning products upon receipt at distributor's/wholesaler's premises	◉	○	○	○	○

*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

Targeted and/or ad-hoc inspections of all process steps mentioned could be carried out. In order to certify the full integrity of the system we support providing full transparency by e.g. auditing our system.

*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;
- [x] c) A security feature is printed;
- [x] d) A security feature is put on the pack/tin/puch/item through a different method;
- [ ] e) No opinion

*D.10.d. Please explain your other method

Text of 1 to 800 characters will be accepted

The Study does not offer any other solution than extending the use of fiscal stamps and does not include any proposal for printed security features.
The security feature should be an intrinsic part of the packaging and this does not necessarily mean printing. There are many security features available on the market which are suitable such as taggants and finger printing which do not need a label, but are intrinsic parts of the packaging. Random secure serialisation is also a feature which has been used over many years with success to authenticate products.

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)

- **64a5e179-da10-4e51-b0b9-b9cc3b026c30/D11_ITG_20150730.pdf**

*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;
- [x] 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)

- **083c8711-e286-4dc5-8ce7-bee3e70d800f/D13_ITG_20150730.pdf**

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

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

*D.14.c. Please explain

Text of 1 to 800 characters will be accepted

Absolute pre-requisite for the development of reporting and query tools is to have a thorough and sound knowledge and understanding both of tobacco industry manufacturing/processes (incl. IT landscape) and of database concepts.

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)

- **6dbe2817-f326-4106-9590-ff77188531c6/D15_ITG_20150730.pdf**

*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

In our view, as many as possible consumers should be empowered to authenticate products, be it by smartphones or web portals or other devices. This is not only to strengthen the system but also to extend it with consumer appropriate features.

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

- **247f6c98-d696-4fd4-987c-dcc8d7c32a3a/D17_ITG_20150730.pdf**

Contact

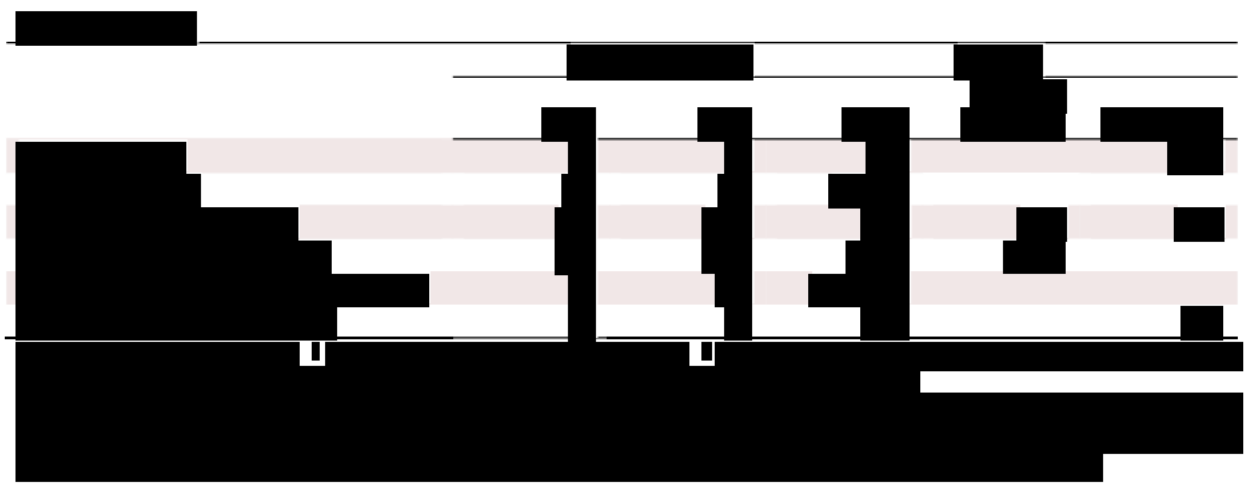
✉ SANTE-D4-SOHO-and-TOBACCO-CONTROL@ec.europa.eu

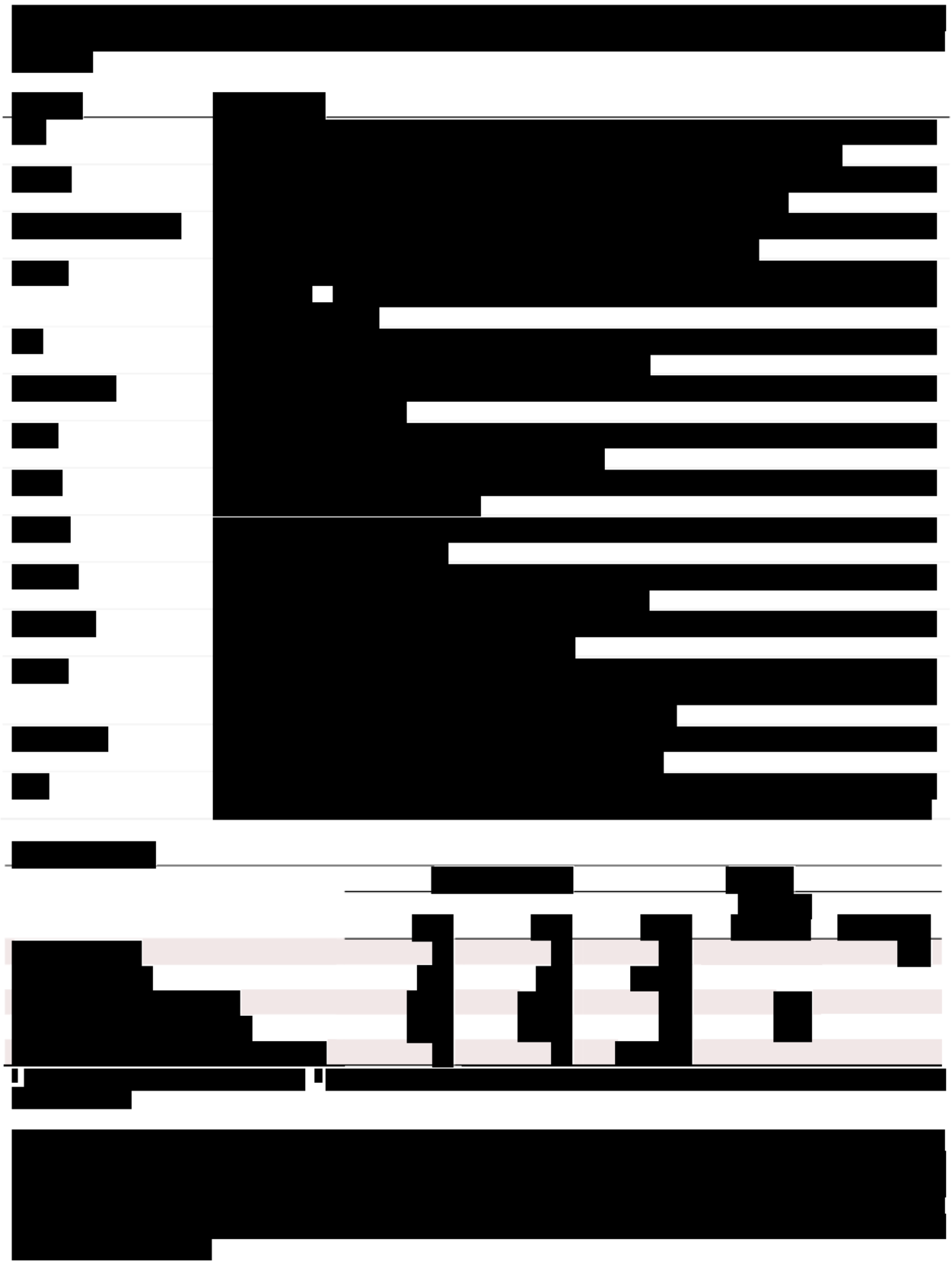
BUSINESS REVIEW

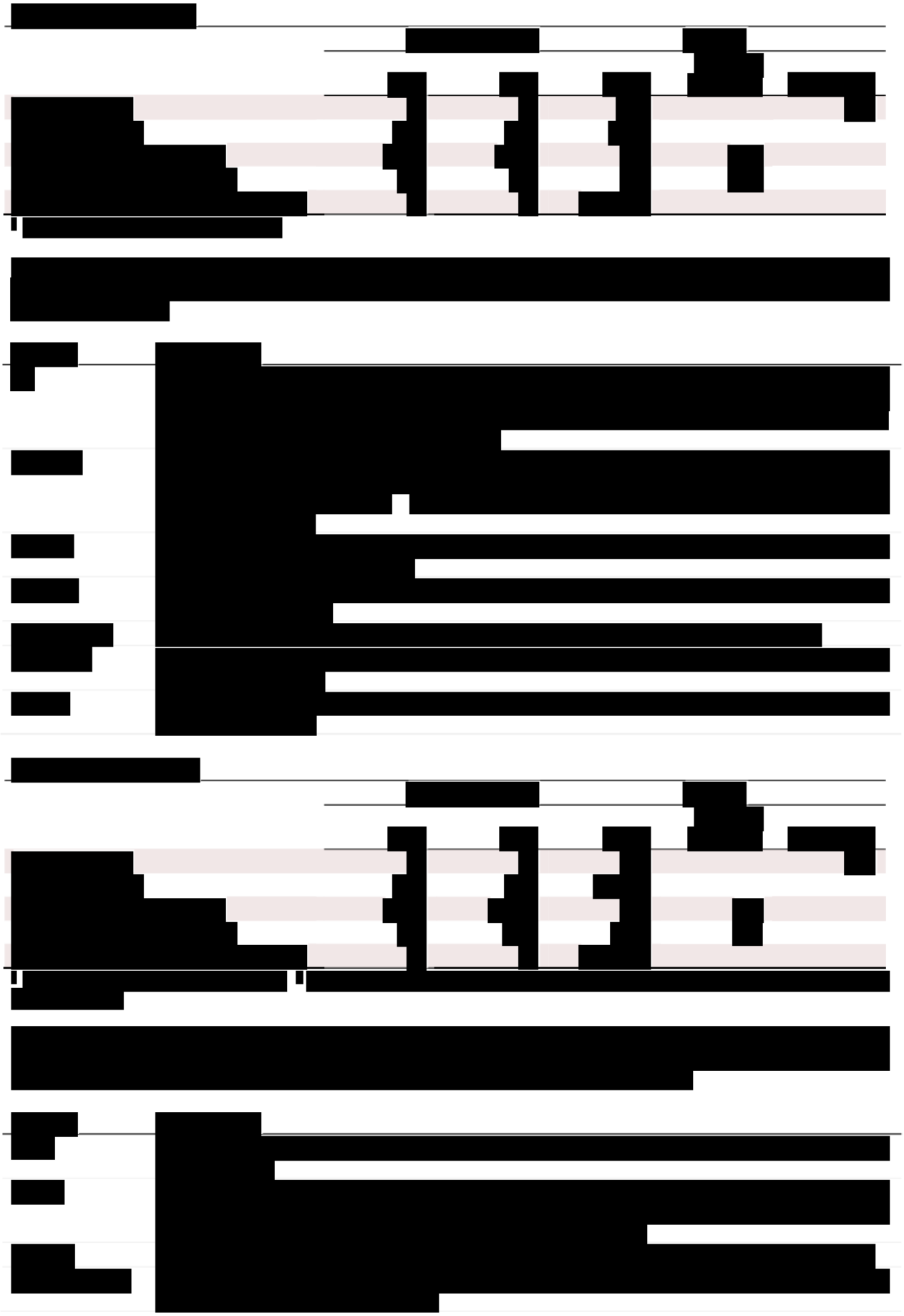
[redacted]

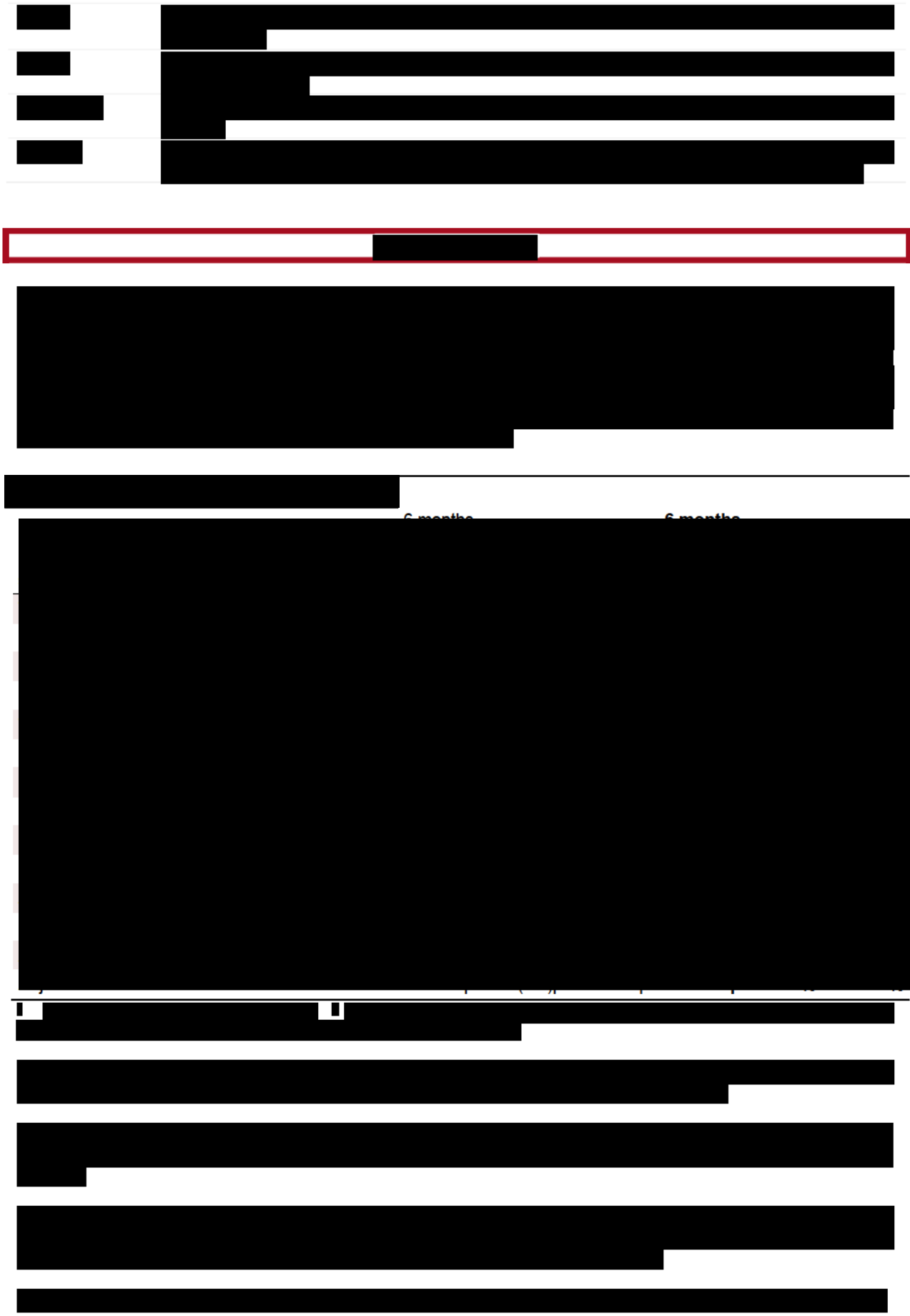
[redacted]

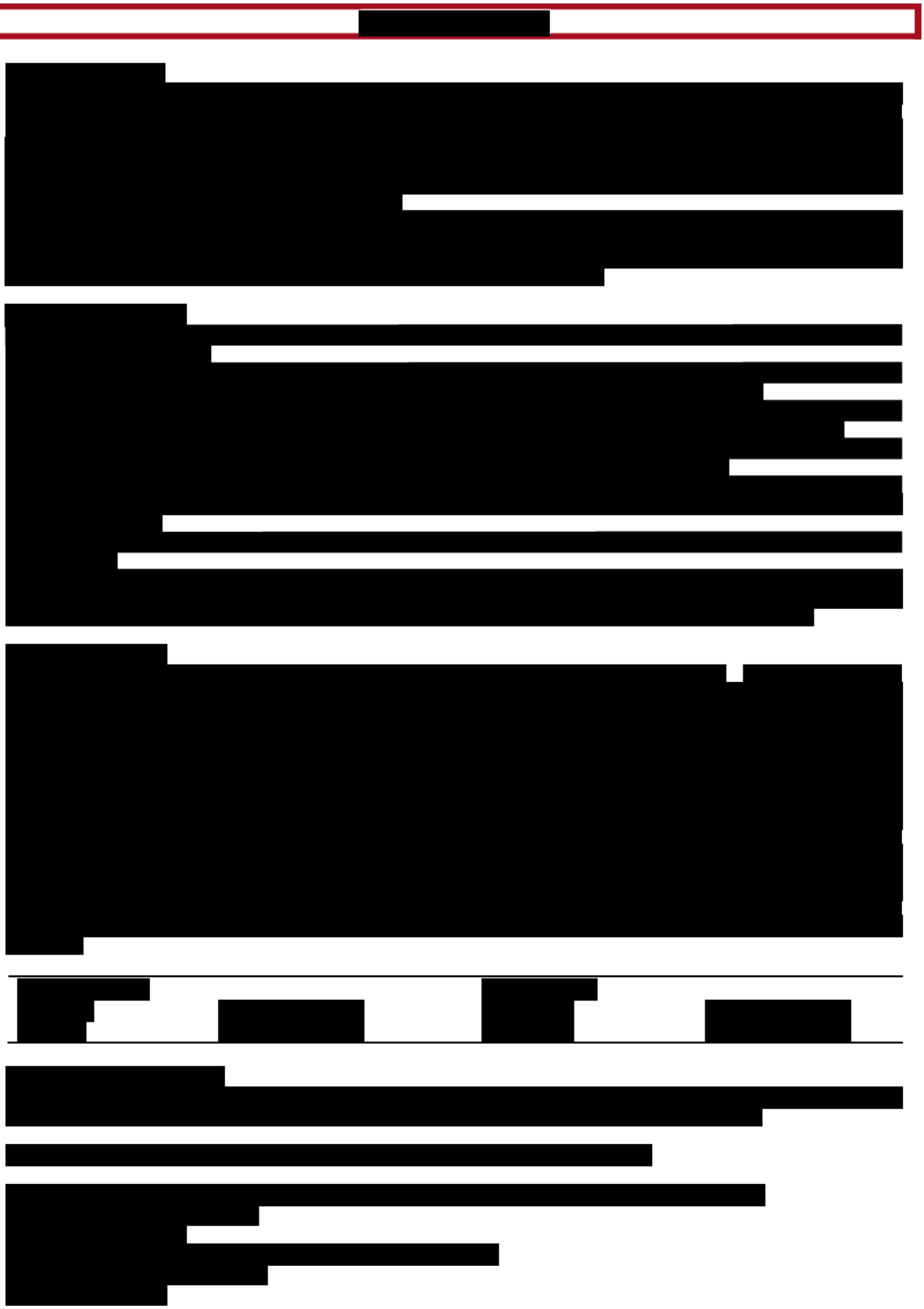
[redacted]











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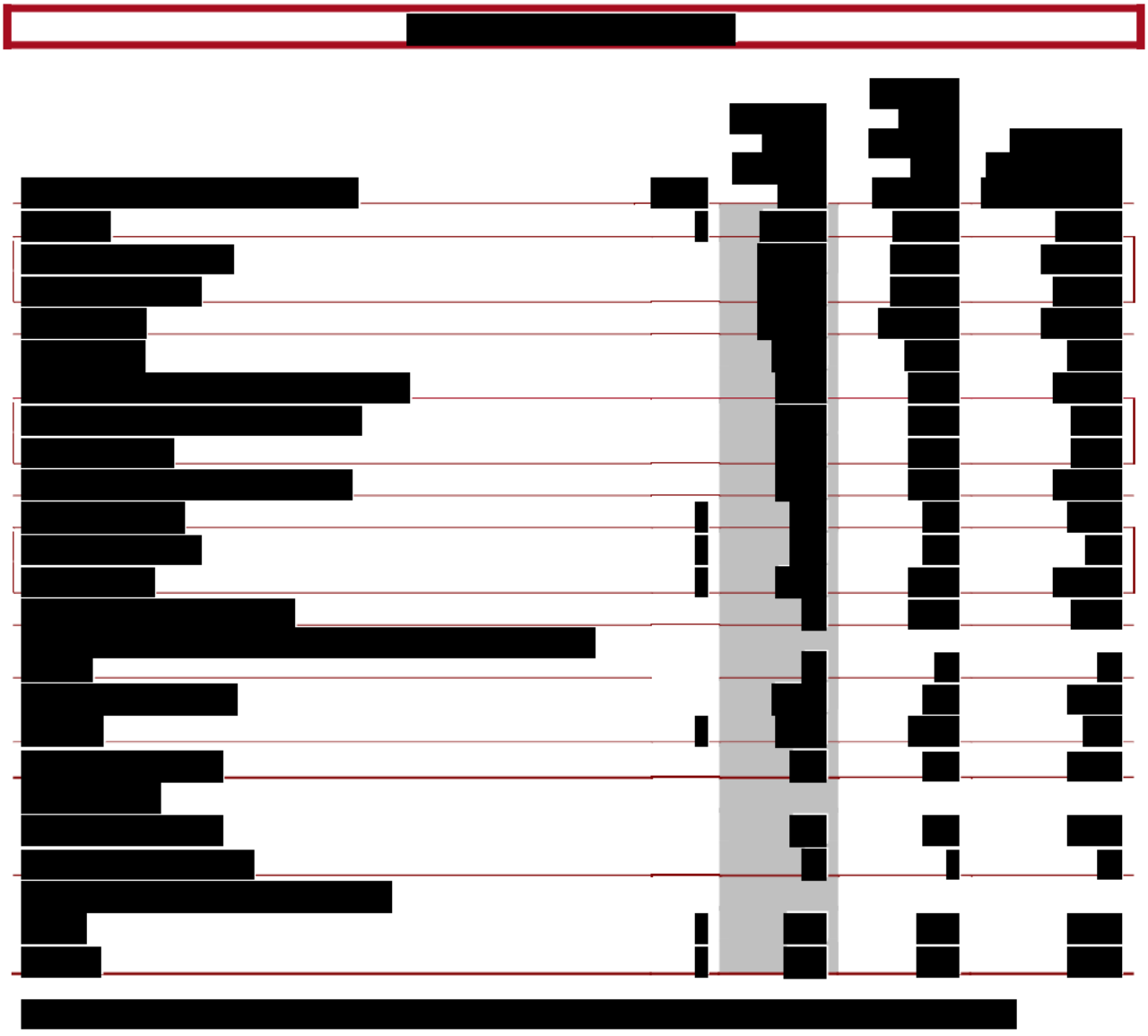

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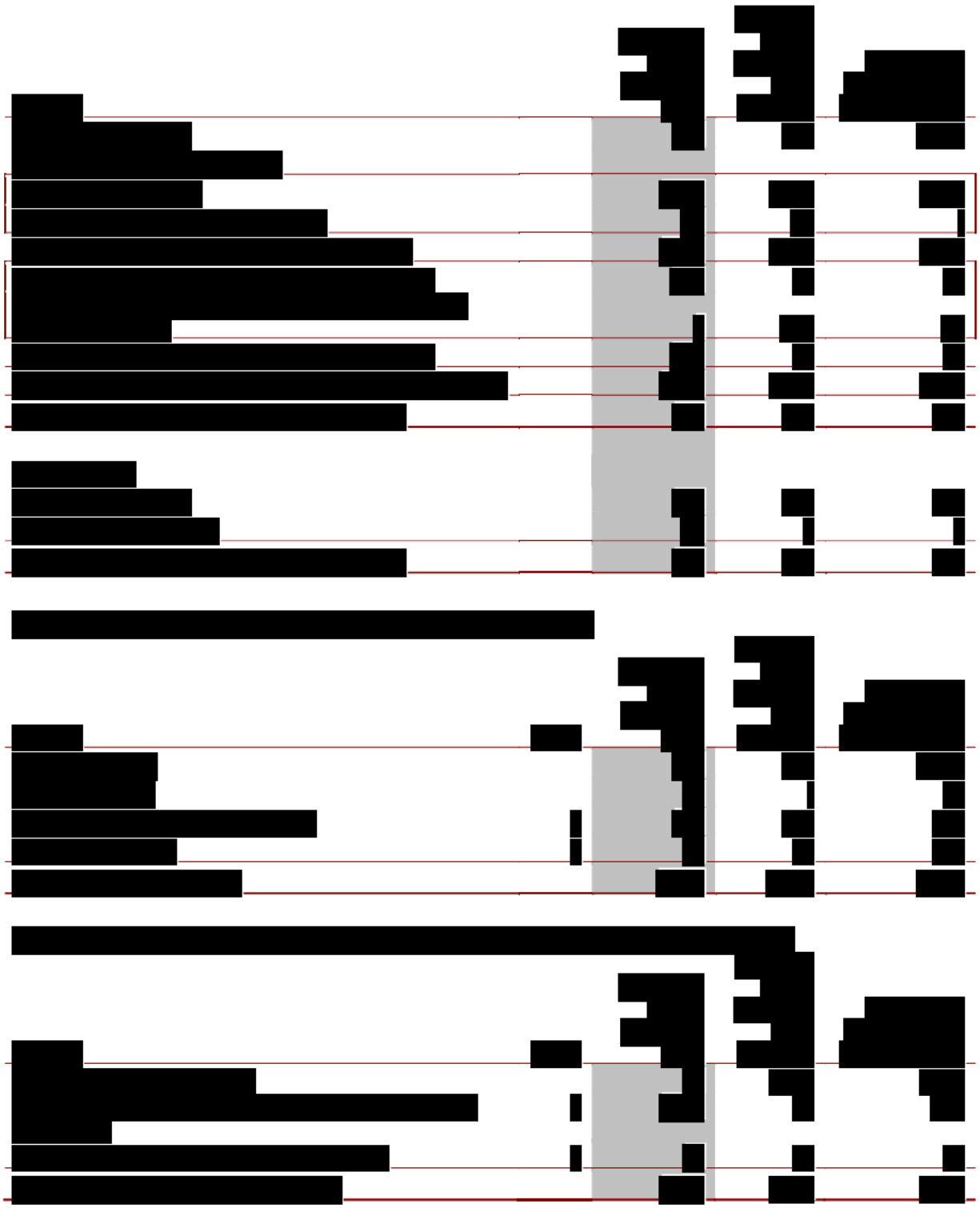

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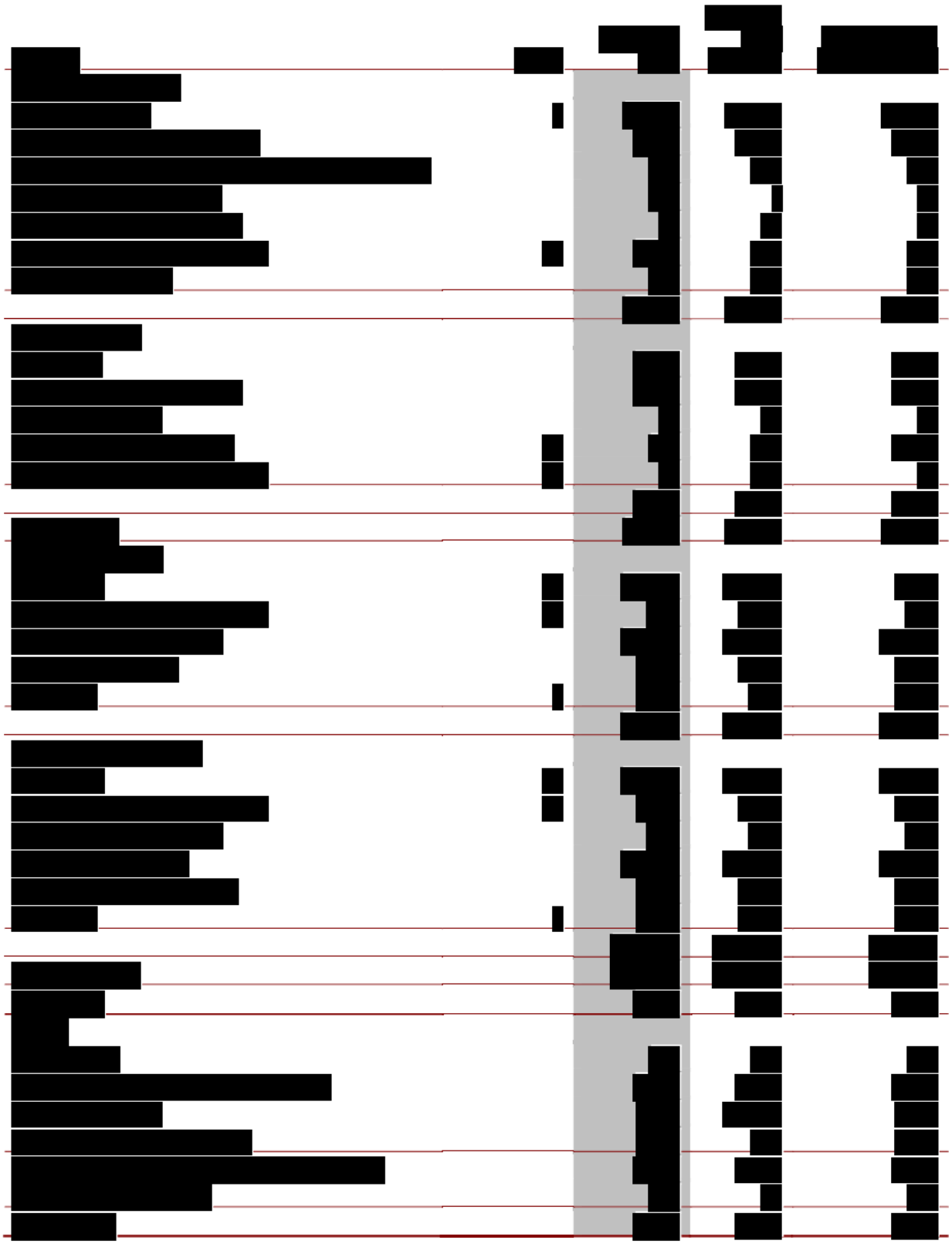

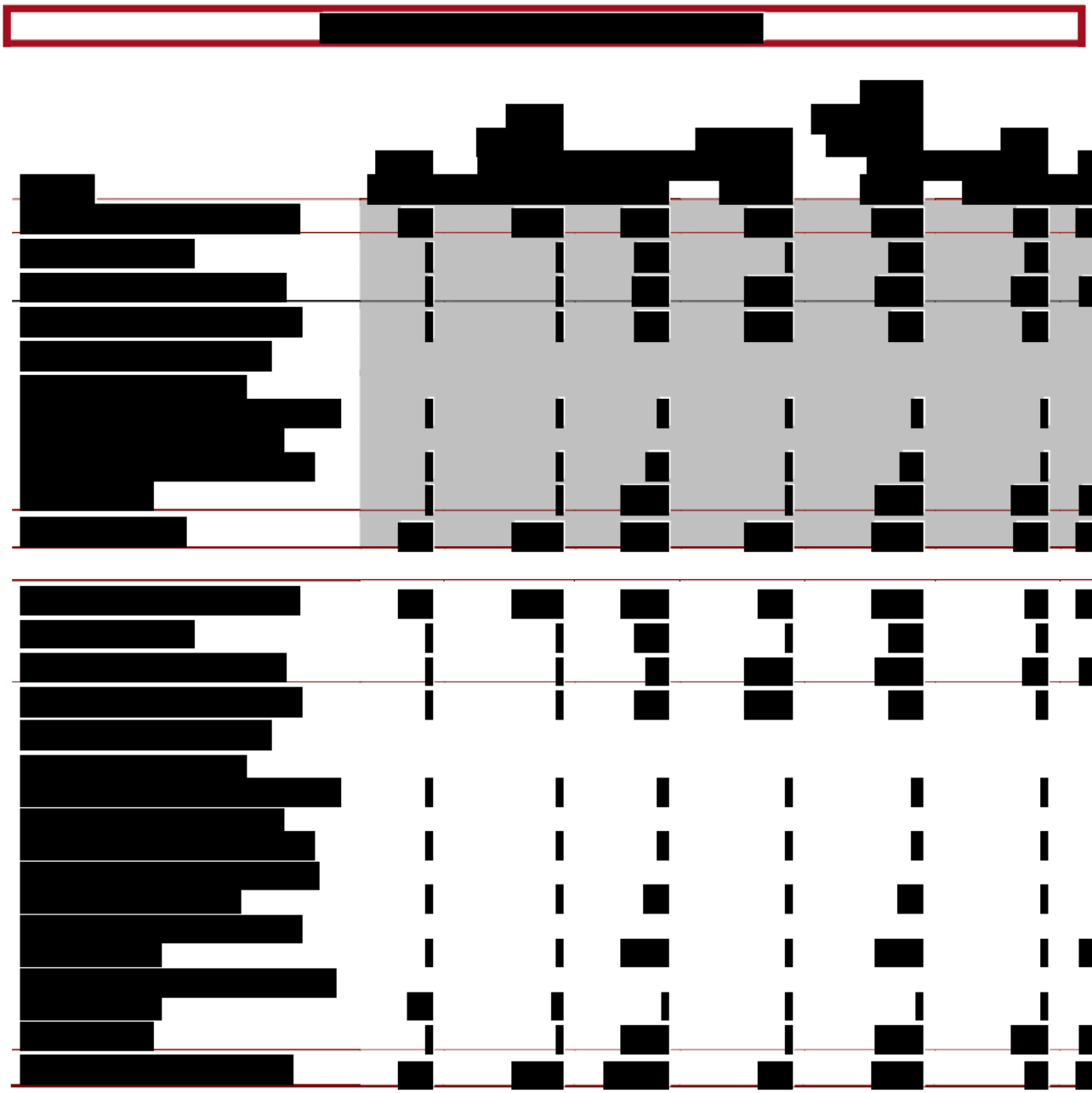

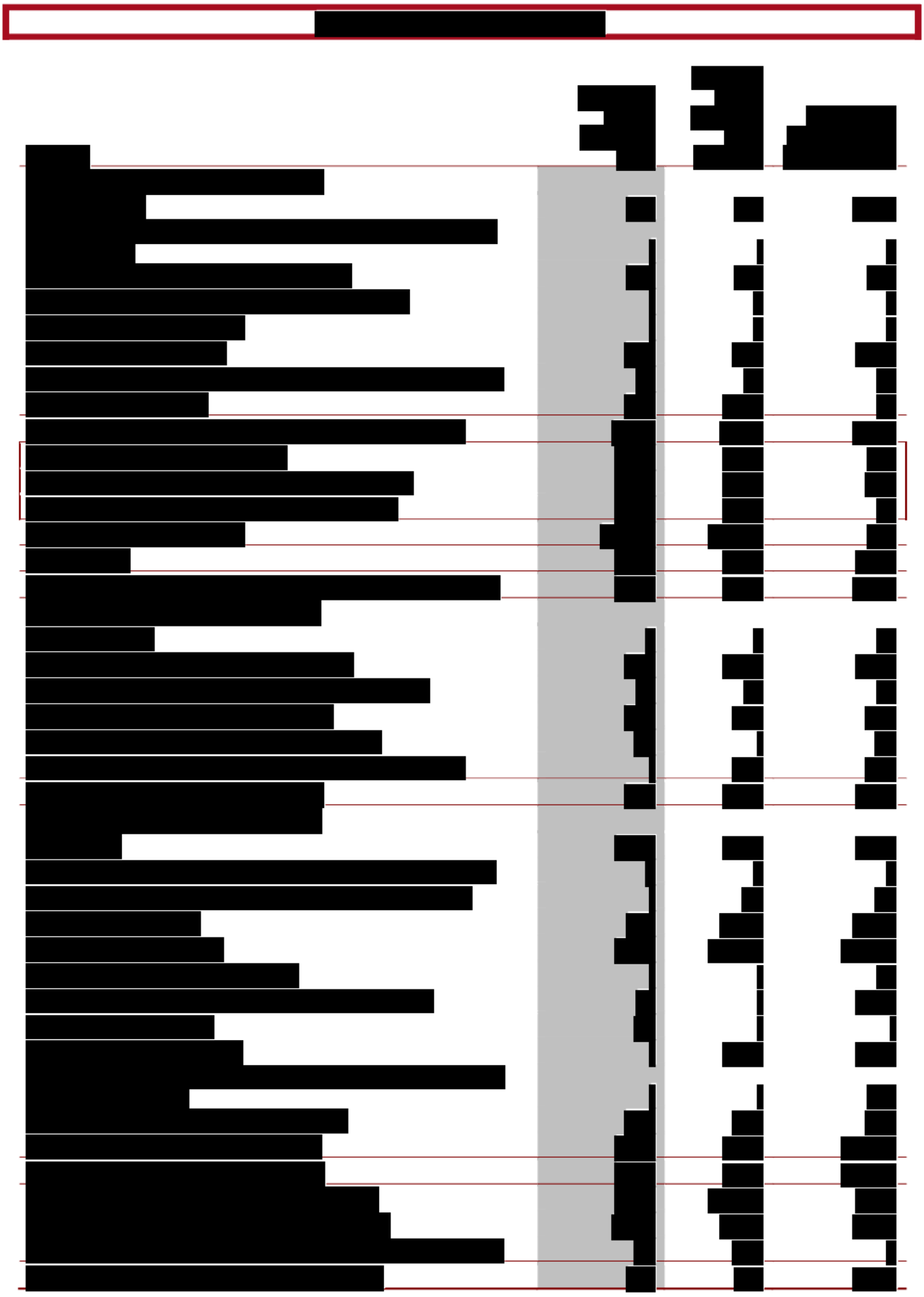

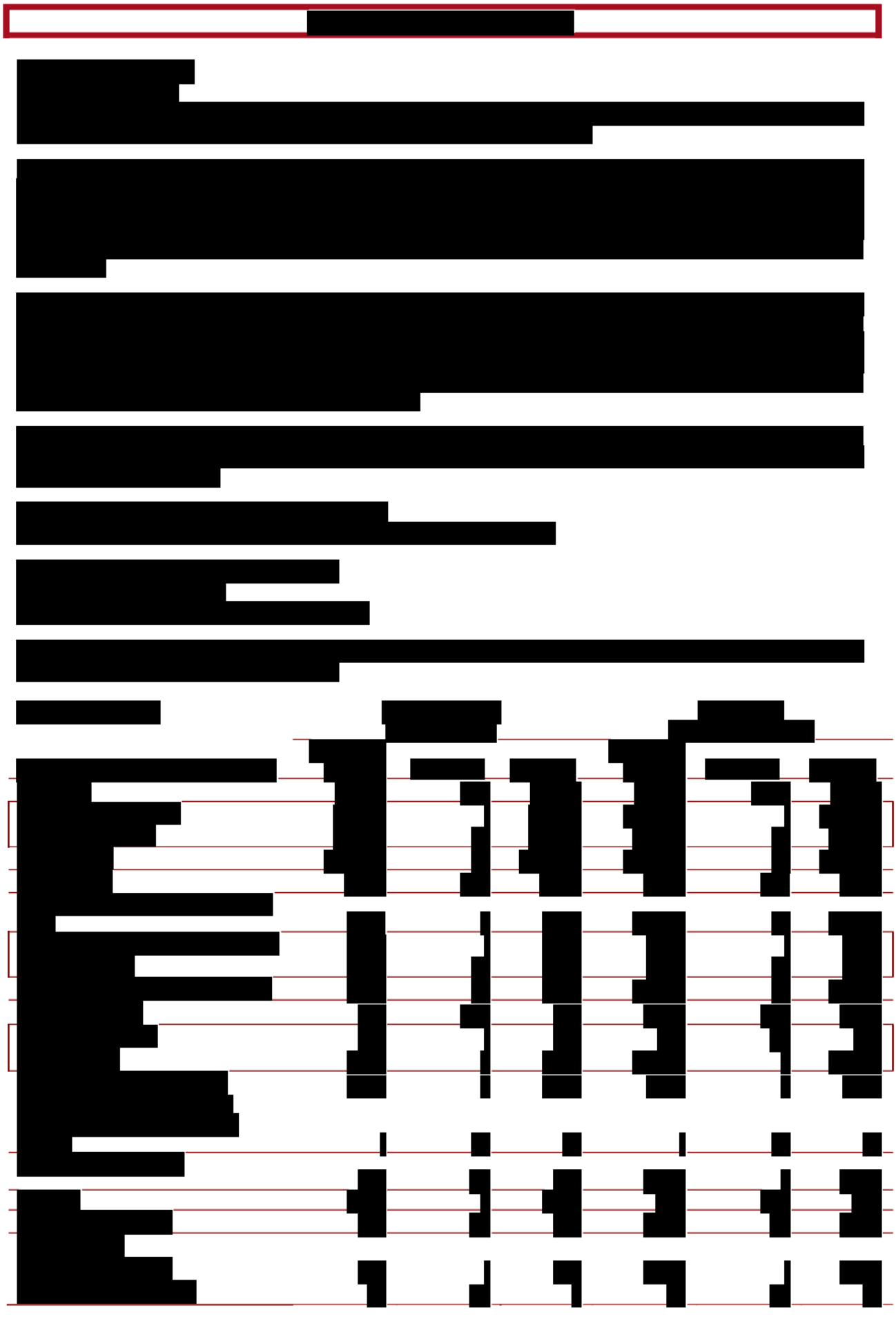

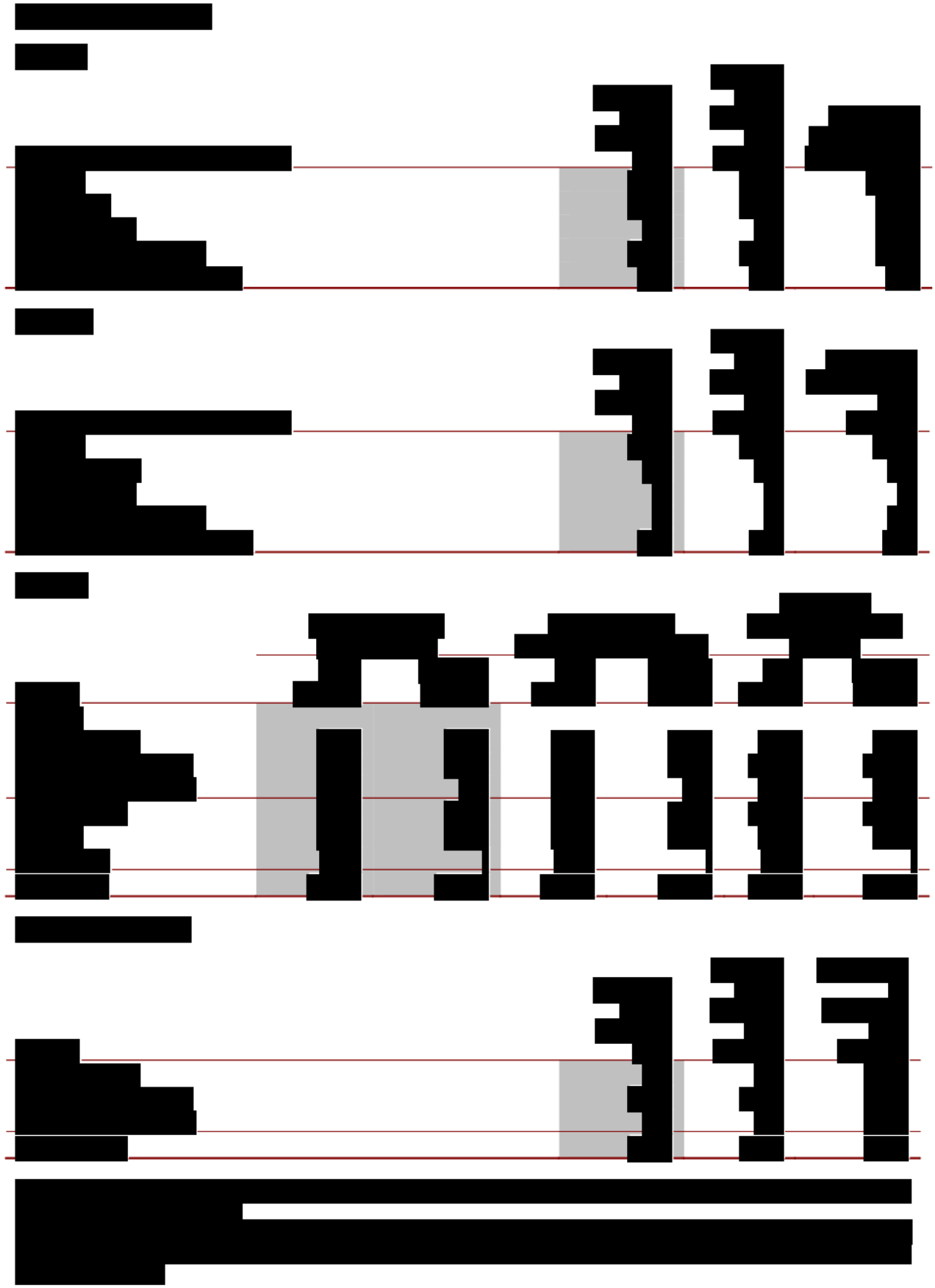

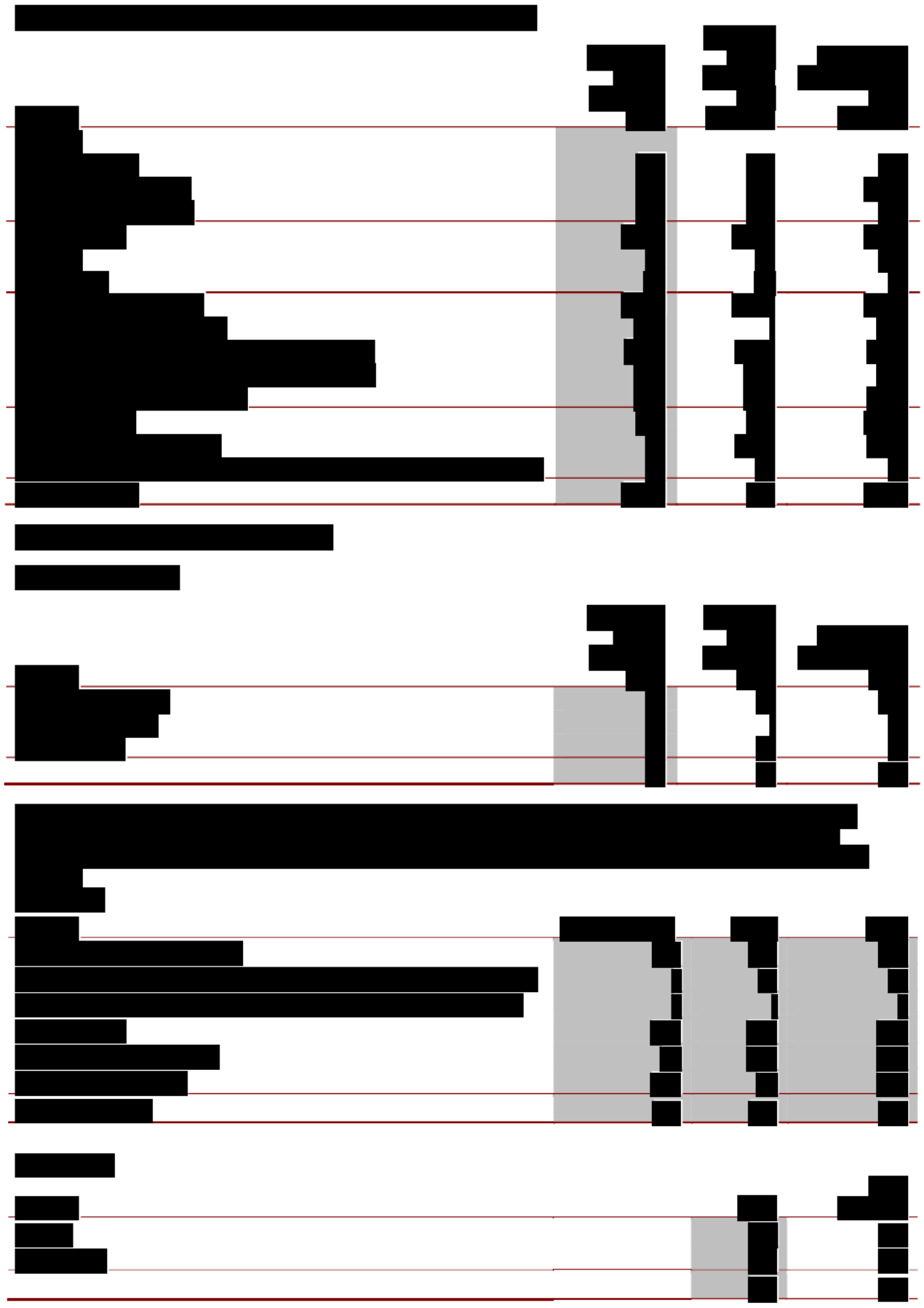

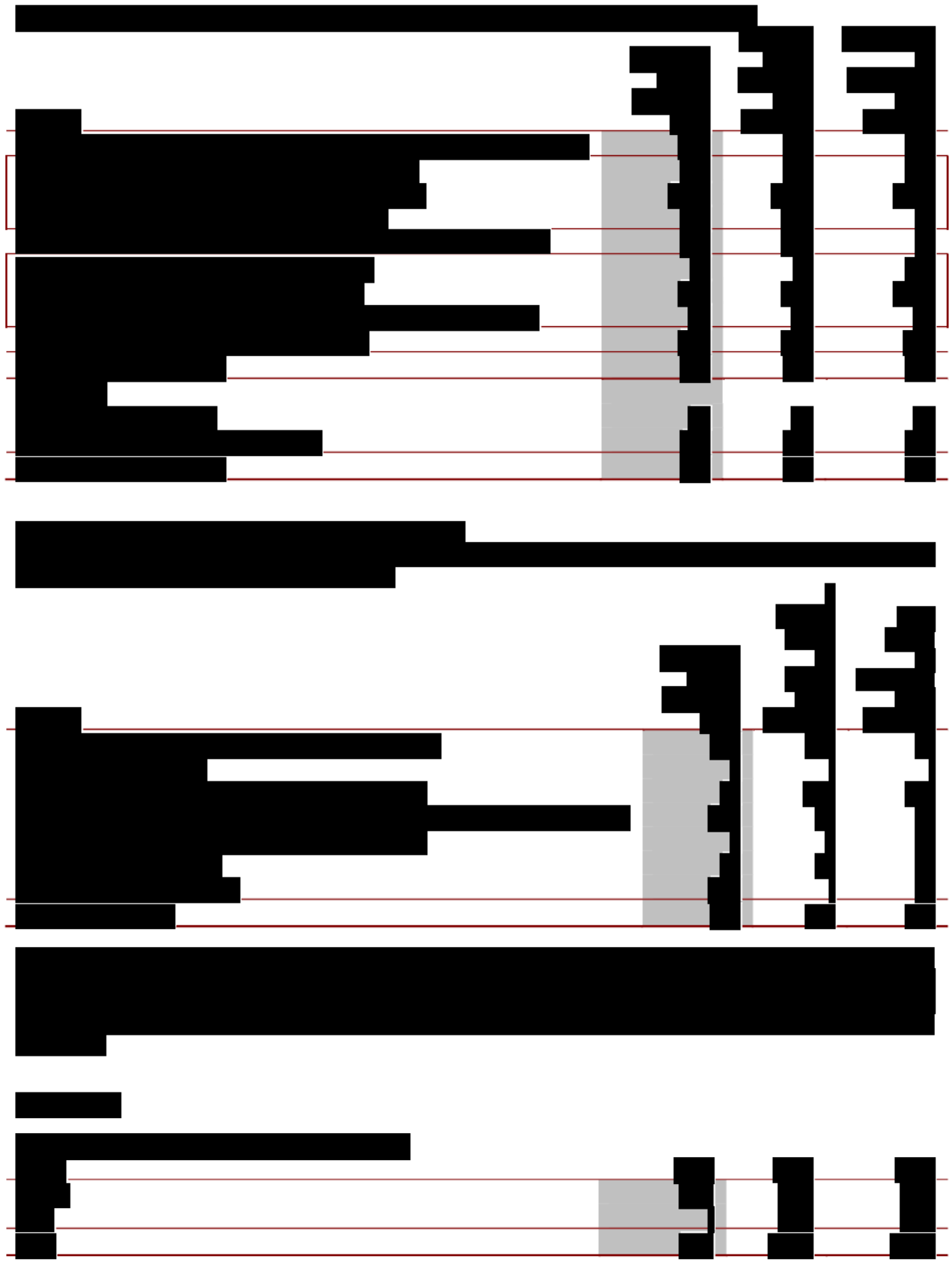

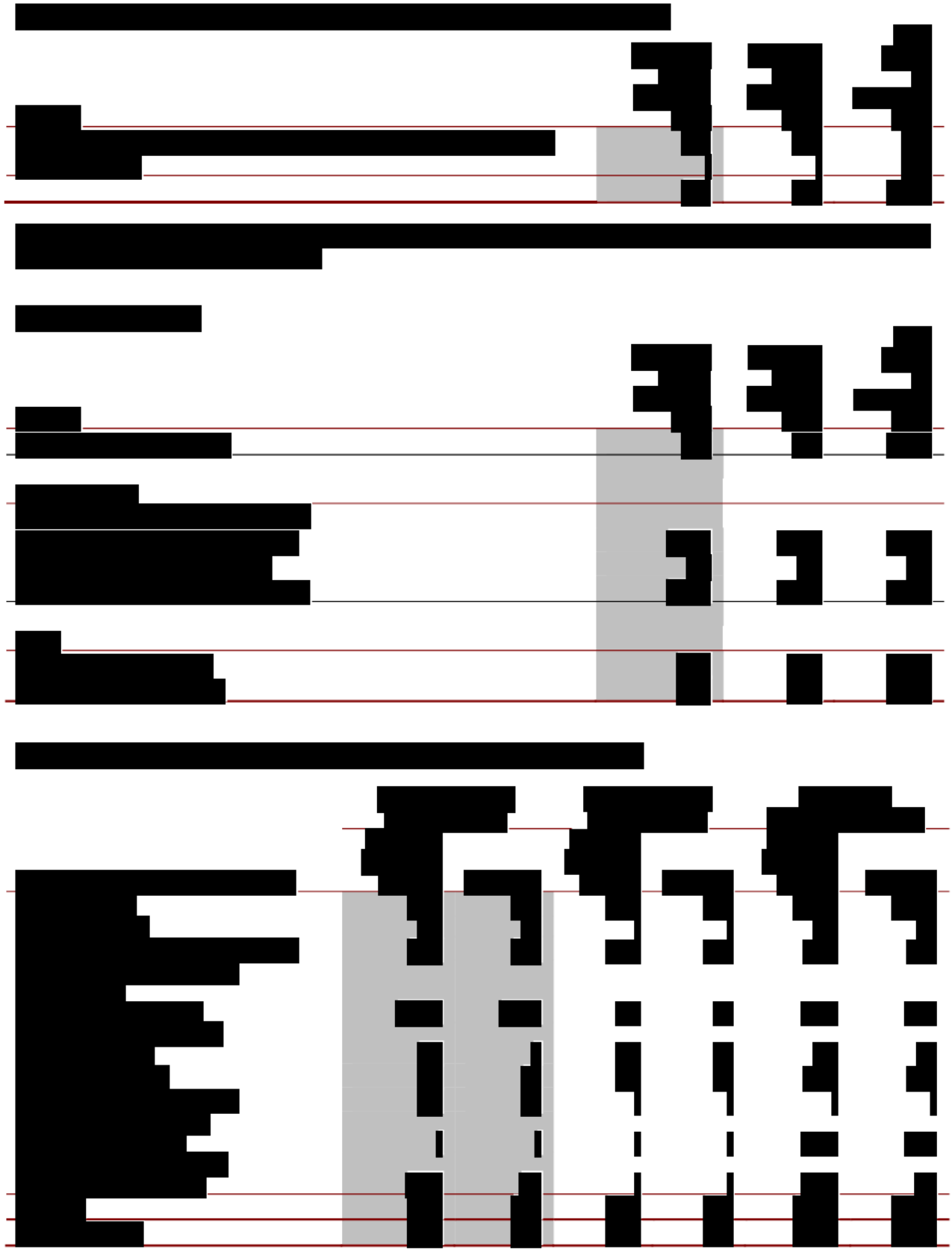

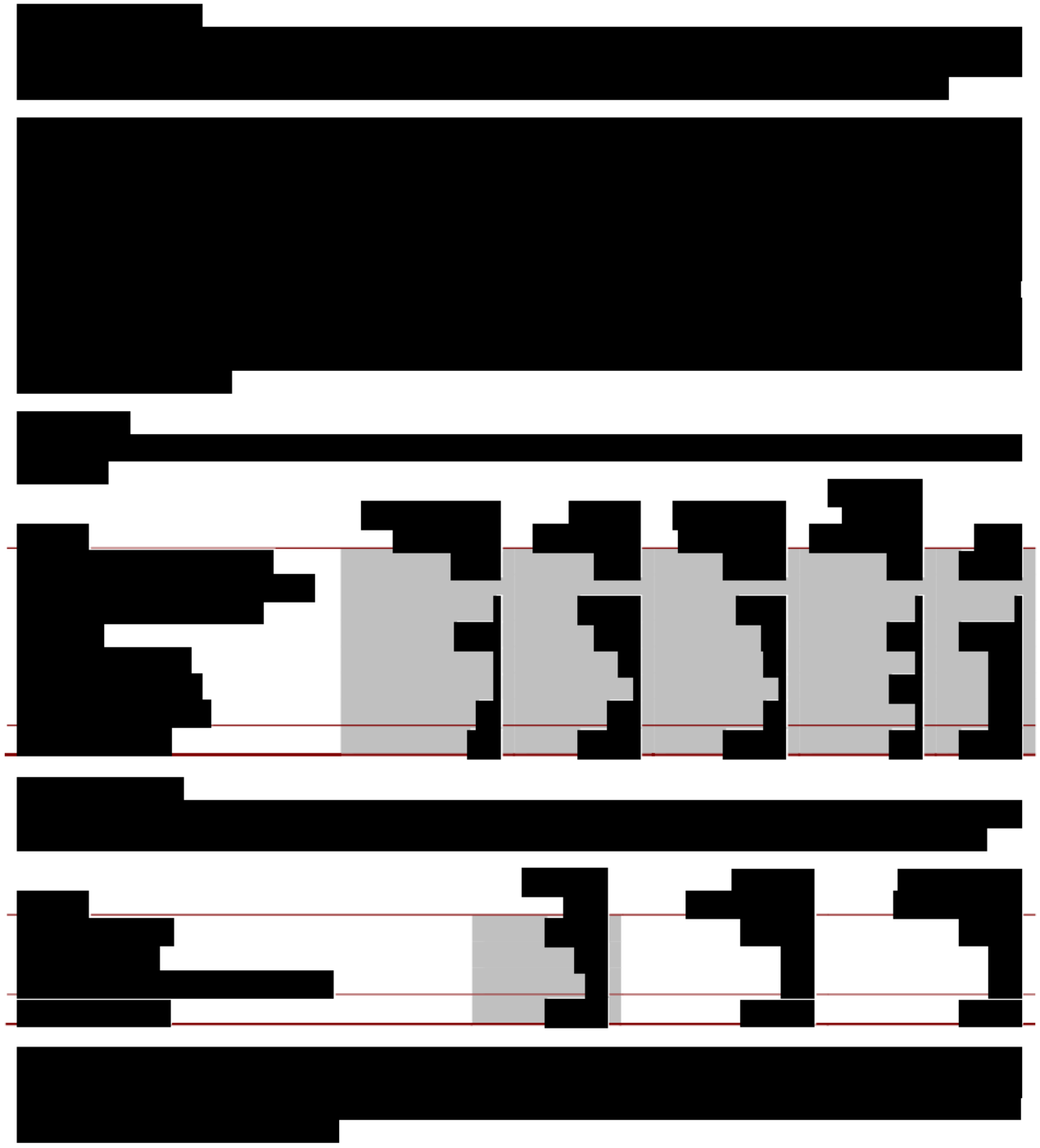

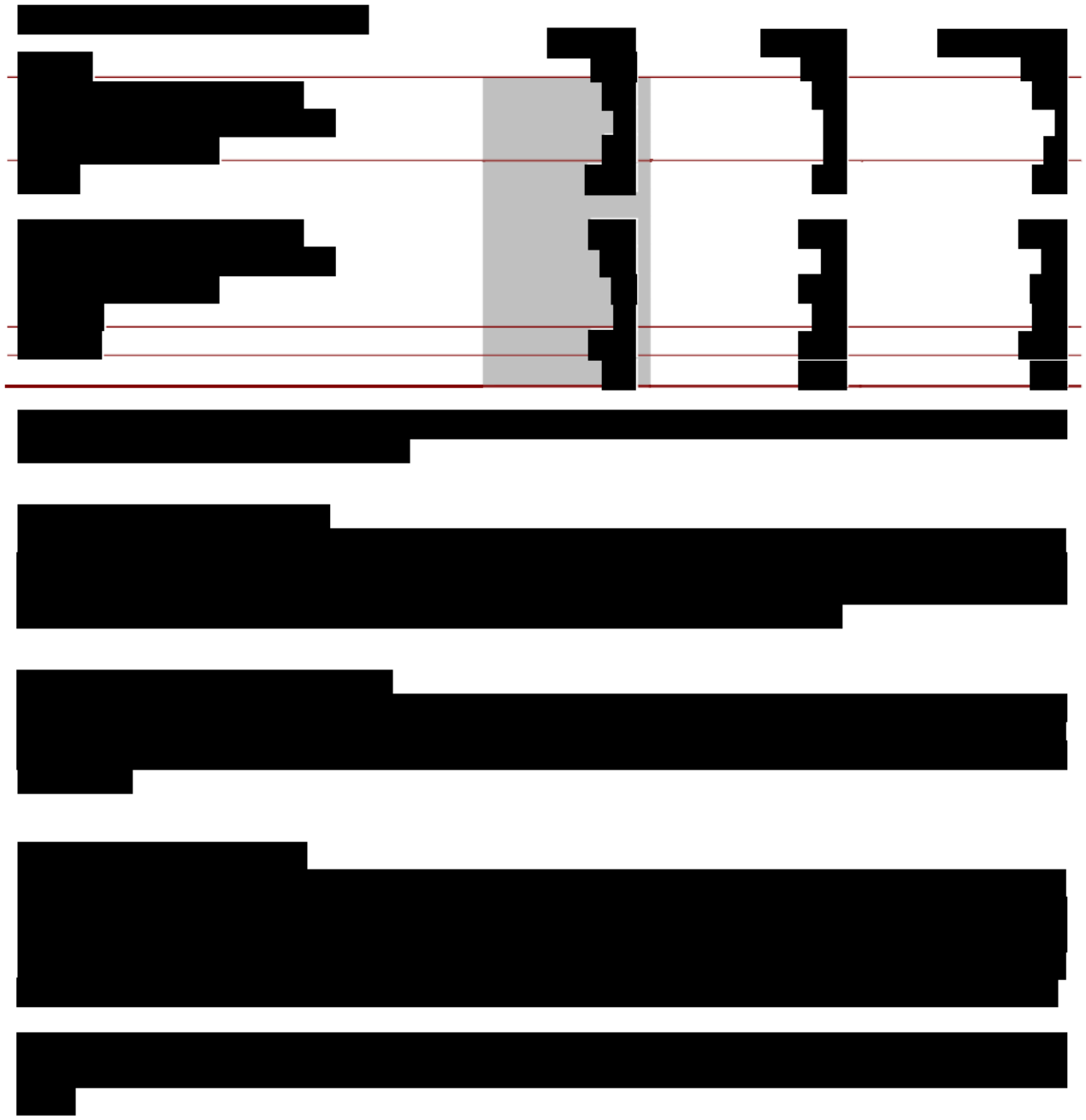

[redacted]

Attachment A4.2

български (bg)

Search Europa

[redacted]

Profile of registrant

[redacted]

Registrant : Organisation or self-employed individual

[redacted]

[redacted]

[redacted]

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B.1 (ITG)

Option 1 is the only technically feasible solution. This solution is used by major international tobacco manufacturers in more than 120 countries under legally binding agreements with the EU and MS. The system uses identifiers, data carriers and communication formats built on global standards (GS1 and AIM Specifications [ISS]). Smart data storage methodology enables manageable data size and reporting (within the Article 15 time line).

Unique Identifiers

Option 4 (pre-printed unique identifier) is not technically or legally feasible as the pre-printed identifier cannot include all information required by TPD Art 15(2) and FCTC Protocol. This information is available only at the time of manufacturing. Additionally, “SF location potentially creates aggregation complexity” (p29) as not all packaging surfaces are camera accessible throughout the aggregation process.

Under Option 1, 2 and 3, the unique identifier would be printed at the time of manufacturing. However, different suppliers offer printers, cameras and other elements of a T&T system with different speeds, quality, technology, reliability and price. Only the manufacturers, taking into account the manufacturing equipment, IT infrastructure and other aspects of their business can make the best choice to balance these criteria. Therefore, there is no ‘one-size-fits-all’ solution for the technical equipment and software. Even the four major international tobacco companies use different technologies to turn unique (Codentify) codes into company-specific, fully-featured T&T systems.

The ISS DotCode is a machine-readable data carrier which can carry all required information in a reasonable coding size. A separate human-readable code cannot include all information required by Art 15(3) as this would require (far) more than 50 characters being printed on each pack. However, a (GS1) EAN pre-printed on the pack plus a unique (human-readable Codentify) code printed at the time of manufacture could provide such information. Therefore, the human readable unique identifier has to have two parts: the EAN (GTIN) and the Codentify code (serialisation).

Data storage

Under Option 2, all data would be stored in one EU-wide database. Unique identifiers would be required for 33bn packs manufactured annually and as the FCTC’s AIT Protocol requires data accessibility for at least four years, the database would have to administer at least 132bn unique identifiers for packs, and additional 13.2nn for cartons – before accounting for packaging aggregation (pack->carton->master case).

However, the major data size results from recording every “product event” (movements between warehouses or sales). Monitoring of actual shipping routes and payments leads to additional events.

The Study refer to each unique identifier and GTIN being made up of only 20 characters. This is clearly not enough: more than twice would be required to encode the data required by legislation. However, all this is only possible at all if additional master data is available elsewhere, otherwise significantly more characters would be required. The Study's assumption that there are only four product events in the supply chain of any product is another clear under-estimate. Some 60% to 80% of products are shipped across borders before final sale. Such a supply chain has a minimum of six transactions. As exit and entry information are both separately required in all transactions, the number of reported events must be at least 12. Adding the actual shipments and payments to the database would lead to a total of ~20 events.

The Study's calculation also does not include any invoicing and payment data (see proposals in 8.6.9 which are clearly not compliant with Art 15 and the FCTC Protocol). This information would have to be requested from the manufacturer and from their trade customers. Even then, the Study suggests that this would allow for some two years of data in direct access ("For further improvement in data processing times, a typical production database of this size would hold two years' worth of records in an on-line database for day to day processing and analysis, with the balance being available by accessing another instance of the database as required" p262). This is half the retention period required by the Protocol.

There are strong indications that the calculation may have underestimated the volume of data required by a factor of 10.

Option 3a, 3b and 4 include national databases. Recreating the movements of unique identifiers through the cross-border supply chain from 28 national databases would be extremely challenging and require each database to use exactly the same data structure and methodology.

The Study concludes that only around 5% of tobacco products are moved across EU borders. This is a significant inaccuracy caused by using the *pre-tax value* of EU cross-border transactions against the *retail value* of the total EU market. The real share of cross-border shipments is somewhere between 60% and 80%. As such, the majority of all identifiers would have manufacturing and selling information in *different* databases. The search would have to

include the aggregation information, and to search for all aggregation identifiers in several national databases to recreate the pack route.

Finally, the proposals for EU-wide or national databases are not compliant with recital 31 or Art 15(8) which state that manufacturer should have a choice of database operator and auditor (to be approved by Commission).

Additionally, the EU/national solution provider(s) would have to implement the system in all factories around the globe that produce goods destined for the EU.

The inclusion of exports is rather speculative as the Directive does not mention exports at all. If the destination market used different obligations, export products would have to carry two different identifiers, possibly generated and applied by two different "independent third parties" and the prescribed location of these two identifiers would have to be most likely the same.

Article 15 timeline

Options 2, 3a, 3b and 4 require public tenders which cannot take place before the Implementing Acts have been adopted. It is unlikely that this could be finalised before the *implementation* deadline in May 2019. The subsequent implementation of currently non-existing solutions in some 332 EU cigarette (and many more non-EU) manufacturing facilities would take decades.

Existing Systems

The Study states that there are currently only two potential solutions in operation: Codentify and Scorpios.

The Scorpios system (developed by the Swiss company SICPA) is in operation only in Brazil. As the Study notes, "SCORPIOS is a production control system" (p101) and "Some concerns related to the fit of the solution in the TPD context: … The current implementation in Brazil does not track tobacco products beyond point of tax payment, which is the manufacturer. Tracking beyond this point would require additional development." This downplays the fact that Scorpios currently offers no *product* T&T features at all (it provides some T&T features for tax stamps). There are also reports about corruption allegations involving Brazil's dealings with SICPA.

In fact "Codentify", an umbrella term for several manufacturer-developed solutions, is the only product T&T system operational – in 120 countries.[1]

[1] On p104, the Study refers to 5% of lines equipped with pack T&T whilst p278 states that "One of the largest companies is expected to have Codentify fully operational (pack and carton level coding, supply chain traceability) by December 2014". Taking into account also our own implementations, the total of equipped lines is significantly above 50% resulting in another inaccuracy be at least factor 10.

Interoperability

All four options would have to comply with technical standards determined by the implementing acts, therefore, there is no difference.

However, under Option 3 and 4 (national databases), it is likely impossible to ensure that 28 independent databases store data using exactly the same methodology. Extremely detailed standards would be needed. If these failed the recreation of cross-border transactions would not be possible.

Easy for operation for users

Option 1 allows for integrated and bespoke systems developed under consideration of individual manufacturers' equipment, product categories, and IT infrastructure. All other options lead to systems requiring integration of company internal systems with T&T provided by external companies. Under Option 2, 3b and 4, responsibility and accountability would be split between up to four parties (manufacturer, solution provider, solution operator and database operator) and permanent external personal would have to be stationed in all factories.

System integrity

To justify Option 2, 3b and 4, the Study argues that manufacturer access to unique identifiers could lead to copied identifiers, and make the system vulnerable to compromise (p26). The Study contradicts itself in later sections, when it implies that manufacturers would need to access identifiers in order to deal with recalls of products and EMCS. Also, in presenting the alternatives for access to invoicing and payment data, the Study's preferred proposal even requests economic operators to keep all unique identifiers as the invoicing and payment data "will be made available upon request utilising the unique identifier as the key for the record" (p227).

According to the AIT Protocol, tracing is "monitoring and re-creation … of the route or movement taken by items through the supply chain" and "determining the origin of tobacco products, the point of diversion where applicable, and to monitor and control the movement of tobacco products and their legal status".

Therefore, the information about product movements and the identity of the purchaser is crucial. The Study's conclusion – that the generation of unique identifiers is the critical part of the T&T system (p28) – is clearly only a justification of preferred external providers.

The flawed arguments against Option 1 are based on accusations such as**:** "This presents a number of potential risks, including that non-compliant manufacturers have the means to reproduce unique identifiers (as well as the corresponding aggregation relationships) onto undeclared tobacco products for diversion into the parallel illicit distribution chain".

This is inconsistent with the proposal for “modern tax stamps” as security features. If such “modern tax stamps” were in place, how could manufacturers duplicate identifiers? Duplicating identifiers (even without “modern tax stamps”) is impossible, as the manufacturer would have to copy all “corresponding aggregation relationships” and move the duplicated products through exactly the same supply chain, all the way to the same retailers: finding the products elsewhere would be clear evidence that the T&T information is wrong. These unfounded claims about “risk[s] of vulnerability” only serve to promote the commercial interests of “independent third parties”.

Potential to reduce illicit trade

Option 1 is the most appropriate one because it is based on a global concept with which illicit trade can only be combatted. It also ensures that the EU agreements can continue and deliver T&T data for all non-EU markets.

Administrative/financial burden for economic operators

Administrative and financial burdens will be significantly lower for individual solutions which take into account company size, products, machinery, IT infrastructure and suppliers operating under free competition compared to monopolistic/oligopolistic “independent third parties”. Issues resulting from the combination of internal and external systems and others such as pricing are additional contributors to cost. External equipment for T&T would require permanent external engineers at manufacturing sites.

Administrative/financial burden for public authorities

The Study wrongly claims that public authorities would face higher costs from controlling the application of the unique identifiers generated by manufacturers. This would only apply if no other controls were in place.

More relevant is:

- For Option 2, 3b, 4, the EU would have to change the legislation as Art 15 does not allow for these concepts resulting in significant administrative/financial burden for the Commission, EP and MS.
- The Commission and MS would have to organise public tenders and deal with legal disputes. These options also most likely constitute Technical Barriers to Trade under WTO Treaties.
- Failed or corrupt tenders would lead to excessive liability, compensation claims, costs and time delays.
- Database in Option 2 would be unrealistically large and the proposed national databases (Option 3a, 3b, 4) would lead to unpredictability regarding a massive (and unrealistic) reporting project.

Summary

Option 1 is the only realistic and compliant solution ensuring flexible implementation within the available time at lowest costs for all stakeholders, maintaining systems developed and implemented under legally binding EU/MS agreements and being endorsed by the EU.

B.2 (ITG)

General remarks

The attempt to establish the term “modern tax stamp” as a standard for EU security features is misleading in the context of Excise Directive 2008/118/EC.

“Tax stamps” are stamps used for excise collection. This practise is not legal within the EU as the only point in time when excise can be charged is at “release for consumption”, not on stamp delivery. However, tax stamps are still tolerated in four MS.

The other nineteen MS that use paper stamps do not link them to excise payments. These “fiscal stamps” are not evidence of excise payment. Five MS do not apply any stamps. Therefore 24 MS do not use tax stamps and rely on reports from manufacturers, reconciliation of tobacco purchases, export declarations, and reported movements of goods in tax warehouses (goods are under duty suspension) as controls. In some MS without any paper stamps (i.e. France and Austria) excise is even paid by wholesalers.

When paper stamp manufacturers promote “modern” tax stamps, they mean old-fashioned stamps with more expensive security elements (overt/semi-covered/covered/forensic). Not only are these outmoded, and contrary to EU legislation, but there is empirical evidence that they have no positive impact on illicit trade. “Modern tax stamp” is simply a contradiction.

Directive 2014/40/EU does not require “modern tax stamps”. Art 16(4) requires “*security features*” with “*visible and invisible elements*” to **authenticate products**. The consultants took their own decision to equate “security features” with “modern tax stamps” and expanded visible and invisible into “overt, semi-covert, covert and forensic” without explaining the need for these expensive translations. However, they fail to explain to what extent the proposed security features would differ from existing stamps. We do not believe that Art 16 is purely an extension of fiscal stamps to the remaining five MS.

Please note that the “vulnerability” argument against the industry-operated T&T solution (the risk of copied identifiers) seems irrelevant if even packs copied identifiers would need infallible security features.

Incompleteness of the Study

Our main criticism of the four options for security features is that they do not cover all alternatives laid out in Art 16: “security feature shall be irremovably *printed or affixed* to the unit packet of tobacco products”.

Within the category of *affixed* security features, the Study does not offer any other solution than extending the use of fiscal stamps. The Study does not include any proposal for *printed* security features.

This option is summarily dismissed in 7.2.1.4 by emphasising the advantages of paper stamps without mentioning their shortcomings, and in 9.1.1.3 by focusing on overstressed, irrelevant and unconvincing disadvantages. We have discussed the advantages/disadvantages of different security features with the consultants on the phone and by written submission. The most important arguments against paper stamps have not been mentioned in the final Study at all.

Our recommendation, to take an image (or fingerprint) of a part of packaging, transform the fibre structure into a code and include that code in the unique identifier had been disregarded in 9.1.1.5 and 7.2.2.3 due to concerns about the costs and other disadvantages for the tobacco manufacturers, despite the consultants' admission that it is "*near impossible to replicate*", and provides an "*incredibly strong level of authentication*" and "*accurate volume verification*". A fingerprint solution does not require any additional paper stamps. The fingerprint itself does not have to be stored in any database: it is part of the identifier. Even if counterfeiters knew the algorithm and produced identifiers matching the fibre structure of a faked pack, the identifier would not be in the legal database.

Common sense demonstrates that industry would not suggest solutions that slow down the manufacturing process and impose high costs. Therefore, the dismissal in 7.2.2.3 "*An area of some concern in evaluation these emerging technologies is the issue as to whether these concepts will prove reliable and affordable operating at sufficient pace to support the high production speeds associated with the tobacco industry*" and in 9.1.1.5 (concerns that packaging design changes may become necessary) make little sense. Instead, the Study recommends options ensuring annual payments of €60m-€140m to paper stamp suppliers.

The only option based on intrinsic characteristics of the product is Option 3: adding paper stamps on top of the fingerprint technology. The fingerprint would serve as a semi-covert and covert security element. In fact, the pack, machine-readable code and human-readable identifier provide three visible elements and the fibre structure an invisible one, without any need for paper stamps.

Another solution would be a taggant tear tape. On page 366, the Study states under "Comments" on the UK: "For tobacco, taggant based marker. Tax marks used as opposed to tax stamps. Since inception of marking, illicit trade decreased from 20% to 12% (2001-2009)".

The advantage of a taggant tear tape is that it is destroyed when the pack is opened. If the destruction/removal of the security elements was not desirable, the taggant could be placed anywhere else on the pack.

Another option is invisible printing on the pack.

In summary, the Study is flawed as the authors manipulated their objectives, measurement criteria and evaluation to favour paper stamps solutions from and particular suppliers.

False security

Whilst commenting on the Codentify code, the Study states "*This could confirm that the code itself is legitimate, but provides little assurance that it is simply not a valid code reproduced from a legitimate pack onto an illicit product*". However, the Study does not admit that this applies to paper stamps as well. An affixed paper stamp can provide evidence that the stamp itself is legitimate but *provides little assurance that it is simply not applied onto an illicit product*. As one of many examples, in the Czech Republic between 2012-2015, around 50 people died due to methanol poisoning from illegal alcohol, some of which carried genuine paper stamps. Stamps are no security.

Nobody would suggest affixing paper security stamps to passports, banknotes or driving licenses. All security features are integrated into the object to be authenticated. Passports go even further, coding the bearer's biometric data into the passport. In our proposal, the fingerprint encrypted in the identifier would contain the biometric data of the pack.

Please note that the critical success factor in the Study reads "Provide court-admissible forensic evidence *of security feature authentication*" rather than "*of the product*" as intended by the Directive. Is this deliberate?

Technical Feasibility of the four options for security features

As the Study states, 23 MS apply paper stamps. It is technically feasible to extend these to the remaining five MS. However, in this case, what would change in the original 23? For this reason, Options 1, 2 and 4 are not technically feasible to achieve the improved product authentication objective of Art 16.

Additionally, the stamps cannot remain in the same position on the pack. If stamps must be destroyed when the pack is opened, the only possible location would be "over the shoulder" of the narrower side, across the edge of the flap. However, this location is not technically feasible for narrow cigarette packs.

As admitted by the Study, depending on the paper characteristics there could also be application on high speed lines. Option 4 can lead to a location and size of the unique identifier which is not accessible by the camera for aggregation purposes. The pre-printed identifier is also not technically feasible under the Art 15 requirements to include information which is only generated at the time of manufacture.

Interoperability

Paper stamps cannot apply to export packs as export packs have to comply with the legislation of the country of retail sale (including stamps). The Study does not provide any workable solution for export products.

Ease of operation

All paper stamps are difficult to deal with as they have to be transported from the issuing destination to the manufacturing country. Damaged stamps must be returned. The change of the current location of stamps leads to additional problems. Paper stamps do not work for narrow packs and require continual machine adjustments. Fingerprints and taggants are easy to apply, inexpensive and deliver far better results.

System integrity

All paper stamps have been counterfeited and will continue to be. Counterfeit accounts for 0.6% of total EU cigarette consumption. However, counterfeiters generally counterfeit packs (and stamps) of low price non-EU countries to justify the lower street price of their products. As stated in the Study, and assumed in the calculations of benefits, illicit products are sold at half the price of legal domestic products: it is clear they are not genuine EU products from the price alone. Seeing any EU markings on a half-price product would be clear indicator that something was amiss. The EU security feature appears to be a measure targeting a non-existing problem.

Potential to reduce illicit trade

Tax stamps do not prevent counterfeit, they only serve as identification of counterfeit for forensic experts. The share of counterfeit is low (0.6% of EU consumption) and the counterfeit of EU stamps is rare. Illicit trade cannot be stopped by any “modern” tax stamps and counterfeiters can easily switch to any other non-EU stamps. Consumers know when they are buying illicit product. Law enforcement knows when they find it. Security features have little added value.

Finally, there is no correlation between the use of stamps and level of illicit trade. Of the ten MS with the highest rates of illicit trade, nine apply paper stamps. Of the top five, four apply sophisticated stamps including holograms and/or microtext. Ironically, the most "modern" paper stamps are used in the MS with the highest levels of illicit trade, while the UK, a country quoted by anti-tobacco activists as a case study for high tax and low illicit trade, does not apply any stamps. If there is any commonality between countries applying "modern" tax stamps, it is that they all have illicit trade between 15% and 30% (i.e. Brazil, Turkey, Malaysia, and Morocco).

Therefore, we recommend a reasonable approach. If cost effectiveness is an objective, simple and proportionate alternatives should be considered.

Administrative/financial burdens for economic operators
It is not clear who would produce the paper stamps and at what cost. Under Option 4, burdens would be roughly twice as high as Option 2. The supposed savings included in the calculation of investments for Option 4 are inaccurate.

Administrative/financial burdens for public authorities
The extension of paper stamps to non-excisable products will lead to increased complexity and costs.

Under Option 4, state-owned printing companies may need (if they are not excluded) new equipment to pre-print the unique identifier.

The administration of stamps should not be underestimated. The implementation includes printing, transportation, warehouses, software, handling returns, destroying and administering payments. It is also unclear how to prevent counterfeiters pretending that they will export to the EU from accessing the security features.

If our recommendations for a pack fingerprint encrypted in the unique identifier, or for the use of taggant or invisible printing are followed, MS that do not currently apply fiscal markings would not have to change anything.

We understand that a number of MS wish to continue using their paper stamp schemes. Therefore, the implementing/delegated acts should allow for a dual approach: using security features in the form of paper stamps *or* as an integrated part of the packaging such as a pack fingerprint, taggant, or invisible printing.

C.1 (ITG)

Flawed assumptions

The Study assumes 8.25% EU illicit trade which is lower than estimations of the Commission, KPMG or Euromonitor.

The Study is correct that counterfeit come mainly from China and Eastern Europe. The Study is also right that EU illicit cigarettes originate mainly from Russia, Ukraine, UAE and, increasingly, Belarus. KPMG estimate that 85% of EU illicit trade is of non-EU origin.

We agree that the assumption "*In determining the effect of price elasticity the team estimated the average price of the illicit product is approximately 50% that of the average price on the EU legal market*" is reasonable.

However, there are at least three major inaccurate or inconsistent assumptions underpinning the Study's calculations.

First, the assumption that all illegal products have a 50% lower street price leads to the conclusion that all participants know when they are buying illicit products. The implementation of T&T and security features is unlikely to have any impact on those who knowingly handle illicit products. If there are any participants "who do not know" they are buying illicit, they must already be paying the regular price. So there is no justification for reducing consumption based on price elasticity. Prices would not change.

The EU law enforcement also know what is illicit: if they find cigarettes with Belarusian tax stamps and health warnings in a container which has been declared as furniture, or at a retail outlet, they do not need T&T or security features to conclude that the shipment is illegal.

The identification of illicit products is not the issue to be solved.

As the differentiation between genuine and counterfeit products is not essential (both are illicit), security features can only play a minor role.

The T&T system may help, as described in FCTC Protocol Art 1(14) for: "*systematic monitoring and re-creation … of the route or movement taken by items through the supply chain*" and in Art 8(4.1): "*to assist Parties in determining the origin of tobacco products, the point of diversion*".

However, what mechanisms do law enforcement agencies have to take action against these legal operators in, for example, Belarus?

If manufacturers are prevented from accessing their own T&T data, as the Study recommends, they would be unable to identify leaks in supply chains and take corrective action as required by the EU agreements. To that extent, "closed" T&T systems would be a significant step backwards.

Second, the vast majority of EU illicit trade is sourced from outside the EU (KPMG 85%) and therefore will not be affected by the EU measures. The Study downplays this: "*It is recognised that beyond this scope, EU traceability requirements cannot be imposed on manufacturers of tobacco product in countries outside the EU that do not intend to import to the EU. In the case these products are brought illegally onto the EU internal market, there remains the need for internationally agreed standards as a traceability minimum, by preference agreed under the FCTC protocol*". There is no consideration of this shortcoming in the benefit calculations.

Third, even if the assumed illicit volume reduction could be achieved, the assumption that 60% of all prevented illicit volume would return to the duty-paid market is not realistic. There are several statements from organisations – independent of the tobacco industry – that highlight how unlikely this assumption is.

ASH UK states "*Poorer people are more likely to be tempted by cheaper prices, and access to smuggled tobacco therefore undermines efforts to quit smoking, exacerbating health inequalities. Research commissioned by ASH found that one in four of the poorest smokers buys smuggled tobacco compared to one in eight of the most affluent*".[1]

HMRC states: "*Approximately one fifth of the UK's smoking population, admit to purchasing illicit tobacco. Around two-thirds of illicit tobacco buyers claim that cheaper illicit tobacco makes it possible for them to smoke when they otherwise could not afford to*".[2]

Even if the EU measures were effective in reducing the availability of illicit product, consumers would be unable to pay for legal products. More likely, they would look for another source of cheap products. One new trend is the use of raw tobacco for smoking.[3]

[1] http://www.ash.org.uk/files/documents/ASH_122.pdf

[2] http://customs.hmrc.gov.uk/channelsPortalWebApp/channelsPortalWebApp.portal?_nfpb=true&_pageLabel=pageLibrary_MiscellaneousReports&propertyType=document&columns=1&id=HMCE_PROD1_031246

[3] Ramboll Study for DG TAXUD, July 2014

Flawed costings

The Executive Summary states: "*The cost analysis was done separately for each of the four traceability solutions*". This is incorrect.

In fact, the investments for hypothetical systems under Options 2, 3 and 4 are estimated to be equal to the assumed investments of the manufacturers, with a discount for Option 4, on the assumption that a pack laser printer is the major part of the investment. This again is inaccurate: on p294 the Study estimates a printer costs €322,500. In reality, the figure is <€30,000, a "saving" that would be wholly offset by an increased rejection rate.

Estimated costs between options were further adjusted for speculative redundancies.

Despite the arbitrary nature of these estimates, the Study gives costs accurate to a single Euro cent (e.g. p299) and concludes that "*the cost differences with regard to options 1-3 are negligible, with option 4 being estimated as the lowest cost option*".

Manufacturers

The assumed total investment of €122.1m for 230 companies, 332 manufacturing facilities and 743 packaging lines (plus non-EU lines manufacturing for the EU) is less than the real investment for any single major manufacturer to date.

For the manufacturers, these calculations only include hardware. These systems are not simply a few plug-in components bought online. They are the result of ten years of research, testing, and iterative improvement in partnership with suppliers. No indications are made that labour costs have been included. The fact that there are no T&T systems available on the market except those implemented by the four tobacco manufacturers demonstrates the challenges.

The Study does not acknowledge that manufacturers operate warehouses and sales forces. Across the EU, each manufacturer has a sales force of hundreds or thousands of representatives.

There are also no indications that software, database or data transfer developments have been included. T&T systems have to be adopted for different machines, products and IT infrastructure. They have to generate unique identifiers including data from ERP systems, print and store them, build aggregation, create data events, integrate the data from invoicing/accounting systems and transmit every event to the database. Also, reports have to be generated for law enforcement agencies.

The Study states that there will be 33bn identifiers for packs and another 3.3bn for cartons generated every year. Each product will be moved on average 6 times (60-80% of products cross-border) and as exit and receipt recording, plus actual shipment route and payments,

are required this will result in around 20 recorded events leading to some 720bn movements per year; 2,900bn for 4 years (required by the FCTC Protocol). Economic operators will record different packaging units: wholesalers will record master cases at receipt and cartons at sale. It is obvious that only highly sophisticated database designs will be able to administer such massive data volumes and aggregation issues. This has not even been recognised by the Study.

The Study does not include costs for integration with other manufacturing/ warehousing/invoicing/accounting systems. This is the most challenging area. This integration has to include systems used by the headquarters, subsidiaries and within national sales forces.

All implementations require several own/supplier experts to visit manufacturing facilities. Under the Options 2, 3 and 4, the "independent parties" would have to travel and implement the technology around the globe on all lines manufacturing for the EU.

The Study also does not include any non-EU facility exporting into the EU and also does not include any fine-cut, pipe, snuffing, chewing or waterpipe tobacco (for assumptions see p293). It is still unclear what the requirements for exports would be. Currently, the four manufacturers collect T&T data in 120 markets in total.

Our conclusion is that the total investments of all manufacturers will be higher at least by a factor of 10, leading to investments significantly in excess of €1bn.

Wholesale / Distributors

The assumptions on wholesale investments are even more unrealistic. Assuming 1 server per wholesaler, 1 uTrack kit for a small/medium warehouse, and 3 kits for a big facility as sufficient is naïve. A single uTrack kit would lead to business closure if it malfunctioned. Big warehouses are automated operations at speed similar to manufacturing lines. The assumption of 3 people with hand-held scanners demonstrates the lack of any understanding of how these facilities work.

The integration of T&T with other systems has not been included in the calculation. One efficient major wholesaler in Germany spent ~€250,000 for a pilot T&T project to equip the warehouse and integrate the systems. Order expedition times increased by 60%. The Study assumes 20% at minimum wages for the operators.

The Study also does not include any costs for the re-configuration of distribution lines and adaptations to buildings to accommodate additional equipment.

We recommend increasing the estimated investments by at least by a factor of 10.

The Directive does not differentiate between single shop

retailers and retailers operating multiple shops (such as Tesco, Carrefour, Delhaize, etc.). According to the Directive, even an owner of two kiosks would have to track products if the supplier delivery is at his home. Therefore, it is very likely that tens of thousands of retailers will be affected in addition to those included in that "calculation".

EU and the Member States

The Study does not provide any way of financing solutions under Options 2, 3 and 4. The proposed charging mechanism to the users also remains unclear. The Study does not state for what the EU and MS would have to pay, it only refers to reporting tools and servers.

It is obvious that national databases would make significant investments necessary, as the manufacturing, movement and sales information for a pack would have to be recreated from several databases. The Study downplays this: "*MSs operate a solution for query and analysis of tobacco traceability data*". We do not believe that this would be realistic and the statement "*It is anticipated that development costs for a mobile application (suitable for smartphone devices), and web portal application would be approximately € 70 k – € 90 k)*". This is naïve. The implementation of the EU's EMCS system took >10 years, and this administers products in entire loads (e.g. one container with 10m cigarettes) whilst the T&T system has to administer all 500,000 packs in that container. Additionally, the EMCS system does not require master data of products, aggregation, invoicing and payment data and the resulting reporting complexity.

Other issues

Despite all these costs, the proposed solutions would not be compliant with either the Directive or Protocol, if the recommendations in 8.6.9 are followed regarding "*the invoice, order number and payment records of all purchasers from the manufacturing to the first retail outlet*". The Study suggest that "*Required data will be stored by the respective supply chain entities and will be made available upon request utilising the unique identifier as the key for the record".* This would require all economic operators to store all movements of all unique identifiers (e.g. master cases) sold and link them to the invoicing and payment information in additional systems, which would have to be developed. This would further increase the costs for economic operators, but importantly, it is completely unclear how the operators *could* supply this information for packs if they sell only cartons or master cases.

D.2 (ITG)

We understand that this question refers to **the human and machine readable** unique identifier. We also assume that this only includes the **unit packet** (pack), as the Directive does not include any obligation to mark any other outside packaging. We therefore interpret this question as: to what extent should be the algorithm for building the unique identifier be based on a single or multiple standard(s).

Human-readable unique identifier

There's no realistic chance of including all information required by Art 15(2) (a) to (h) to be part of the human-readable identifier. In addition, serialisation information is needed as the information (a) to (h) does not lead to unique identifiers. 50-80 characters would be needed to fulfil these requirements.

It is not necessary to print all information at the time of manufacturing as part of this information is (or can be) pre-printed as GTIN on the pack. At the time of manufacture, only information available at the time of manufacture (i.e. date, machine, location, and serialisation) must be added.

The unique identifier consists of two elements: a pre-printed (by the pack supplier) GTIN on the pack and the additional element printed at the time of manufacture.

Due to the technical need for a two-part *human-readable* unique identifier, the question on single/multiple standard(s) should be asked for each of the two parts individually.

We believe that a single standard determined by the governments would pose a significant risk to international trade. If individual governments set their own single standards, the likelihood of different standards in the country of manufacture/consumption/transit would be high and require multiple identifiers. In the case of cigarettes (but also for other tobacco) they would even have to be placed in the same place, as there are only two locations which allow for aggregation: the top and the bottom smallest surface of the pack. All other locations are not accessible for the camera when the 10 packs are being assembled into a carton (the identifiers could be read by the camera at an earlier stage, but this would compromise the accuracy of the process).

The risk of contradicting standards between individual countries is even higher given that TPD significantly extended the amount of information required by the Protocol to be part of the unique identifier. As a consequence, TPD compliant manufacturers will be compliant with the Protocol, but not vice-versa.

We also believe that the GTIN is a common standard and can be set as a single standard by the EU. GTIN is also required by retailers for their electronic cashiers and stock-keeping systems.

For the remaining part of the unique identifier (manufacturer information and serialisation) we would suggest freedom of choice or at least multiple standards.

Machine-readable unique identifier

The coding for machine-readable identifiers allows for more information to be included in the code and printed during the manufacturing process on the pack. In fact, the machine-readable code can provide all information required by Art 15(2) and include the serialisation information. Therefore, there is no need for a two-part *machine-readable* unique identifier.

For high speed cigarette machines, only the ISS DotCode has proved to be appropriate. Therefore, our proposal is clearly to include the ISS DotCode into the list of accepted EU coding standards, hereby following the sGTIN principle of GS1 and comprising 2 elements: GTIN (product identification) plus (Codentify) serialisation number.

Algorithm to generate the unique identifier

We respect the right of governments to information and a high level of transparency. Therefore, we support registration/formal approval of the algorithm used by manufacturers.

Summary

We believe our proposal for a range of accepted standards provided to manufacturers is the best solution for technical feasibility, interoperability (EU and non-EU), ease of operation, administrative/financial burden for economic stakeholders and public authorities.

Under these scenarios, manufacturers would be able to use the same standard globally.

D.5 (ITG)

A. Comment D.3

We believe there should be a range of options as requirements differ for:

- Individual product categories given their specific size, shape, manufacturing speed and process
- Different packaging aggregation levels (pack, carton, master case and pallet).

Cigarettes

For cigarette packs, only the ISS DotCode is appropriate. Other data carriers failed the speed test. The location of the data carrier must be on the bottom surface as this has been tested and implemented. Other surfaces are not accessible by the camera at the time of assembling the carton.

Other tobacco products

DotCode is applicable although not technically required. GS1 DataMatrix would also be appropriate from the manufacturing point of view.

Cartons (all product categories) not required by Art 15

Due to higher space availability and lower manufacturing speed, GS1 DataMatrix is the most appropriate data carrier. Some manufacturers may prefer different GS1 standards.

Master case and pallet (all product categories)

GS1-128 is the most common carrier. Some manufacturers may prefer different GS1 standards.

We believe these proposals are the best solution for technical feasibility, interoperability (EU and non-EU) and ease of operation, administrative/financial burden for economic stakeholders and public authorities. We do not see any link between the coding standard for the unique identifier and system integrity/potential of reducing illicit trade.

Giving the freedom of choice to manufacturers is the only way to ensure a certain level of international (EU, non-EU) interoperability.

Summary

Our proposal is that at least the ISS DotCode and GS1 standards are allowed by the implementing acts.

B. Comment D.4

In our view, both machine and human readable codes are required.

Machine readable codes are clearly required for the aggregation, subsequent monitoring of movements (scanning) and any other operations involving electronic equipment including smartphones.

Human readable codes are also required, in case law enforcement officers are offline/ without the appropriate equipment allowing for the storage of scanned identifiers. In many countries, law enforcement agencies do not provide staff with smartphones. Here, the human readable code is the only solution as the reproduction of a machine readable code is not a realistic option.

D.7 (ITG)

We believe there is not much difference between generating and printing unique identifiers immediately before, or after, the packaging is finished on the manufacturing line, as long as the unique identifier includes the required information found in Art 15(2) (a) to (h), **and** if damaged/destroyed unique identifiers are discarded (not entered into the database or marked "unused") and not released into a market.

Practically, the number of discarded unique identifiers will be minimised if the physical placement of the unique identifier on the packaging occurs at the latest possible stage: **after** the packaging has been filled with content (before any potential cellophane is applied).

For cigarettes, the best solution is after the pack has been filled. We believe this to be the case for other categories as well. However, there may be exceptions for some product categories or specially-shaped packaging.

We do not believe that the implementing acts must specify when the unique identifiers must be applied, as long as the manufacturing information is part of the identifier and compliant with Art 15(3).

Unique identifiers generated and printed some time prior to manufacturing would not be compliant with the Directive and the Protocol.

D.11 (ITG)

Affixing a security feature (SF) to a pack does not provide evidence that the pack is genuine, as counterfeiters have several means of acquiring genuine paper-based SF.

Paper stamps may be appropriate for tax collection, as the use of a genuine tax stamp demonstrates that tax has been paid. The differentiation between genuine/counterfeit packs is irrelevant for this particular fiscal purpose.

If authentication is the objective, the tool must provide evidence that the product (and not only the stamp) is genuine.

Therefore, options a) and b) in this question D.10 are not tenable solutions.

SF printed on the pack or put on the pack through a different method could provide such evidence if applied in a way which cannot be easily copied by counterfeiters, e.g. a taggant on the pack, tear tape or the fingerprint of the packaging.

The tear tape taggant has been successfully implemented in the UK (see B.2). The UK is a prime example of how high taxation and low illicit trade can occur, but this has not always been the case. A few years ago, the UK was among the top inflow countries. However, as the Study states on page 366, the UK "*Since inception of [taggant based] marking, illicit trade decreased from 20% to 12% (2001-2009)*". This is a simple, low cost, high efficiency solution.

Supporters of "independent third parties" including SBS will argue that the tear tape taggant is not a visible element as required by Art 16 (and not appropriate for the consumer) and that the tape will be removed after opening the packaging.

These arguments do not hold merit: **all** visible security elements can be faked (otherwise there would be no need for invisible elements). Good quality faked paper stamps are just as easy to produce as anything else that is currently counterfeited. The consumer relies on looking at the packaging as they "know" their regular brands. Additionally, the unique identifier is another visible security element (though the Study argues it is only an invisible feature that secures authentication). If the removal of the tear tape is an issue, the taggant could be applied to other parts of the pack instead. There are also other printed or sprayed solutions available.

The most secure authentication is the combination of the packaging “fingerprint” and the unique identifier- which is 100% counterfeit resistant. This solution takes an image of a defined surface of the packaging, analyses the fibre structure, converts the structure into a digital code and incorporates this code into the unique identifier. If the unique identifier is copied on another pack, the fibre structure will not match the identifier. If the counterfeiter has the algorithm and generates an identifier matching the faked pack, this identifier will not be in the database of legal identifiers. This is a test which **cannot be bypassed** and compared to this, all paper attachments to the packs provide only a false sense of security.

There is no evidence that paper stamps have any impact on illicit trade. Of five Member States without any stamps, one is at the EU illicit trade average, two are above and two are below.

As stated previously, there are some facts which cannot be ignored when selecting the EU solutions:

- Counterfeit is around 0.6% of the EU consumption
- This counterfeit mimics non-EU products to justify a street price of 50% lower than the shop price.

Therefore, EU security features are a response to a non-existing problem. The Commission should take into consideration that, in addition to direct costs of security features proposed by SBS and EGC, Member States not applying any stamps would have to set up the legislation, administration and processes to handle orders, printing and distribution of SF, including returns of damaged stamps and products.

Art 16 has been adopted and has to be implemented. Our advice would be to minimise the cost/administration burden and adopt implementing acts which allow security features printed by manufacturers at the time of production and utilise the fingerprint technology, which is clearly the best possible and most robust solution.

If the Commission wished to authenticate products independently from the manufacturer, it could contract an independent laboratory, as foreseen in the agreements between the EU and the four manufacturers. Such additional product authentication by an independent laboratory would be reliable and free from any perceived industry interference.

D.13 (ITG)

1. Compliance with Art (15)

Our understanding is that Art 15 does not allow for single EU centralised or national data storage (database).

In our understanding it is the right of any manufacturer to nominate an independent third party hosting the database and an independent auditor monitoring the data access activities. The Commission has the authorisation to approve or to reject the nominated candidates based on criteria postulated by the delegated acts.

2. Technical feasibility

The future EU T&T system will certainly be one of the biggest commercial IT projects in the history of the EU.

So far, there is no detailed ***concept*** but only global declarations outlining some basic pillars of the EU solution. However, the Study questions even these pillars by promoting non-compliant central EU or national databases.

Due to the lack of details, it is difficult to estimate the database size and any such attempt would be purely speculative. Additionally, there is no specification of the number of years for which the T&T data should be kept in online access (Protocol: at least four years). Therefore, the calculation of the database size cannot start before these basics have been sorted out.

The Study significantly underestimates the size of the unique identifier, the number of events (movements/sales), aggregation/disaggregation and does not even include any compliant solution for invoicing and payment information required by Art 15 and the Protocol. Despite that, the Study assumes online access to two years only and escaping any clear solution by the phrase "*with the balance being available by accessing another instance of the database as required*". Therefore, our conclusion is that the technical feasibility of a single EU database is unclear and would require further investigation.

The 28 national databases would be more realistic, regarding the database size, as the data would be split across 28 databases. However, cross-border transactions (manufacture in one and sale in another Member States) would be in at least in two databases (if information from *transit* Member States is not required). The calculated share of cross-border transaction went wrong in the Study due to flawed methodology (Study: 5%, reality 60% to 80%).

It is by no means evident how a complete standardisation of structures of all 28 databases could be achieved. Without such a full standardisation the re-creation of the journey of a pack through the cross-border supply chain simply would not be possible.

Therefore, we do not classify the single EU or the national databases as feasible solutions.

The ‘database per manufacturer’ concept splits the data size across several databases and ensuring that all movements for a product are in ***one*** database. It is simple, easy to operate, does not lead to disputes about cost sharing, ensures free and fair competition between service suppliers, puts no burden on the EU or MS, is quick to implement (to large extent already in place) and is Art 15 compliant.

3. Implementation time

A single EU or the 28 national databases would require public tenders which cannot be started (or even prepared) before the implementing acts have been adopted in Q2 2017. Realistically, the preparation and evaluation of tenders would take several years. All this would go beyond the May 2019 deadline. Also some years would be needed for development, implemention and testing.

We would encourage the Commission to contact DG TAXUD regarding the experience in planning and implementation of the very simple EMCS system (only replacing well established paper procedures). We also have the impression that the fiscal authorities in de facto all MS (and also parts of the Commission) are shy to take any responsibility for the implementation of the EU T&T system and limit their role to observations under the leadership and responsibility of the public health authorities as they largely consider the ambitions as excessive, disproportionate and of limited use (despite the claims of the Study about the alleged beneficiaries).

In our view, any consideration of a single EU or 28 national database(s) leads potentially to chaos and a significant delay of the implementation (beyond May 2019) in the magnitude of decades.

4. Wider considerations

We have a legally-binding agreement with the EU (all 28 MS) and 10 non-EU Member States including obligations to establish a T&T system for our products within and outside of the EU. Due to these obligations we have spent a multiple of three-digit millions on implementing our T&T system, database and reporting system. If the EU secondary legislation (implementing and delegated acts) significantly changed the obligations (despite claims that these would only ensure level playing field for all manufacturers) of our agreement and made all investments obsolete, the EU would most likely to revalue the agreement as well losing the current extra-benefit of our non-EU T&T data.

D.15 (ITG)

We are afraid that this question indicates a misunderstanding of IT systems in general and an underestimation of the T&T system complexity in particular.

Any IT system requires a system design which includes definition of data input, processes, interaction with other systems, data storage (methodology, design, structure) and reporting. It is not beneficial that different companies would be responsible for different tasks.

Due to the large amount of data (per manufacturer), it is necessary to find a balance between the database size, methodology of data storage and reporting. The general rule is that the smaller the database (compressed data), the more challenging the reporting is. Additionally, the data transferred by economic operators to the database will regularly be for different aggregation levels (manufacturers: master cases, wholesalers: cartons) and the request for recreation of the movement can be the pack. To allow for this, the aggregation have to be accessible (in the expected methodology and structure).

In order to maintain a reasonable database size, the design phase must include the database structure which are answers to questions such as:

(i) will all individual identifiers be stored or are there any more sophisticated solutions,
(ii) what is the most effective way to store the aggregation data,
(iii) what information should be part of the unique identifier record and which should be stored as separate master data,
(iv) how to deal with disaggregation and new aggregation,
(v) should only the aggregated data transferred by economic operators be stored or should they be disaggregated and stored individually, and
(vi) how to establish the link between identifiers and payments or actual shipment route.

For obvious reasons, the answers will be completely different for individual companies depending on the manufacturing volume (and thereof resulting database size).

If only aggregated information for each event is stored (e.g. sale master case), the data size will be smaller but the reporting tool has to access the aggregation information to recreate the journey of a carton or pack. If the event (e.g. sale master case) is at the time of data transfer immediately stored in disaggregated form (sale master case and its 50 cartons and its 500 packs), the database size would be significantly larger but the reporting easier (simple search).

The system design must identify all relevant types of events (manufacturing, aggregation information, inter-warehouse movements, sale, product destruction, payment, actual route information, return/revocation to all these transactions).

The design has also to include processes for exceptional events such as product use for quality test purposes or inventory difference (very challenging exercise as the missing identifier is not available). Subsequently, appropriate data collection and transfer processes have to be assigned to all relevant types of events and appropriate handling within the database has to be specified (e.g. cancellation record versus cancellation mark).

As stated in other parts of our submission, the Study also trivialises the T&T system as a simple scanning exercise.

In fact, scanning can only supply the unique identifier. All other data such as market of retail sale, customer, payment, actual route or invoice number has to be entered by hand or supplied by other systems. The designed processes can be significantly different and so the timing of the data supply.

It is also important to take into consideration that development and update of data reporting requires test data and verification of results based on real data.

Finally, all IT systems have to be updated, extended and for several reasons adapted to new legislation or manufacturing requirements.

Therefore, the design of the T&T system has to be in one hand. This applies also for system maintenance.

It is not possible to generally assign this role to any individual entity involved in the process.

In the case of bigger manufacturers this will frequently be the in-house resources (supported by external expertise). However, other companies may select a third party data storage provider for all stages of the development including operation of the data storage and reporting tools whilst other manufacturers may split these two areas in system development/maintenance and physical data storage hosted by third party.

In summary, the implementing acts should not prescribe a specific entity for developing the reporting query tools as the situation will be different for individual manufacturers. The implementing acts should include technical standards for reports (although not mentioned in paragraph 11 or 12 of Art 15) and provide a free choice of the developing entity provided that all data access provisions of Art 15) are strictly respected.

We would also like to reiterate our view that Art 15 does not allow for any (by the Commission or Member States) appointment of:

- Solution provider(s)

- Independent third party(ies) hosting the database

- Provider(s) of reporting and query tools.

D.17 (ITG)

Introductory remarks

The EU tracking and tracing system and the security features represent a business opportunity worth billions of Euros. Measures must be put in place to ensure an objective assessment and to protect the process from vested interests.

The Study is wholly inadequate. It lacks any conception of how a system might work. Important questions such as the obligations of warehousing and distribution companies, retail organisations, EU exporters and non-EU economic operators for imports and exports remain unclear. Previous (relative) clarity about obligations of manufacturers, data hosting, auditors, reporting of customer, invoice and payment data has been replaced with naïve and contradictory suggestions.

Instead of focusing on the feasibility of the adopted TPD, the Study undermines it by promoting unrealistic and noncompliant solutions, and by calling for several additional feasibility studies which would delay the process and increase the level of uncertainty for all stakeholders.

Shortcomings of Options 2, 3 and 4

Legal

There are multiple legal aspects to be considered.

- Directive 2014/40/EU does not include any authorisation of the Commission or the Member States to **appoint** any specific provider(s) or operator(s).
- The **exclusion** of implemented T&T systems based on legally-binding agreements between the four manufacturers and the EU may create legal issues. As a consequence, the agreements could become obsolete.
- Article 15 clearly refers to **one database per manufacturer** hosted by an independent third party and monitored by an independent auditor (selected by the manufacturer and approved by the Commission).
- There is no obvious **definition of "independent"** provider or operator in the study; all relevant companies have been (or still are) suppliers to the tobacco manufacturers and were even involved in development of industry T&T solutions.
- The specification of a certain supplier constitutes a **Technical Barrier to Trade** under the WTO agreements as it excludes non-EU manufacturers from access to the EU market unless they use EU appointed supplier(s).
- For the implementation and operation, we would expect complex **liability** issues if the solutions are not implemented on time or do not work properly.

All these options would also require **excessive legislation** for:

- **Rights and obligations** of all stakeholders
- **Financing** of development and operation of the mandatory systems
- **Specification** of functionality of the system(s) and equipment choices
- **Accountability** for incomplete and inaccurate data (data integrity)

- Legal issues regarding mandatory supply (and potential leak) of **highly sensitive commercial information** to commercial "independent" third parties (data security)
- Issues around the **mandatory presence** of commercial "independent" third parties in manufacturing premises that are tax warehouses
- Legal aspects of AIT Protocol provisions which require systems controlled "**by the Parties**" instead of by "independent third parties".

Option 2 to 4 would lead to **non-compliance of EU exports** with the legislation of many destination markets unless two technologies are used at the same time.

Under Option 4, two stamps could be necessary.

In addition, **Option 4** (pre-printed identifier) is **non-compliant** with Art 15(3) or the AIT Protocol.

Organisational

All options requiring the appointment of providers or operators would require **public tenders** that could not start before the adoption of implementing acts (optimistic date: 2Q 2017). To prepare detailed tender(s) to ensure that the solution covers all EU requirements and that national solutions are based on the same structures and methodology would take years.

The Study confirms that there is **no existing "independent" system** in operation. SCORPIOS, operated in Brazil, is a system managing the distribution of *tax stamps* and not that of *products*. The Study also admits "Some concerns related to the fit of the solution in the TPD context: The current implementation in Brazil does not track tobacco products beyond point of tax payment, which is the manufacturer. Tracking beyond this point would require additional development". To that extent, the tender(s) would have to select a winner based on an unapproved capability to develop a potential solution to a challenging timescale.

The solution would have to be implemented by the solution provider(s) in at least 230 EU manufacturing companies on 745 EU cigarette manufacturing lines. All these companies would have to integrate the solution(s) with their existing ERP software, invoicing and accounting systems (non-EU and other tobacco product manufacturers even not included in these numbers). There are also at least 2,450 wholesale companies operating 7,690 warehouses; 1,944 vans for vending machines; and 3,699 sales vans using mobile IT solutions which would also require integration. There are probably many more as the Study excluded all retail operators. It is extremely unlikely this amount of work could be realised within a decade.

Solutions 2, 3b and 4 require the **permanent (supervised) presence** of "independent" solution providers or operators at any global manufacturing premises manufacturing for the EU.

Technological

Some of the Study's findings betray a poor understanding of basic business practices. For example, providing "indications that the volume of tobacco products at a particular location exceed the capacity of the facility" requires stock accounting and information on the maximum capacity for all possible combinations of products for any single warehouse. Similarly, "automated checking of value of goods vs. adequate bond" would require the excise amount information per pack and the inclusion of all excise payments as the outstanding excise is the balance between excise obligations and payments. Proposals under 8.6.8 (linkage to EU Customs and Excise systems) are similarly unrealistic.

To avoid having up to 28 differing technologies on production lines that manufacture for different EU markets, the Study suggests in 8.6.4 (p217) that the system selected by the manufacturing country (Options 3b and 4) would apply for all products including those sold in other EU markets. This may solve the issue of a factory, however, as a consequence (that has not been addressed), products sold in a MS would be tracked and traced by **up to 28 different technologies.** The Study does not clarify which data storage would apply (manufacturing/destination market) but all possible solutions would lead to even more chaos. Also, a manufacturer would have to deal with factories in different MS with individual national technologies, providers and operators. It is also unclear which technology and national database could apply for non-EU manufacturers. The most bizarre consequence could be that up to **28 different security features in a MS** are required as option 4 is a combination of security features and unique identifiers. It is very likely, that the Study's authors could not handle their own proposed complexity as they, at the same time, suggest that national tax stamps would also apply.

The Study significantly underestimates the data size for 30bn unique identifiers, aggregation, disaggregation and events (movements and sales). This is despite admitting that only two years of data would be accessible online. The FCTC Protocol requires four years retention and the Study refers even to seven years as necessary. Therefore, we consider the **single EU database as unrealistic**.

We also consider **national databases unrealistic** as there is no practical way to implement 28 identical structures (and concepts to store the data) and to develop software recreating the cross-border products events from these 28 databases. The Study makes no further feasibility analysis beyond the meek recommendation that the "EU operates a query messaging service for the routing of tracing queries that span multiple Member State data repositories".

Realising the limits of Option 4 for export products, the Study suggests special methods to generate printed identifiers for exports or, preferably, the use of export stamps. The Study has obviously not recognised that this would lead to **two stamps, technologies and identifiers for export markets** applying national stamps and rules for T&T. As space is very limited on the pack, the two stamps would most likely have to overlap.

The Study makes also no suggestions on the feasibility of reporting intended and actual shipment routes.

Advantages of Option 1

Option 1 is the only compliant and technically feasible solution. It allows all manufacturers to design a system based on their manufacturing equipment, products, speed of lines, company size, degree of automation and IT infrastructure using local suppliers, in local languages and providing local servicing. This solution is also best placed to accommodate requirements of export markets.

Such individual systems are in operation in 120 countries (some at pack level) and some software components are even available for free. Over the past decade, several independent suppliers and consultant companies have built significant expertise to support the remaining manufacturers in implementing tailored solutions.

Under Option 1, all data concerning a product are in the same database (manufacturing, aggregation, events) and the manufacturer must ensure appropriate reporting tools are in place.

To ensure interoperability, the Commission must adopt minimum technical standards. There is no need for full alignment of structures and concepts. Only identifiers, data transfer and reports have to be standardised. For data carriers, the ISS DotCode and GS1 symbologies are the most suitable solution. For the data transfer between the trade and data storage, the GS1 EPCIS data transmission standard is the most suitable solution.

Finally, there is no need for any SKU reporting (p141) as individual manufacturers can maintain their own master data (for products and customers).

Speculations regarding manufacturer-generated unique identifiers

The Study has based all evaluations and conclusions of the suggested T&T options on a strong bias against the tobacco industry, and unfounded insinuations that it is complicit in the illicit trade. It claims that manufacturer-generated identifiers are “a key risk for a tobacco control regime” (p197) and that only “solution components that are considered lower risk such as recording distribution chain events from manufacture to last point prior to retail are operated by industry” (p197) could be left to the manufacturers.

The purpose of T&T systems is to recreate the journey of genuine products that have been diverted from the legal supply chain, to identify the last legal transaction (“the point of diversion” in see Art 1(14) and Art 8(4.1) of the AIT Protocol). Therefore, the identification of customers is the purpose of all T&T systems. The unique identifier is a relatively mundane technical enabler of this process, not a talisman whose ownership must be fetishized.

In the Executive Summary the Study makes discrediting statements such as “Is shared industry software and systems free from vulnerabilities that may compromise integrity?” and downgrades Option 1 in its (highly questionable) critical success factors (CSF) tables. First of all, the four manufacturers and some others share very few components, and the implemented systems (after the pack-coding phase) are individual for each manufacturer (reflecting different equipment, technology and IT infrastructures). All four manufacturers use SAP systems for much more important areas such as accounting, invoicing, stock

accounting *and excise administration* – so far, there are no claims that these functions should be operated by an "independent" third party.

The main insinuation in the Study is that under Option 1 "non-compliant manufacturers have the means to reproduce unique identifiers (as well as the corresponding aggregation relationships) onto undeclared tobacco products for diversion into the parallel illicit distribution chain". This conclusion is based on the assumption that the unique identifier would be the only tool to verify the quantity declared for excise purposes. This is not the case in 23 MS where paper stamps provide a cross-check. We are not aware of any problems of legal manufacturers under-declaring release for consumption in the remaining MS. The majority of illicit products are *duty-paid* in one country and smuggled into another.

The Study apparently assumes that packaging lines would be able to recreate the "corresponding aggregation". Also any replicated identifiers entering a "parallel distribution chain" would provide clear evidence that a manufacturer is cheating the system.

It is contradictory for the Study to suggest "modern tax stamps" and at the same time assume that manufacturers could illegally produce undeclared volume with copied identifiers.

Finally, our proposal for pack fingerprints as security features completely excludes any such speculative replication of identifiers, as the identifier has to match the fingerprint of the pack, and the identifier has to be in the database. There is simply no way to bypass this test.

The "critical success factors" and the evaluation of options in the Study is not credible, as the only option compliant with all requirements of Art 15 (Option 1) was marked "amber" regarding factors 4 (p158) and 9 (p159), based on purely speculative interpretation of the Directive and on unsubstantiated accusations. However, the non-existent 28 national systems in Options 3 and 4 passed the compatibility test (factor 5) and all non-existent options including Option 2 passed the test on minimisation of impact on manufacturing (factor 9) and trade (factor 11). The most basic critical success factors of a feasibility study such as "compliant with applicable legislation" or "realistic implementation within the adopted timeline" have not even been included.

The authors admit on several occasions that there are significant feasibility issues regarding options 2, 3 and 4, however, these do not find any consideration in the conclusions and recommendations. On the contrary, Options 2, 3 & 4 are presented as the winning solutions, ticking all boxes.

Security features

The role of the security feature is to authenticate products for consumers and authorities. Counterfeit is around 0.6% of EU cigarette consumption (and barely exists for other tobacco products).

The Study takes a confusing approach. It correctly states that 23 Member States already use affixed paper stamps for fiscal purposes. Therefore, the four proposed security feature options ("modern tax stamps") would only extend tax stamps to the remaining 5 MS.

However, the objective of Art 16 is obviously to authenticate the product. For fiscal purposes it is irrelevant whether a product is genuine or counterfeit: the focus is on whether excise has been paid. For authentication of products themselves, different measures are required. From that perspective all four options presented by the Study are misguided and would simply duplicate the current fiscal stamps without adding any *product* authentication evidence.

The only option providing evidence of authenticity could be developed from elements of Option 3. This is the only option including the characteristics of the product itself: the fibre structure (fingerprint) of the pack. However, the Study makes flawed conclusions. First, if the fibre structure of a pack is digitalised and encrypted in the unique identifier, there is no need to store that fingerprint in a database. A copied identifier on a counterfeit pack would not match the fibre structure. If counterfeiters created a unique identifier matching the fingerprint of the pack, this would be obvious because it would not be in the database *of legal identifiers*. There is also no need for any additional paper stamps for authentication. This system would give three visible security elements: the pack itself, the machine-readable and the human-readable identifiers, and the fingerprint serving as the invisible element of the security feature.

The supposed disadvantages of fingerprint (stated on p256) are not specific to the fingerprint solution. However, to address these issues, alternative authentication solutions should be considered as well. Whilst the fingerprint technology is the most sophisticated, other invisible security features authenticating the product are widely available and easy to apply: invisible inks, taggant on the pack, tear tape and/or cellophane. Unlike paper stamps, all these technologies authenticate the products rather than the paper attached to them.

Also, Art 16 calls for "printed" *or "*affixed*"* security features. The focus of the Study on purely affixed solutions is one-sided. Finally, Art 16 refers to "visible" and "invisible" security elements. Instead of following adopted legislation, the Study has invented "modern tax stamps" with "overt, semi-covert, covered and forensic" elements and created a list of critical success factors which do not reflect Art 16.

Benefit analysis

Law enforcers already know whether a product is legal or illegal through the health warnings, language, seizure circumstances, and fiscal markings.

Including the impact of EU measures on inflow from non-EU countries (85% of EU illicit trade) into the benefit calculation and dealing with this shortcoming with vague statements such as ("In the case these [non-EU] products are brought illegally onto the EU internal market, there remains the need for internationally agreed standards as a traceability minimum, by preference agreed under the FCTC protocol") leads to drastic overestimates of the potential benefits.

Costs to tobacco manufacturers

The Study's estimate of total investment by all manufacturers (€122.1m) in fact represents the investment of one single big manufacturer. Only hardware costs have been included in the Study's estimation, and the investments for low and medium speed lines are significantly underestimated. Warehouses, sales forces, investments in the development

and implementation of central T&T systems and the integration with other IT systems have been ignored.

However, the high point of the Study's misrepresentation is the assumption that Options 2 to 4 require only the same investment as Option 1, and passing this guesswork off as "modelling" in the Executive Summary. In fact, not only are investments under Option 1 significantly underestimated, but costs for Options 2, 3 and 4 have not actually been calculated at all.

Finally, the Study fails to state that the investments under Options 2, 3b and 4 would be in addition to investments already made by manufacturers, in particularly those with existing T&T systems under the EU agreements.

Costs to other economic operators

The underestimation of investments by other economic operators is even more significant. A wholesaler pilot in Germany required an investment of around €250,000 to implement the T&T system and incorporate it into the IT infrastructure of one operator. The time needed to dispatch orders increased by 60%.

We do not think that the Study has even realised that many "retailers" fall within T&T obligations. Therefore, in the case of other economic operators, even giving the Study a factor 10 error margin looks inadequate.

Costs for the EU and Member States

This section of the Study is confusing as it refers to an unspecified "Traceability Information System" of Option 1 as a basis for EU and MS costs. Under Option 1, manufacturers implement their own systems and provide the Commission and MS with reporting tools (to be specified by the implementing acts). The EU or MS do not make any investments (except scanning devices).

It is unclear what investments are anticipated for Options 2 to 4. Statements such as "Additional to the system development costs detailed above, it is envisaged that a query tool / mechanism would need to be developed for use by EU and Member State authorities to conduct tracing queries using tobacco data from the independent data management provider. It is anticipated that development costs for a mobile application (suitable for smartphone devices), and web portal application would be approximately € 70 k – € 90 k)" indicate that the Study underestimates the costs by a multiple of factor 10. We would recommend contacting DG TAXUD to share experience with development and implementation time and costs for a very simple EMCS system replacing established paper-based processes for excisable products under duty suspension, and a professional IT company for an independent estimate of time and costs for development, implementation and operation of a national or EU-wide solutions including all reporting functionality.

AIT Protocol and compliance of proposed options

Article 8(2) of the Protocol states that "Each Party shall establish … a tracking and tracing system, controlled by the Party for all tobacco products that are manufactured in or imported onto its territory". This provision is regularly misinterpreted to exclude T&T

systems *operated* by the tobacco industry into “controlled by the tobacco industry”. If *operation* equalled *control* a consistent reading would have to exclude third-party solutions not operated directly by governments.

The most misused provision is Article 8(12) which states that “Obligations assigned to a Party shall not be performed by or delegated to the tobacco industry”. However, there is not any single provision that the Parties have to develop or operate a T&T system, only that they *control* and *regulate* it. There is no obligation on Parties to *operate* the system, hence no bar to delegating this. It is obvious that the Parties shall only legislate, control and regulate the systems.

In fact, Art 8(5) explicitly states: “Each Party shall require, within the time limits specified in this Article, that the information set out in paragraph 4 is recorded, at the time of production, or at the time of first shipment by any manufacturer or at the time of import onto its territory.” This clearly shows it is the Party’s obligation *to require recording*, but the manufacturer’s obligation *to record*.

Similarly, Art 8(6) obliges the Parties to “ensure” manufacturers make records “accessible”, which obviously implies that the T&T data is stored by the manufacturer. Under Art 15 of TPD this storage would not be possible as the manufacturer cannot have access to customer’s commercially sensitive information.

Finally, Art 8(7) states “Each Party shall ensure that the information recorded in accordance with paragraph 5, as well as the unique identification markings rendering such information accessible in accordance with paragraph 6 shall be included in a format established or authorized by the Party and its competent authorities”, reconfirming that it has to be provided *by the manufacturer* in an agreed format.

In summary, the obligation of the Parties is to set the legislative framework and it is the obligation of the *manufacturers and importers* to apply systems and procedures complying with these requirements. Therefore, the wording “shall not be performed by or delegated to the tobacco industry” refers only to regulatory control not everyday operations.

Our conclusions and recommendations

The Study is poor. It lacks any expertise, uses an ill-designed methodology and reaches flawed conclusions. It offers a contradictory patchwork of poorly defined, inconsistent recommendations. Several issues are either not recognised or addressed inadequately.

Furthermore, the Study is not a true feasibility study. Rather it is an advocacy document for the granting of a Europe-wide monopoly to one particular solution provider. There is no evaluation of the achievements and reliability of industry systems already in place. Instead, the Study makes speculative and flawed assessments and conclusions that do not stand up to basic scrutiny.

For the security features, our recommendation is to allow for a dual approach consisting of paper stamps supplemented by pack fingerprints for Member States wanting to continue using stamps; and pack fingerprints plus taggants for MS which do not wish to introduce unnecessary stamps.

Finally, as we have previously stated, only traceability Option 1 complies with the requirements of Article 15.