NOTE
This document incorporates all technical documents prepared by the Panel of Experts on the Protocol to Eliminate Illicit Trade in Tobacco Products as part of its work conducted between the seventh and eighth sessions of the Conference of the Parties (COP) as mandated by the Seventh session of the COP. This report serves as a supplement to document FCTC/MOP1/10.

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Report of the Panel of Experts on the Protocol to Eliminate Illicit Trade in Tobacco Products

Technical documents

BACKGROUND

1. At the Seventh session of the Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control, the Parties decided to intensify the work of the Panel of Experts. COP7 requested the Panel of Experts:

   (a) to report to the Eighth session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control (COP8), and if applicable to the First Meeting of the Parties (MOP1) to the Protocol, on the progress of its work and any findings; and

   (b) to establish the following priorities as guidance for its work:

      i. assistance to the Convention Secretariat with the preparation of a draft agenda and, as appropriate, documents for MOP1;

      ii. development of a forum for the exchange of best practices among the Parties;

      iii. provision of technical assistance to the Parties by documenting exchanges of best practices and by mapping of emerging traceability systems;

      iv. support to Parties with free-trade zones in implementing the Protocol;

      v. advice to Parties on experiences with licencing regimes; and

      vi. development of proposals for consideration at MOP1 as to the future work in the area of fighting illicit trade, including the initial thoughts on the structure of a global information-sharing focal point.

2. This document incorporates all technical documents prepared by the Panel of Experts on the Protocol to Eliminate Illicit Trade in Tobacco Products (Protocol) as part of its work conducted between the seventh and eighth sessions of the Conference of the Parties (COP) as mandated by the seventh session of the COP.

3. The technical reports presented as part of the present document include the following:

   A. Initial thoughts on the structure of a global information-sharing focal point p. 3

   B. Recommendations on minimum technical requirements for developing a tracking and tracing system compliant with the Protocol p. 7

   C. Recommendations on roadmap for implementing a tracking and tracing system compliant with the Protocol p. 13

   D. Report on Good Practice Models for Licensing under the Protocol p. 20

A. INITIAL THOUGHTS ON THE STRUCTURE OF A GLOBAL INFORMATION-SHARING FOCAL POINT
1. **Introduction and purpose**

In decision FCTC/COP7(6) entitled Status of the Protocol to Eliminate Illicit Trade in Tobacco Products, the Conference of the Parties (COP) decided to intensify the work of the Panel of Experts on the Protocol to Eliminate Illicit Trade in Tobacco Products (Protocol), which should be developing proposals for consideration at the First session of the Meeting of the Parties (MOP1) as to the future work in the area of fighting illicit trade, including the initial thoughts on the structure of a global information-sharing focal point.

It is on this basis that the Secretariat of WHO Framework Convention on Tobacco Control (WHO FCTC) and the Panel of Experts commissioned Mr Carlos Acevedo, an independent expert, to develop a conceptual design tool on a Global Information-sharing Focal Point (GSP) based on the discussions and input of the Panel of Experts at their second and third meetings.

This document is intended to provide decision-makers with the information and a conceptual framework necessary for making top-level decisions in relation to the design, implementation and operation of the Protocol GSP.¹

2. **GLOBAL INFORMATION-SHARING FOCAL POINT (GSP) Setup**

There is a series of initial vital elements that is required to set up the GSP. The Panel of Experts notes that there are multiple design and data parameters that need to be established for the GSP to have initial functional capacity.

(a) Registration of Party users’ critical elements.

i. Given that the Protocol (Article 8.9) provides for information to be provided only to the Parties or competent authorities, potential users of the GSP must be limited.

ii. Furthermore, given the requirements for the exchange of distribution, commercial and tax information, the Panel of Experts recommends that the Parties review existing multilateral information instruments² to determine and adopt the current best practices for the exchange of tracking and tracing (T&T) system information among the Parties as envisioned under the Protocol.

iii. Unique identifier (UI) generators must be registered with the GSP for the GSP to be able to determine from the UI, which UI generator issued the UI. This is a vital function for the global T&T regime. The Panel of Experts recommends the use of an existing international accreditation system so that the accreditor resolves registration issues, with completed accreditations reported by the accreditor to the GSP. This would greatly simplify the management and administration of the GSP, which would provide accreditors the needed UI generator codes, and keep a registry thereof.

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¹ The GSP is the central contact point for each Party and their relevant authorities to obtain T&T information for a UI (or a series of UIs), for the detection or investigation of illicit trade in tobacco products. The GSP gives each Party a single location for obtaining this information.

² For example, the Global Forum on Transparency and Exchange of Information for Tax Purposes, the United Nations’ Uniform Rules of Conduct for Interchange of Trade Data by Teletransmission (UNCID) or Electronic Data Interchange for Administration, Commerce and Transport (EDIFACT), or indeed any other existing multilateral exchange of confidential information, that has established rules for the transfer of confidential information, either automatically, or on request.
iv. Along with the registration of the UI generator, each Party must provide the GSP with routing information for queries from the GSP to the Party’s T&T system.

(b) The Panel of Experts recommends that the Parties determine the language(s) to be used in the GSP query process, and establish data dictionaries for queries to the GSP and Party responses to GSP queries.

i. In order to facilitate communication with the GSP, the Panel of Experts recommends that the query system be automated via a UI generator (GUI) or similar system that simplifies most queries to the GSP, and automatically provides the required format (and language). For non-automated queries, the Panel of Experts recommends that a glossary of query terms be established.

ii. To ensure standard response content, the Panel of Experts recommends that the Parties determine the minimum data fields to be provided in the Party T&T system response to a GSP query.

(c) To facilitate the direct transfer of sensitive T&T information, and to provide for the most efficient administration of the GSP, the Panel of Experts recommends that Party queries sent to the GSP and forwarded to the relevant Party T&T system be answered via a communication from the queried Party directly to the querying Party. The Panel of Experts further recommends that the responding Party provide notice of the response to the GSP, and the querying Party provide confirmation of the receipt of the response to the GSP.

(d) To facilitate the secure transfer of sensitive T&T information, the Panel of Experts further recommends that all communications to and from the GSP be sent using an agreed encryption system, to be agreed by the Parties. The Panel of Experts recommends that the Parties consider using asymmetrical encryption systems, such as Public/Private key systems already widely available in the market.

3. Channels for communication with GSP

The ultimate viability and usefulness of the GSP as envisioned under the Protocol depends on its efficiency as a point of query and its ease of use across cultures, languages and geographic location. For this reason, the Panel of Experts recommends that the Parties determine the channels to be made available to the Parties and their competent authorities for the creation and sending of a GSP query. The Panel of Experts recommends that the query channels primarily be Web/App based through a GUI which provides for back-end formatting and transmission. The Panel of Experts further recommends that the Parties establish a secondary e-mail system, to be used as a backup only and not as the primary means for query transmission.

4. GSP Parameters

In order to avoid confusion, facilitate use and to eliminate, to the greatest extent possible, the need for processing of the query by the GSP itself, the Panel of Experts recommends that the Parties determine the specific parameters and content for queries from a Party to the GSP. The Panel of Experts recommends that the parameters and content be kept to the minimum required to allow for the efficient use of the GSP system, as well as the greatest ease of use by Party users.
Accordingly, the Panel of Experts recommends that the query contain only the following:

(a) The UI or UIs to be queried.

i. In order to ensure the limited use of the GSP and the T&T systems as envisioned under the Protocol, the identity of the entity submitting the query, the purpose for which the query is being submitted and the commitment to confidential treatment to be given to any query response, should be made part of each query. The Panel of Experts notes that these issues should be resolved through the adoption of a multilateral information exchange standard to allow for Party-to-Party exchange of confidential information, as noted above in (1)(a)(ii).

(b) In order to guarantee efficiency of the GSP system, and to minimize burden on the GSP, the Panel of Experts recommends that the Parties establish a specific set of additional specific queries to be allowed, and that all other queries be excluded.

5. Handling of GSP Queries

The Parties must determine the parameters for handling a query by the GSP. These parameters must include:

(a) Determination of the level of automaticity of GSP processing.

i. Options for GSP:
   1. Fully automated
   2. Partially automated
   3. Fully manual
   4. Progressive automaticity (through time/according to Party experience).

(b) Determination of GSP requirements concerning records and logs of queries and notices of response/receipt. This will require the creation of query identification (ID) numbers and other parameters:

i. Determine Query ID
   1. The Panel of Experts recommends that a timestamp be combined with the first UI to create the Query ID.

ii. Determine if query is valid (i.e. not frivolous)
   1. The parameters for the determination of whether or not the query is frivolous must be established by the Parties or by the GSP, under a specific grant of authority from the Parties.
   2. The subsequent handling of a query determined to be frivolous must also be established.

iii. Determine GSP record-keeping parameters
   1. Register queries received
   2. Register processing in/out
   3. Register Party Notices of Responses sent and Response Received.

(c) Determine routing issues for queries to a Party. The Panel of Experts notes that any information required for routing of a query to a Party must be collected as part of the GSP setup, Party registration and UI unique identifier processes described above.

i. The Panel of Experts recognizes that the GSP routing of queries is a practical matter that must be considered and determined by the Parties at the earliest possible
date. A functioning GSP is the cornerstone of the global T&T regime envisioned under the Protocol. As such, the Parties should instruct the Secretariat to commence work on the design and implementation of the GSP as soon as reasonably practicable, with due regard to the preferential use of pre-existing communication systems, and the availability of resources.

1. Web/App
2. Email
3. Telephone.

(d) The most efficient and least burdensome procedure for GSP query response is a direct response from the responding Party to the querying Party.

6. (Party/Database operator(DBO)/UI Gen/Other processing)
   (a) (This is according to routing instructions provided by Party.)
   (b) Ultimately, the responding Party should send a response to the querying Party.
   (c) The responding Party should send a confirmation to the GSP that the response was sent.
   (d) The receiving Party should send a confirmation to the GSP that the response was received.

7. Secretariat Resources

The Panel of Experts recommends, given the critical nature of the GSP to the efficient functioning of the global T&T regime as envisioned under the Protocol, that the Parties assess Convention Secretariat financial, human resources (HR) and information technology (IT) resources for the design, building and operation of the GSP.

8. Scalability

The Panel of Experts notes that total volumes and peak flow of queries are difficult to predict. Accordingly, the Panel of Experts recommends that the Parties determine an initial minimum capacity for the GSP, with a view to being able to add further capacity as needed as the volume and flow of queries is better quantified, and as more and more connections are made to national and regional T&T systems.

9. GSP Training

The Panel of Experts notes that communication of GSP parameters and training on GSP issues will greatly facilitate efficient connection to and use of the GSP facility. Accordingly, the Panel of Experts recommends that the Parties establish a training programme and training materials covering the parameters of the GSP needed by the Parties to connect to and to use the GSP.

B. RECOMMENDATIONS ON MINIMUM TECHNICAL REQUIREMENTS FOR DEVELOPING A TRACKING AND TRACING SYSTEM COMPLIANT WITH THE PROTOCOL

1. This document developed by the Panel of Experts summarizes its recommendations in terms of the minimum requirements for developing a Tracking and Tracing System (T&T system) compliant with the Protocol to Eliminate Illicit Trade in Tobacco Products (Protocol).
2. It is divided into seven sections:
   a. a unique, secure, and non-removable identifier;
   b. a secure database (national and regional);
   c. supply chain/events for data capture (scanning);
   d. enforcement procedures and sanctions (to be developed further by the parties);
   e. T&T system cost;
   f. exceptional scenarios; and
   g. recommended additional steps.

MINIMUM TECHNICAL REQUIREMENTS

UNIQUE, SECURE, AND NON-REMOVABLE IDENTIFIER

UNIQUE IDENTIFIERS (UI)

1. A UI must be applied to every tobacco product item (i.e. each regular unit of sale) and for the purpose of aggregations, to aggregated units (e.g. carton/outer, master case, pallet).
2. The top level of global uniqueness shall be supported with any broadly recognized, standardized registration system for entities that are responsible for subsequent independent generation of UI, e.g. ISO/IEC 15459-2:2015/or as established by the Convention Secretariat.
3. The tobacco industry (TI) or any party related to the TI or with a conflict of interest shall not be responsible for generation of UIs.
4. UIs shall be defined as to their basic structure, notably their maximum length (e.g. 50 characters), the character set applied (ISO 646), the probability of being guessed (e.g. one in 10 000) and the permitted method by which the information required under the Protocol as forming part of the UI is embedded in the UI.
5. UI shall be delivered in a secure manner from the generator to the premises of application.
6. UI data should allow for easy aggregation (linking of individual items to their encasing entities (carton, master cases, pallets, etc.).
7. Asymmetric encryption of the UI should be considered (mechanism to segregate keys used for encryption and keys used for decryption) to improve security of UI handling.
8. While a tax stamp is not strictly a component of a T&T system as envisaged by the Protocol, if a party wishes to use them as such, those tax stamps must have a UI, and be otherwise compliant with the provisions of the Protocol.
9. The following are the minimum mandatory data fields that must be coded on pack and kept in database:
   A. Must be marked on tobacco products themselves:
      i. UI
      ii. date of manufacture
      iii. location of manufacture
      iv. designation of manufacturing facility
      v. product description
      vi. the intended market of retail sale (where available).
   B. Must be kept in the T&T database:
      i. All information placed on tobacco products (See list in Point A above);
ii. machine used to manufacture tobacco products;
iii. production shift or time of manufacture;
iv. the name of the first customer who is not affiliated with the manufacturer;
v. designation of the invoice to the first customer who is not affiliated with the manufacturer;
vi. designation of the order number of the first customer who is not affiliated with the manufacturer;
vii. payment records of the first customer who is not affiliated with the manufacturer;
viii. warehousing;
ix. shipping;
   x. the identity of any known subsequent purchaser;
   xi. the intended shipment route;
   xii. the shipment date;
   xiii. shipment destination;
   xiv. point of departure; and
   xv. consignee.

10. The UI should be encoded into a data carrier. There are many such technologies readily available for this purpose. However, the Parties should agree on a limited number of standard data carriers, as this will allow for non-problematic reading of UIs by all the Parties. The Parties should also require the UI to be available in human-readable characters to facilitate field use.

SECURITY & INDEPENDENCE

11. Data carriers of the UI should either be printed directly on the product package or sit on a label (e.g. paper stamp) affixed directly to product package (not printed or affixed to cellulose or other product wrapper, or removable part of packaging).
12. UIs should independently identify each individual retail unit (pack, tin, pouch, carton, etc.) and, when aggregated, each shipping unit (master case, pallet, etc.). The UI differs from a Stock Keeping Unit (SKU).
13. The security of communication and data storage shall be the responsibility of competent authorities who may allocate/delegate the responsibility to specific entities to (e.g. IT administrators, non-TI company, etc.) but preclude entities affiliated to the TI.
14. Where the UI is affixed to the package is a decision that should be left to each Party to make, as long as it is permanently affixed and non-removable.
15. The generator of UIs should not be affiliated, financially, operationally or otherwise with the TI.
16. The TI shall not be involved in the process of approval and implementation of contracts for the generation of the UIs, and contracts for such generation should be between the generator and the regulating authority.
17. Selection of limited number of permitted data carriers, i.e. machine-readable UI representations, should be based on open standards broadly adopted by economic operators (see above).
18. Data carriers shall be produced with 100% readability for products that enter the market and be durable at least for the same time as the data retention period. Generated but not used UIs or UIs rendered unusable should be accounted for and effectively destroyed.
19. Data carriers shall be complemented with human-readable codes allowing queries to the database (i.e. the UI).

20. The security concept to be developed further at a later time. Security of data communication/encryption should be considered, with consideration of a minimum set of security features.

**DATABASE (national and regional)**

21. The following are the minimum mandatory data fields that must be coded on the pack and kept in database:
   
   **A.** Must be marked on tobacco products themselves:
   
   i. UI
   
   ii. date of manufacture
   
   iii. location of manufacture
   
   iv. designation of manufacturing facility
   
   v. product description
   
   vi. the intended market of retail sale (where available)
   
   **B.** Must be kept in the T&T database (DB):
   
   i. all information placed on tobacco products (See Point A above);
   
   ii. machine used to manufacture tobacco products;
   
   iii. production shift or time of manufacture;
   
   iv. the name of the first customer who is not affiliated with the manufacturer;
   
   v. designation of the invoice to the first customer who is not affiliated with the manufacturer;
   
   vi. designation of the order number of the first customer who is not affiliated with the manufacturer;
   
   vii. payment records of the first customer who is not affiliated with the manufacturer;
   
   viii. warehousing;
   
   ix. shipping;
   
   x. the identity of any known subsequent purchaser;
   
   xi. the intended shipment route;
   
   xii. the shipment date;
   
   xiii. shipment destination;
   
   xiv. point of departure; and
   
   xv. consignee.

22. DB to be securely administered by non-TI contractor or by the Party itself (DB operator).

23. Party should establish basic operational requirements (primary/secondary, need for independent router, uptime, data processing time requirements, retention, logging, redundancy, automatic and on-demand reporting requirements, etc.).

24. DB Operator to establish other T&T operator connection procedures (technical specifications for connection, transmission and receipt of information, etc.).
25. Information shall be securely stored independently from the industry for the entire data retention period, as required by the Parties.
26. The data storage shall be organized on the basis of a single data dictionary, which shall refer to labels of data fields in human-readable format.
27. The data storage shall be subject to basic requirements in terms of existence of backup, access rights (strictly limited to government operators with no access given to TI), non-removal of data, monthly uptime, maximum time for processing incoming data, and maximum time for responding to queries. Parties may also require alerts and periodic reports, subject to the provisions of the Protocol which limits access to specific purposes.
28. Data shall be portable, i.e. none of the elements of data storage architecture shall be an obstacle in transition to any subsequent provider, if such a need arises.
29. For any communication, one entity shall be designated as responsible for defining connectivity and security protocols. Consideration should be given to use of open standards.
30. Further deliberation is required on minimum standards for verification and readability of codes.

**SUPPLY CHAIN/EVENTS FOR DATA CAPTURE (SCANNING)**

31. Information in database shall be updated as needed to include all Protocol information on orders, invoices and payment records, warehousing, etc. via scanning, as required.
32. Information in the database shall be updated up to the point in the distribution chain designated by the Party, which shall be at least to the premises or control of the first customer (first non-related party to the manufacturer) or the final payment of any applicable tax, duty or excise, whichever is later.
33. All operational and transactional events shall be predefined by the parties and not the TI, including setting time requirements for reporting each event. Furthermore, a full message shall be also predefined in terms of mandatory and standardized data fields and methods of message data encoding, e.g. standardized date and time format, with reliance on universal time coordinated (UTC) recommended to avoid confusion.
34. Any reporting messages shall be identifiable in terms of their sender, recipient and timestamp.
35. The system shall be capable of validating the sender and the format of received messages and providing acknowledgements to sender.
36. Security of data capture and transmission.
37. All operators and facilities shall be preregistered and identifiable by means of unique codes. (Parties should consider extending registration/identification to machines).
38. A sample event map follows:

<table>
<thead>
<tr>
<th>generated</th>
<th>printed on label</th>
<th>associated with master case/wholesale unit</th>
<th>assigned to container</th>
</tr>
</thead>
<tbody>
<tr>
<td>transmitted</td>
<td>read verified</td>
<td>assigned to master case/wholesale unit</td>
<td>printed on master case</td>
</tr>
<tr>
<td>receipt confirmed</td>
<td>activated</td>
<td>associated with pallet/shipping unit</td>
<td>printed on pallet label</td>
</tr>
</tbody>
</table>
assigned to retail unit | associated with carton/retail unit 2 | assigned to pallet/shipping unit | printed on container label
---|---|---|---
printed on retail unit | assigned to carton/retail unit 2 | associated with container | tendered for transport
tendered for storage | tendered for retail sale | payment record added | IMRS updated
stolen | destroyed | disassociated [with xxx] | associated [with xxx]

**ENFORCEMENT PROCEDURES** *(to be developed further by the Parties)*

39. Parties shall provide mechanisms for verification and interdiction of noncompliant products, and such mechanisms should provide a timely response.
40. Parties should ensure provision of any needed field-inspection devices or develop applications for law enforcement that allow for verification of UIs and retrieving T&T information.
41. Parties shall ensure that tobacco products, which are not compliant with the Protocol, are subject to seizure in accordance with applicable national law.
42. Parties should consider imposing Article 17 seizure payments in amounts equal to any unpaid duties at time of seizure, and/or a minimum amount per unit seized.
43. Parties should assess current enforcement procedures and capabilities, and the ability to use the T&T system for effective enforcement – with a view to ensuring the ability to effectively use T&T system tools.

**T&T SYSTEM COST**

44. Parties should bear in mind that the overall cost of the T&T system implementation is relatively negligible in relation to the final retail price of the tobacco product.
45. Parties should identify parameters that will affect pricing, reference documented costing scenarios and specify benchmarks not to be exceeded.

**EXCEPTIONAL SCENARIOS**

46. Provide guidance to parties based on their status/specific circumstances, e.g. countries that manufacture, export, import, transit through and/or have free trade zones (to be presented by each Party).
47. These exceptional scenarios should be captured via typology exercise and event mapping; and incorporated into the T&T event map.

**RECOMMENDED ADDITIONAL STEPS**

48. The Panel of Experts strongly recommends, as per the Article 8.10 of the Protocol, that Parties extend tracking and tracing beyond the first customer or the point where taxes have already been paid, to the extent of the supply chain that they deems practicable.
49. Parties should consider the imposition of Article 17 seizure payments.
C. RECOMMENDATIONS ON ROADMAP TO IMPLEMENTING A TRACKING AND TRACING SYSTEM COMPLIANT WITH THE PROTOCOL

1. This document, developed by the Panel of Experts on the Protocol to Eliminate Illicit Trade in Tobacco Products (Protocol), summarizes the process of implementing a tracking and tracing (T&T) system as provided for by the Protocol.

2. It provides a practical roadmap and is divided into three sections:
   a. recommended initial assessment of the current environment in relation to the critical elements relevant to the implementation of a Protocol-compliant T&T system;
   b. recommended T&T system conceptual design considerations; and
   c. recommended process to meet the specific challenges of illicit trade.

   (a) RECOMMENDED INITIAL ASSESSMENT OF ENVIRONMENT SURROUNDING T&T SYSTEM IMPLEMENTATION

Legal framework

3. A detailed understanding of the legal framework applicable to tobacco products regulation is crucial to ensure clear regulatory authority exists for the establishment of the Protocol T&T system. The Panel of Experts therefore recommends that the legal framework applicable to the implementation of a T&T system be assessed along the following lines:
   a. What is the source of the regulatory authority to impose obligations on the tobacco manufacturing and distribution industry?
   b. Is the current regulatory authority sufficiently specific for T&T obligations, or will additional regulatory authority be needed?
   c. Which entities hold current regulatory authority?
   d. If it is determined that additional regulatory authority is needed, the Panel of Experts recommends that such authority be sought promptly.
   e. The Panel of Experts notes that it may be necessary to cycle through this step several times as specific T&T implementation decisions are made, and specific features of the T&T become defined, so as to ensure proper (and specific) regulatory authority is in place as needed to cover all features and obligations under the Protocol T&T system.
   f. A supervision and sanctions regime must be put in place and communicated through the industry.

Current environmental analysis

4. A functional understanding of the current tobacco products environment is crucial as it will guide and inform the policy determinations and decisions required for the implementation of a Protocol-compliant T&T system. The Panel of Experts therefore recommends that the tobacco products environment be assessed along the following lines:
   a. A full review of the current tobacco products environment, including supply chain processes; data analysis of production, sales, consumption and excise duties; and enforcement processes and controls should be conducted.
   b. As part of this analysis, an overview and taxonomy of the illicit trade problem should be developed or updated.
Technical capacity (IT and HR)

5. An understanding of the current information technology (IT) capacities, in particular in relation to the management of the supply chain, and human resource (HR) availability is necessary to guide and inform the policy decisions required for the establishment of a Protocol-compliant T&T system. The Panel of Experts recommends that IT and HR capacity be assessed along the following lines:
   a. The IT resources available for T&T design, project management, implementation and oversight should be assessed.
   b. The operational resources available for enforcement activities should be assessed.
   c. The envisioned T&T system will require network capacity and connectivity. Accordingly, current network capacity and sufficiency should be assessed. Furthermore, any connectivity constraints by regulatory authorities or input providers should be assessed.
   d. The HR available for T&T project management, implementation and oversight should be assessed.
   e. Any procurement model for external (nongovernmental) IT or HR resources should be in accordance with local procurement regulations/Protocol.
   f. The Panel of Experts recommends that outsourcing be considered for any needed additional IT or HR support, and underscores the need to ensure that no TI influence is present in any outsourced elements.

Financial resources

6. An understanding of the resources available for the design, implementation and operational phases of the Protocol T&T system project is necessary to inform and guide the process.

7. Accordingly, the Panel of Experts recommends that available financial resources be assessed along the following lines:
   a. The financial resources that can be made available to start and complete the Protocol T&T system design and implementation process should be assessed.
   b. A funding model in compliance with the Protocol should be defined. In the design and implementation phase, the Panel of Experts recommends that preference be given to general public resources to avoid potential influence of the tobacco industry (TI) on the critical design and implementation phases through direct or indirect funding provided by the TI. In addition, the Panel of Experts noted that multilateral institutions can be providers of technical cooperation, grants and financial assistance.
   c. For the operational phase, the Panel of Experts recommends that consideration be given to T&T system user fees and T&T transactional fees such that the operation of the system (and potentially the recoupment of design and implementation costs) be borne by the TI.
   d. If the TI is to be source of funding for the T&T design and implementation, the Panel of Experts recommends that consideration be given to the minimization or elimination of the ability of the TI to influence the design and implementation process through the funding mechanism.
   e. In order to ensure design and implementation independence from TI influence or other interested vendors, the Panel of Experts recommends that in no instance should TI funding be tied to any specific design or implementation issues or processes.
   f. In order to further ensure design and implementation independence from TI influence or other interested vendors, the Panel of Experts recommends that the design and implementation team and any outsourced actors should be independent from industry and have no conflicts of interest, and user or transaction fees payable by the TI be paid directly to the competent authority or to its designee.
   g. The Panel of Experts recommends that the Meeting of the Parties (MOP) to the Protocol consider instructing the Convention Secretariat to provide guidance to assist individual Parties in securing
T&T funding\(^3\) from the TI, while at the same time ensuring compliance with all aspects of the Protocol and the obligations under the WHO Framework Convention on Tobacco Control (WHO FCTC) Article 5.3.

**Organizational framework at the national/regional level**

8. The nature of Protocol T&T implementation will require multiple non-TI stakeholder contributions and coordination. Towards this end, the Panel of Experts recommends:
   a. Analysis be undertaken to understand the non-TI stakeholders involved and appreciate the potential impact of a T&T solution across the spectrum of non-TI stakeholders.
   b. A structure should be put in place and activated to bring non-TI stakeholders up to speed and to provide for a decision-making process.
   c. Consideration should be given as regards when and how to provide information to TI in order to minimize TI ability to influence design and implementation process.
   d. A structure should be put in place for regular meetings of non-TI stakeholders during the entire design and implementation process, both to inform and to provide a basis for timely decision-making.
   e. A structure should be put into place after implementation for a periodic review of the sufficiency and efficiency of the T&T system.
   f. The Panel of Experts notes, that potential non-TI stakeholders may include:
      i. any entity with legal authority over any component of T&T system
      ii. health authorities
      iii. customs authorities
      iv. governmental trade/industry/commerce authorities
      v. tax/finance authorities.

**Assessment of existing systems**

9. Existing systems currently in operation may be seen as potential candidates and starting points for several elements of the T&T system. The Panel of Experts recommends that should there be any candidate systems for one or more components of the T&T system, an assessment should be undertaken of any such candidate to determine its compatibility with the minimum recommended standards, as enunciated in Annex 3.\(^4\)

**Use of standards**

10. The Panel of Experts recommends that, to the greatest extent possible and where practicable, existing internationally recognized standards (e.g. ISO) should be used as part of design specifications for any T&T system component. This will ensure that there are common definitions, maximize default interoperability, and provide a ready market of potential service providers to support such components and technologies. However, before being included in the system design, each standard should be screened for roles and functions that it may allocate to the TI and their impacts on operations of the T&T system.

   (b) **RECOMMENDED T&T SYSTEM CONCEPTUAL DESIGN CONSIDERATIONS**

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\(^3\) Article 8(14) of the Protocol provides that: “Each Party may require the tobacco industry to bear any costs associated with that Party’s obligations under this Article [8].”

Specification of output and functionality

11. The Panel of Experts recommends that the required output and functionality of the T&T system be established as a design parameter, without determination of specific technologies, techniques or methodologies that must be used by T&T operators to obtain the required output and functionality.

Reporting, analytics and audits

12. The Panel of Experts recommends that the individual components of the T&T system be capable of providing reports and other information as may be needed to support system analytics and periodic audits.

Design elements

13. The Panel of Experts recommends that the following elements be included in the T&T system design:
   a. The use of open source or readily available technologies will enhance multiple aspects of the T&T system, including but not limited to allowing for an increased solution provider base, system replicability and disaster recovery. Accordingly, the Panel of Experts recommends that as much as possible, the components of the T&T system be based on open source or readily available technologies, with ample code documentation.
   b. Independence of the T&T system from potential influence by the TI is critical to the proper functioning of the T&T system. The Panel of Experts recommends use of non-TI contractors for critical operations related to T&T system operation.
   c. The Panel of Experts recommends that each Party consider the following in relation to the design of the unique identifier (UI):
      i. Consideration should be given to who will generate the UIs themselves. The Panel of Experts recommends that this critical function be carried out by either the Party or a non-TI designee.
      ii. Further consideration needs to be given to how the T&T system will optimize UI uniqueness, as required by the Protocol.
         a) The Panel of Experts recommends that serialization, non-sequentiality and non-predictability be required elements of UI generation.
         b) The Panel of Experts recommends that registration of UI generators be required. This UI generator registration information will then have to be supplied to the global information-sharing focal point (GSP) for routing of enquiries.
         c) The Panel of Experts recommends that UI generators be required to be independent of the TI.
         d) The Panel of Experts recommends that consideration be given to the implementation of a common system to guarantee uniqueness of generator IDs, and that such common system be made a part of the GSP.
      iii. The Panel of Experts recommends that consideration also be given to how the T&T system will optimize UI security. The Panel of Experts recommends that security be ensured at each of the following critical points:
          a) security of the process by which UIs are generated and processed, up to point of printing; and,
          b) the printing of the UI on the label or on the tobacco product.
      iv. The Panel of Experts recommends that the T&T system optimize UI non-removability by requiring that the UI be:
          a) printed directly on substantial packaging or
b) incorporated into tax stamp and non-removable.

v. The Panel of Experts recommends that the content, format and functionality of UI be established in conjunction with the method of marking tobacco products in a manner consistent with the Protocol. Towards this end, the Panel of Experts recommends that:
   a) A minimum standard be chosen or established that allows for the expression of at least (1000 or 10,000) unique UI generator codes, plus a serialization component with negligible predictability that along with the UI generator codes will provide for an overall pool of codes covering the global production of all tobacco products over an extended period of time.
   b) Given the potential length of information required by the Protocol to be printed on the tobacco products, the Panel of Experts recommends the use of compression methods.

d. The product manufacture and distribution events that must be recorded in the T&T system should be determined via an “event mapping” exercise. In this regard, the Panel of Experts recommends that the following be included in the events that must be logged by the T&T system:
   i. the UI generation events, and critical events up to the placement of the UI on the tobacco product; and
   ii. the tobacco products production and distribution events up until the distribution point determined by the Party.

e. The scanning and capture of the events is a critical T&T system function. Accordingly, the Panel of Experts recommends that consideration be given to the T&T system operators that may be tasked with recording/scanning each event, with preference for use of non-TI operators where feasible, or that a strict set of reporting rules is established that if not followed may lead to the seizure of products that do not have a full traceability record.
   i. In any event, the Panel of Experts recommends that T&T operators be subject to registration/authorization processes. It is also suggested that service agreements and contingency plans be part of the T&T system in case information cannot be validated on line.

f. The management of the T&T system data is another critical T&T system function. Accordingly, the Panel of Experts recommends that the parameters be established for T&T data management, including:
   i. Determination of the entities that will be tasked to receive/maintain/dispose of the T&T database information.
      a) The Panel of Experts recommends that consideration be given to requiring the use of a non-TI contractor (DB operator). The Panel of Experts further recommends that:
         (1) the operational and functional parameters for DB operators be established;
         (2) The verification/audit procedures of the DB operator be established; and
         (3) the DB Operator should be charged with establishing the parameters for T&T operator connection.
      b) Determination of the T&T system interface for responses to queries from the Global Information-sharing Focal Point (GSP) will most likely be done through the DB operators. Parameters and routing for the receipt of GSP queries and remission of GSP responses should be determined in consultation with the Convention Secretariat. (Note: the GSP is addressed separately).

G. A frank and early discussion of how costs for each stage (design, implementation and operation) of the T&T system will be handled will greatly facilitate efforts to establish the T&T system. Accordingly, the Panel of Experts recommends that early consideration be given to the following elements:
   i. The determination of how design, implementation and operational costs will be handled and covered.
ii. Operational costs can be transferred to the TI through user, transactional and other fees. However, special attention should be given to how costs for design, implementation and enforcement will be met, as there may not yet be fees to cover these initial phases.

iii. Furthermore, the Panel of Experts recommends that TI payments should not be used directly to fund the design, implementation or enforcement processes, or actors. The risk of TI influence through the funding mechanism cannot be discounted, and the sensitivity to the process at these stages is heightened. Accordingly, non-TI sources of funding are recommended.

h. The Panel of Experts notes that an important part of illicit trade in tobacco products comes from products sourced from a “free zone” (FZ) or tobacco products shipped in transit. The Panel of Experts recommends that the T&T system apply to FZs and to tobacco products in transit. The Panel of Experts further notes that special consideration needs to be given to tobacco products that are imported into a Party from Protocol Parties, as well as tobacco products that are imported into a Protocol Party from non-Protocol countries. The Panel of Experts notes that these elements are vital to an integrated global Protocol T&T system, and that the starting point is that no circulation of tobacco products with non-compliant marking should be allowed. Accordingly, consideration must be given to what T&T system requirements will apply to:
   i. tobacco products manufactured within a FZ located within the Protocol Party;
   ii. tobacco products deemed to transit through the Protocol Party;
   iii. tobacco products imported from another Protocol Party with an operational T&T system meeting the requirements of the Protocol;
      a) in this instance, one option would be to adopt the compliant UI and relevant security features already on tobacco products;
      b) the other, potentially much more complex, option is to replace the original markings with entirely new markings, or to add additional markings; the Panel of Experts notes that for re-marking or additional marking of tobacco products to be practicable, full information of the product, including origin information must be coded on arriving tobacco products; and
   iv. tobacco products imported from a non-Protocol Party;
      a) establishment of parameters for the marking of tobacco products (time, location and content); and
      b) the Panel of Experts notes that compliance with the Protocol would require specific manufacturing information and recommends that in instances where such information is not provided by the importer, that the non-complaint goods be refused entry.

Seizure payments under Article 17

14. The Panel of Experts recommends that consideration be given to making manufacturers and persons identified by a T&T system responsible for seizure payments (at a sufficiently high level to act as a deterrent) on seized illicit tobacco products. Effective sanctions should be imposed for malpractice, and these should extend through the entire supply chain.

Justifications and rationales

15. The Panel of Experts recommends that the Parties explain the justification and rationale for each T&T requirement and policy decision taken in the design and implementation of the T&T system.
16. The Panel of Experts recommends that the Parties develop a risk matrix to understand the specific risks that each Party faces.

17. The Panel of Experts further recommends that each Party invite TI-independent stakeholders to an illicit-trade typology exercise, with a view to ensuring that T&T system features provide appropriate tools to combat each scenario. This process may require going through several rounds until a high level of confidence of having the right T&T tools to combat the scenarios is presented.

18. The Panel of Experts notes that illicit-trade typology information can be shared, and thus recommends that Parties consider sharing such information with the Convention Secretariat.
D. REPORT ON GOOD PRACTICE MODELS FOR LICENSING UNDER THE PROTOCOL

INTRODUCTION AND PURPOSE

Allen + Clarke, a public policy consulting firm, was commissioned by the Secretariat of the WHO Framework Convention on Tobacco Control (WHO FCTC) to develop an analysis of good practice models for licensing, as required under the Protocol to Eliminate Illicit Trade in Tobacco Products (Protocol). This includes licensing of manufacture, import and export of tobacco products and tobacco product manufacturing equipment.

This report presents the findings of our desktop review and analysis of licensing models to help inform the discussion of the Panel of Experts on the Protocol at its meeting on 10–13 March in Cape Town, South Africa. Our review and analysis covers:

- licensing regimes from various jurisdictions for manufacturing and distributing tobacco products and manufacturing equipment; and
- other licensing regimes from various jurisdictions for a range of non-tobacco-related products, which may serve as models or provide lessons to assist Parties design and implement good practice licensing regimes under the Protocol.

METHODOLOGY

This report was developed in response to terms of reference set out in a WHO Agreement for Performance of Work to undertake research and analysis of good practice models for licensing under the Protocol. The work is tightly focused on licensing of import, export and manufacture of tobacco products and tobacco manufacturing equipment (rather than of retail licensing or other forms of licensing across the tobacco supply chain).

Personnel from the Convention Secretariat and the Panel of Experts on the Protocol were contacted and asked for any examples of countries, licensing models and contacts they may know of that could be relevant to this work. All responses were followed up and combined with our own desktop-based search of tobacco- and non-tobacco-related licensing schemes, which has included information from academic, government, and nongovernmental organization (NGO) sources.

The selection of jurisdictions and other models of licensing regimes was based on consultation with expert practitioners in tobacco control policy and what was readily identified through our online research.

Given the period available to undertake this work (8 January 2018 to 5 March 2018), we have employed the following mitigations:

- limited our follow-up of known and identified contacts to making two approaches; and
- restricted the time spent searching for information on licensing regimes of suggested models, and from suggested countries, where that search was proving fruitless.

This paper presents a credible assessment of international approaches to licensing given the information and time available.
ROADMAP FOR THIS PAPER

This report is split into four key sections:

- **Executive summary**: this section summarizes the detail contained in Parts A, B and C and provides a more abridged version of our research and analysis.
- **Part A – Licensing**: this section provides a summary explanation of the nature and purpose of licensing in the tobacco control context. It also sets out the legal basis for, and obligations on, Parties to the Protocol to implement licensing regimes to help control the production and distribution of tobacco products in order to prevent their illicit trade.
- **Part B – Licensing Models**: this section provides an overview of approaches to licensing schemes in identified jurisdictions. It includes both licensing schemes for manufacturing and distributing tobacco products and manufacturing equipment, and also covers licensing schemes for other products that may be relevant in assisting the Parties design and implement licensing schemes to meet their Protocol obligations.
- **Part C – Lessons**: this section identifies options for authorities to issue, renew, suspend, revoke and cancel licences. It also provides examples of how Parties may seek to control the supply chain beyond the Protocol licensing requirements, and sets out our discussion on these matters.

EXECUTIVE SUMMARY

Article 6 of the Protocol sets out clear mandatory requirements on Protocol Parties to license specific parts of the tobacco supply chain. Even so, the Protocol envisages a range of different compliant supply chain control mechanisms being employed by Parties (“…pursuant to a licence or equivalent approval…”), and there is a spectrum of licensing schemes Parties may ultimately choose to design and implement.

We looked at six jurisdictions with tobacco supply chain licensing schemes, and seven other non-tobacco licensing models, in order to identify core features and good practice elements of licensing regimes that the Parties could consider when designing their own regimes. Tobacco supply chain licensing schemes were considered from:

- the United Kingdom of Great Britain and Northern Ireland
- the United States of America
- California
- Kenya
- Malaysia
- Singapore.

The non-tobacco licensing schemes analysed as part of this report were:

- Australia Group (controlling inputs for chemical and biological weapons programmes)
- AEO (European Union accreditation scheme for trusted traders)
- CTPAT (accreditation scheme in the United States of America for trusted traders)
- precursor chemical licensing
- controlled drug licensing
- alcohol retailing
- pharmaceutical industry licensing.
We identified common and key features from both tobacco and non-tobacco regimes that Parties could consider implementing to give effect to the Protocol requirements. Good practice features of a licensing scheme included expected elements of any licensing scheme, such as a sound and transparent application and decision-making process for licences, providing for fees for licences, and imposing record-keeping and reporting requirements on licensees. In addition, we identified features that also cover more novel aspects of a licensing regime that may improve its effectiveness, such as restricting licensees to only transacting with other licensees, and requiring evidence of appointment as an actor in the supply chain by an existing supply chain actor as a criterion for receiving a licence (for example, an appointment as an exporter of tobacco products by the manufacturer of those tobacco products).

Other good practice considerations for Parties seeking to implement a licensing scheme include:

- ensuring the cost of implementing the scheme is proportionate to the potential impact (the more stringent a licensing scheme is in terms of the information required to be provided by applicants and the obligations it imposes on licensees, the more burdensome the regime will be on both businesses and the authorities who have to administer and enforce the scheme);
- considering other compatible control measures as the regulatory scheme is designed and implemented;
- considering how the licensing scheme will operate with existing, and future, WHO FCTC requirements for tobacco products to bear stamps/markings, and link with track and trace regimes; and
- ensuring compatibility of the licensing scheme with the jurisdiction’s existing regulatory environment.

Given the Protocol envisages future work on controlling inputs into the tobacco supply chain, and that some jurisdictions are already taking action on this front, we consider it prudent for the Parties to turn their minds to the potential for future expansion of the scope of any licensing regime at the time they design it. Non-tobacco licensing schemes also included increased international cooperation and trusted trader accreditation that may provide mechanisms for achieving good practice supply chain control beyond the mandatory requirements of the Protocol.

Some Parties may choose to go beyond the minimum licensing requirements of the Protocol to also license inputs into the tobacco supply chain to increase the difficulty for non-licensed persons to access essential ingredients or machinery used for tobacco product manufacture as a further control on the supply chain to prevent production of illicit tobacco products. Other methods identified to increase supply chain control beyond the Protocol licensing requirements include:

- increased international cooperation:
  - to share intelligence on illicit trade;
  - to share good practice on the design and implementation of licensing regimes; and
  - to seek to control the tobacco trade with jurisdictions who are not Protocol Parties; and
- implementing an accreditation scheme that provides benefits for accredited operators in the supply chain that have demonstrated secure and reliable processes and high levels compliance with a set of requirements.

Implementing a licensing scheme is mandatory, however, assessing where to strike the balance in the complexity/strictness of a licensing regime will be a matter of careful consideration for the Parties given the scale of tobacco-related trade, the availability of public resources and the existing regulatory environment in their respective jurisdictions. As such, what is good practice for any country will be, in part, context specific.
PART A – LICENSING

1. LICENSING

This section sets out the requirements of licensing schemes as mandated by Article 6 of the Protocol, and also explores the spectrum of licensing schemes ranging from light-touch registration at one end to comprehensive positive licensing schemes at the other end. Examples of licensing regimes are noted which are discussed more fully in later sections of this report.

1.1. Licensing requirements under the Protocol

Article 15 of the WHO FCTC and Article 6 of the Protocol provide the legal basis for, and obligations on, Parties to implement licensing to control tobacco products and prevent their illicit trade.

1.1.1. WHO FCTC – Article 15

Article 15(1) of the WHO FCTC provides that the elimination of illicit trade in tobacco products is an essential component of tobacco control. Article 15.7 of the WHO FCTC states that Parties shall endeavour to implement measures to control the production and distribution of tobacco products, including licensing where appropriate, in order to prevent illicit trade.

1.1.2. PROTOCOL – Article 6

The mandatory licensing requirements for the tobacco supply chain under Article 6 of the Protocol require Parties to provide for a licence, or equivalent approval system, for the manufacture, import, and export of tobacco products and manufacturing equipment.

Other activities, such as retailing tobacco products, growing tobacco, and transporting, wholesaling, brokering, warehousing or distributing tobacco products or manufacturing equipment, should be licensed where possible, given national circumstances.

Article 6 outlines the measures to be taken so that the licensing system is effective. It also states that five years after the entry into force of the Protocol, the Meeting of the Parties (MOP) will take action to identify any “key inputs” that are essential to the manufacture of tobacco products and that can be subject to an effective control mechanism. On the basis of such research, Parties will consider appropriate action.

The Protocol sets out the following elements the Parties shall implement to ensure the effectiveness of the licensing system:

- establish or designate a competent authority to issue, renew, suspend, revoke and/or cancel licences;
- require licence applications to include all necessary information about the applicant, including:
  - identity information of the applicant;
  - business location and production capacity;
  - details of the tobacco products and manufacturing equipment covered by the application;
  - a description of where manufacturing equipment will be installed and used;
- any criminal records;
- identification of the bank accounts intended to be used; and
- a description of the intended use and market of sale of the tobacco products;

- collect licence fees and consider using them in administering and enforcing the licensing system;
- prevent, detect and investigate irregular or fraudulent practices in the operation of the licensing system;
- periodically review, renew, inspect or audit licences, where appropriate;
- set a time frame for the expiry of licences;
- oblige licensed persons to inform the competent authority of any significant change in information relevant to the licensed activities; and
- ensure the destruction of manufacturing equipment takes place under supervision of the competent authority.

Parties are also to ensure licences are not assigned or transferred without the proposed licensee providing the necessary information and the competent authority granting approval.

1.2. Licensing schemes – general

Despite the clearly set out minimum requirements of Article 6, there is a spectrum of licensing schemes that may be adopted. These range from light-touch registration of businesses and operators, through to comprehensive positive licensing models that require would-be operators to apply for a licence and demonstrate ongoing compliance with eligibility criteria in order to gain market entry.

A licence to undertake an activity is different from a register of people undertaking an activity. Licensing has recently been described as:

…a permission issued by a competent authority following the submission of an application and/or other documentation. Governments can require participants throughout the supply chain (e.g., tobacco growers, manufacturers, distributors, wholesalers, retailers) to be licensed, imposing obligations or restrictions on them under the threat of administrative, civil, or criminal penalties. The cultivation of tobacco and the production of other materials necessary for the manufacture of cigarettes, such as filter tips and cigarette papers, is usually not subject to licensing, with the exception of Australia that license tobacco growing.

Governments can also prohibit licensed operators from dealing with unlicensed ones, thereby creating a stronger chain of accountability. A license can be revoked if the holder breaks the law, creating economic disincentives for engaging in illegal business such as illicit production and/or evading taxes. There is also an option of a “negative licensing” scheme, where regulated entities can be specifically excluded from engaging in any tobacco business due to their previous noncompliance.

... Licensing should be implemented at costs as low as possible with one centralised registry and without undue administrative burden. Multi-jurisdictional licensing
can create confusion and slow-response. Licensing will not prevent all illegal business, since some entities can decide to operate illegally without a licence and some licensed entities will risk losing the licence in order to engage in illegal activity.

Other control measures, such as requirements for record-keeping and limits on quantities of tobacco products sold, can regulate the supply chain without explicitly requiring formal licensing.  

**Benefits of licensing**

Licensing is a contract between regulators and the licence holder with terms and conditions laid down in legislation or attached to the individual licence. Licensing is a mechanism for policy implementation for meeting public health objectives and for encouraging and ensuring the responsible sale of tobacco products. Furthermore, licensing is also a mechanism or tool to give effect to policy that needs to evolve in the future. By establishing a contract between the regulators and the licensee, licensing allows for a much more fine-tuned and adaptive approach to future tobacco control strategies.

Licence application processes enable licensees to be vetted and educated about the tobacco laws. Licensing schemes go beyond prohibiting specific behaviour to requiring good management practices, such as training, age verification and other service standards.

Furthermore, licensing assists health authorities to monitor compliance with tobacco control requirements. It allows greater and more responsive enforcement on the detail of regulating business activities. For instance, suspension or cancellation of a business’ licence can potentially have a far larger financial impact than prosecution and a fine for offences.

**Positive licensing schemes**

Positive licensing schemes are distinguished from negative licensing models which require participants to notify government authorities that they are undertaking an activity (for example, manufacturing tobacco products). Participants in a negative licensing model do not need to seek permission or prove their suitability to undertake the activity, but they may be removed from a register and have their right to undertake the activity revoked on a temporary or permanent basis. In contrast, a positive licensing scheme requires would-be participants to apply for a licence, which is only granted where licence criteria and conditions are met. Positive licensing often incurs a fee and imposes continuing obligations on the licence-holder.  

A positive licence has been described as:

\[
\text{… a notification which also requires prior approval as a condition for conducting prescribed business activities, and compliance with specified minimum standards.}
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Breaches of the required standard may result in the suspension or revocation of permission by a specified agency.\(^7\)

**Good practice licensing**

More stringent, complex licensing schemes provide more tools to influence the behaviour of businesses in the market, but also place higher demands on these businesses to comply, and place larger administrative, cost, and resource burdens on regulators to administer and enforce the scheme. The more complex a system is to comply with, the more complicated and expensive administering that system is likely to be. Discussions about good practice licensing of the supply chain under Article 6 of the Protocol therefore need to be placed within the context of resourcing and capability of the regulators. Parties should carefully consider the varying levels of resource they have available, and the relative impact that a stricter, more complex licensing scheme might have compared with the implementation of other WHO FCTC interventions.

In addition, good practice licensing in this area will be strongly linked to the varying level of trade and amount of manufacturing that takes place in different jurisdictions. As discussed further in Section 6 of this report, schemes to licence operators in a supply chain can be bolstered by additional layers of regulation, such as:

- licensing inputs into a supply chain, for example, as Ontario, Canada, has done with recent regulations to licence a key input in the manufacture of cigarette filters (see Section 6 of this report);
- formal frameworks for international cooperation, such as the Australia Group with regard to chemical and biological weapons precursors (see Section 3.1 of this report); and/or
- accrediting trusted operators who have demonstrated high levels of compliance with exacting standards and therefore require less intervention by authorities and can gain easier passage of their goods through borders, such as the Authorised Economic Operator (AEO) and the Customs Trade Partnership Against Terrorism (CTPAT) regimes (see Sections 3.2 and 3.3 of this report).

These steps may add additional complexity and cost to the licensing scheme but may improve the effectiveness of the scheme overall. However, it should be noted that these steps go significantly beyond the minimum requirements of Article 6 of the Protocol.

Discussion about good practice for licensing needs to take into account the wider tobacco control context in each jurisdiction, as the outcomes sought by Article 6 (licensing of the supply chain) can be reached by a range of interventions that may exist under different legislation, such as customs controls and approvals, taxes, business reporting requirements and others.

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\(^7\) The Allen Consulting Group, ‘Licensing of Tobacco Retailers and Wholesalers: Desirability and Best Practice Arrangements’, Report to the Commonwealth Department of Health and Ageing Endorsed by the Intergovernmental Committee on Drugs, December 2002, Sydney.
PART B – LICENSING MODELS

2. JURISDICTIONS WITH LICENSING SCHEMES APPLYING TO THE TOBACCO SUPPLY CHAIN

Sections 2 and 3 of this report discuss good practice elements of licensing schemes based on analysis of jurisdictions that have already implemented a tobacco supply chain licensing model, as well as good practice from other, non-tobacco licensing schemes.

Section 2 covers our review of six jurisdictions that have licensing schemes applying to various parties in the tobacco supply chain. These jurisdictions are the United Kingdom of Great Britain and Northern Ireland, the United States of America, California, Kenya, Malaysia and Singapore. Other than the United Kingdom of Great Britain and Northern Ireland, which has draft regulations on point, we found no other jurisdiction with a specific licensing regime for tobacco product manufacturing equipment. However, we consider the good practice licensing features identified in other regimes apply equally to manufacturing equipment as any other product.

The experience of these jurisdictions in establishing licensing regimes, which may be relevant to other jurisdictions seeking to give effect to the Protocol licensing requirements, is summarized below. We note that we have not repeated all the ordinary and usual features of each licensing scheme but have instead sought to give a high-level overview of what the scheme involves, while drawing attention to features of it that we consider are examples of good practice or might be of interest to Parties.

2.1. United Kingdom of Great Britain and Northern Ireland

The Government of the United Kingdom of Great Britain and Northern Ireland undertook a consultation process in 2016 on Article 6 of the Protocol to seek stakeholder views on licensing aspects of the tobacco supply chain and manufacturing equipment.8

Licensing the supply chain

Perhaps unsurprisingly, public submissions generally fell into two distinct camps. Respondents associated with the tobacco industry were in favour of a light-touch registration model, believing that licensing

8 Manufacturers of tobacco products in the UK are already required to have a licence so consultation was not undertaken on this part of the supply chain.

The consultation document can be found at the following link:

The summaries of responses to the licensing of tobacco machinery, and of the supply chain, were published in December 2016 and November 2017, respectively, and available at the following links:


legitimate operators would have little impact on illicit trade but would be burdensome on business. Respondents from local authorities and health promotion groups, however, were in favour of a positive licensing system for the entire supply chain with fees used to fund enforcement of the system.

The Government’s response was that it considered further controls on importers, exporters and retailers of tobacco products would not significantly contribute to combating illicit trade. The Government was mindful that a range of controls and sanctions are already available for authorities to apply against errant operators.

The Government responded that sales of illicit tobacco through legitimate retailers represent only a proportion of total illicit sales and most retailers are fully compliant with the law in this area. Therefore, they concluded, it is difficult to make a strong case for retailer licensing for anti-illicit purposes only as retailers that choose to sell illicit tobacco do so knowingly. Therefore, the government considered breaching licence terms is unlikely to be a significant deterrent. Her Majesty’s Revenue and Customs (HMRC) already applies sanctions against retailers found selling illicit tobacco, including financial penalties and removal of alcohol licences.

The Government concluded that the costs of a national HMRC administered licensing scheme aimed at tackling illicit trade, particularly a positive licensing scheme, would appear to be disproportionate to the additional benefits which would accrue. It would also be burdensome for those businesses already registered under the Scottish, Welsh or Northern Irish health schemes as tobacco retailers to require them to apply for a second national registration for the sale of tobacco products. The forthcoming track and trace requirements of the Protocol are also likely to add additional supply chain controls and some form of registration for at least part of the tobacco supply chain, and it seems this played a part in the Government’s determination that additional supply chain controls were not needed in the United Kingdom of Great Britain and Northern Ireland. The Government did not consider the case had been made for an additional tobacco supply-chain licensing system aimed specifically at reducing illicit trade.

From this experience it may be suggested that licensing might not make sense in some jurisdictions with existing controls over steps in the tobacco product supply chain. The case for introducing a new positive licensing scheme will need to overcome the argument of burdening business. Illustrating how licensing can be introduced consistently with the wider regulatory environment, and identifying the extent of the benefits likely to accrue from its introduction, will likely be an important aspect of the public debate.

**Licensing manufacturing equipment**

The consultation in the United Kingdom of Great Britain and Northern Ireland on manufacturing equipment reached a different conclusion to that on the supply chain.

The Government was aware that “manufacturing equipment” could include a spectrum from large plant machinery to portable equipment. The Government sought to narrow the definition of manufacturing equipment, making it clear a licence was not being proposed for the manufacture of hand-operated machines to roll single cigarettes.

Until the Protocol, there was no obligation in the United Kingdom of Great Britain and Northern Ireland to seek a licence or approval for tobacco products manufacturing equipment. Some respondents raised the issue of burdens on business and questioned the impact of licensing on illicit trade. However, the Government considered the number of businesses affected would be small as there are few tobacco manufacturers and no manufacturers of machinery in the United Kingdom of Great Britain and Northern
Ireland. As well as meeting an obligatory part of the Protocol, the Government considered licensing machinery to be an additional tool to control the avoidance of excise duty through the manufacture of illicit tobacco products. However, the Government decided not to charge a fee for a licence for a tobacco manufacturing machine in order to keep costs imposed on businesses to a minimum.

Specific aspects of the consultation in the United Kingdom of Great Britain and Northern Ireland on licensing manufacturing equipment are summarized below.

Effectiveness of a licensing system to control the manufacture, import, and export of manufacturing equipment

Many submitters were in favour of a licence system,9 while tobacco industry respondents considered a register should be introduced as an alternative.

One respondent suggested there should be a responsibility to dispose of manufacturing equipment in a secure manner to prevent potential use in the manufacture of illicit product.

The Government’s response was to introduce a simple licensing scheme for all tobacco manufacturing machinery in the country including machinery being used and machinery being imported, exported or destroyed.

Conditions on obtaining a licence

Many respondents wanted a licensing system to require applicants to prove they are fit and proper persons, mirroring the conditions for obtaining Personal or Premises Licences under the Licensing Act 2003.10 Any applicant that had committed a relevant offence would be denied the licence. Licences could also be suspended or revoked if the holder was found to be breaking the terms of the licence.

Other conditions suggested included:

- manufacturers applying for a licence should demonstrate they are complying with the provisions of the WHO FCTC in relation to illicit trade in tobacco products;
- corporate bodies applying for licences should be required to supply details of a responsible person, that person, in addition to the corporate body, would be liable to any enforcement action or loss of a licence;
- licences must be renewed annually and subject to review at any time; and
- licences and proper business records must be retained for a reasonable time for inspection by any authorized officer, and authorized officers shall have rights of entry and search.

The Government agreed that a fit-and-proper person test should be applied for all applicants for a licence. Licence holders would be subject to inspection and checks that they are complying with the terms of their

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9 Local government, Trading Standards, public health bodies and groups, some representative bodies and anti-smoking charities.
licence. Registered manufacturers of tobacco products are already required to comply with legislation designed to tackle the illicit market.

Sanctions/penalties for non-compliance

The majority of respondents considered reasonable sanctions for non-compliance (not arising from a genuine mistake or error) could include:

- formal warnings
- penalties
- fixed penalty notices to deal with minor infringements where a penalty is justified
- fines
- suspension of the licence.

In these circumstances, some respondents believed permanent revocation of the licence was appropriate. Respondents suggested persistent breaches of conditions should lead to closure of the business and/or criminal prosecution, and that fines should be proportionate to the size of the business breaching licence conditions.

The Government’s response was that non-compliance with the licensing requirements will be subject to a range of sanctions according to the offence. Tobacco manufacturing machines discovered without a valid licence will be subject to seizure, enhancing existing controls available to prevent the manufacture of illicit tobacco products.

Licence fees

Those submitters in favour of introducing licensing consider a fee should be charged for licences. Many thought the fee should be set at a level appropriate to cover administrative and enforcement costs. Those involved in the tobacco industry did not think a fee would be appropriate.

The Government’s response was that, in line with existing regulatory frameworks to tackle duty evasion, a fee will not be charged for a licence for a tobacco manufacturing machine. This will keep the costs to legitimate businesses to a minimum.

Commentary on the regime’s contribution to good practice licensing

The following features emerged from the consultation, as elements submitters consider should be part of a licensing scheme.

- Licensing is a more effective control than registration.
- Conditions on licences should include provision for secure disposal of machinery.
- Applicants for licences must pass fit and proper person test.
- Applicants who have committed a relevant offence would be denied a licence.
- Breach of licence terms will result in suspension or revocation of licence.
- Applicants should demonstrate compliance with the WHO FCTC regarding illicit trade.
Corporates should supply details of a responsible person who would be liable in addition to the body corporate.

Licence would be renewed annually and subject to review at any time.

Hierarchy of penalties from formal warning to revocation of licence, with suggestion that persistent breaches should lead to closure of business and/or criminal prosecutions

Suggestion that fines should be proportionate to the size of the business.

The Government of the United Kingdom of Great Britain and Northern Ireland decided not to set a fee for a licence.

Tobacco products manufacturing machinery (licensing scheme) regulations 2018

The Tobacco Products Manufacturing Machinery (Licensing Scheme) Regulations 2018 (Regulations) set out a framework for a licensing scheme for tobacco products manufacturing machinery.

The Regulations are due to come into force on 1 April 2018 and 1 August 2018 (there are different commencement dates for different parts).  

Summary of scheme

The regulations provide that a person may not manufacture, purchase, acquire, own, or be in possession of an item of tobacco products manufacturing machinery without a licence.

The United Kingdom of Great Britain and Northern Ireland uses the term “manufacturing machinery”, rather than the Protocol’s “manufacturing equipment”, in order to distinguish manually operated equipment which manufactures individual tobacco products.

The regulations also make provision for:

- exemptions from the licensing scheme
- who is eligible to have a licence
- conditions and restrictions to apply to licences
- the administration of licences
- penalties
- forfeiture
- enforcement
- reviews and appeals.

In the United Kingdom of Great Britain and Northern Ireland, tobacco products manufacturing machinery can only be legally used to manufacture tobacco products in registered tobacco products factories. Prior to

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11 The Regulations can be found at this link: [http://www.legislation.gov.uk/uksi/2018/75/made](http://www.legislation.gov.uk/uksi/2018/75/made)
the new proposed licensing scheme set out in the Regulations, there were no other controls on manufacturing. This meant manufacturing machines could be freely sold, moved and stored. Machines could only be seized if there was evidence of them being used to manufacture illicit tobacco products.

The new proposed scheme requires a person who carries out certain activities in respect of a machine to be licensed. Any person who carries out an activity without a licence will be liable to a penalty and the item of machinery liable to forfeiture. This means that any machine not specified in a licence may be seized (without the need for evidence of that it is being used to manufacture illicit tobacco products). This power is designed to help prevent evasion of tobacco products duty.

A summary of the regulations is set out below.

**Part 1** of the Regulations makes provision for commencement and definitions, including:

- “regulated activity” means to manufacture, purchase, acquire, own or be in possession of an item of tobacco products manufacturing machinery.

**Part 2** provides for the prohibition against engaging in regulated activity without a licence. It also provides for two exemptions to the prohibition: in relation to tobacco machinery designed for the manual production of a single cigarette; and in relation to the transportation of machinery.

**Part 3** provides that the commissioners of HMRC:

- can only grant a licence if they are satisfied the applicant is a fit and proper person and will not use the machinery for the fraudulent evasion of duty charged on tobacco products;
- may prescribe in a notice, and specify in a licence, conditions and restrictions to which a licence is subject; and
- may vary or revoke a licence at any time for reasonable cause.

**Part 4** provides for the administrative procedures for the licence scheme, including:

- that the commissioners must prescribe the form, manner and information to accompany applications for licences and for variations and renewals;
- making applications; and
- determining applications, including provision for when additional information is required.

**Part 5** makes provision about penalties and forfeiture, in particular:

- a person who contravenes the prohibition is liable to a penalty in the amount specified in section 9(2)(b) of the Finance Act 1994 and the machine is liable to forfeiture; and
- the assessment of penalties and exceptions from liability to a penalty.

**Part 6** provides for enforcement.

**Part 7** provides for review and appeal of decisions.

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12 currently £250
13 Exceptions are if the contravention is not deliberate and there is a reasonable excuse for the contravention.
A licence granted to an applicant must specify:

- a unique licence number;
- the name and address of the licensee, and company registration number if applicable;
- each regulated activity permitted;
- a description of each item of tobacco products manufacturing machinery in respect of which the licence is granted;
- the address at which each item of tobacco products manufacturing machinery must be kept;
- the date on which the licence will expire, which must be a date within two years of the date on which the licence is issued; and
- any conditions or restrictions to which the licence is subject.\(^{14}\)

**Commentary on regime’s contribution to good-practice licensing**

Matters which may be of interest to the Expert Panel and the Parties about this scheme include that the regulations redefine “manufacturing equipment” to apply to a narrower set of equipment than the Protocol definition which, while broad enough to capture all types of manufacturing equipment, may need refining in regulation depending on the target of the licensing scheme. The regulations’ definition expressly excludes manually operated equipment that is used to produce single cigarettes.

The regulations enable the forfeiture of unlicensed machinery without the need for evidence of misuse or any other wrongdoing.

The criteria for the grant of a licence include passing a “fit-and-proper person” test.

The monetary penalty for breaching the regime is comparatively low, at £250, although, forfeiture of the equipment may be more of a deterrent.

### 2.2. United States of America – Federal Scheme

The United States of America requires everyone who intends to manufacture, import or operate an export warehouse for processed tobacco and tobacco products to obtain a permit from the Alcohol and Tobacco Tax and Trade Bureau (TTB).\(^{15}\)

The TTB permit regime requires applicants to submit a substantial level of information, including providing evidence of the consent of the owner of the property where the proposed business will be undertaken, and evidence of the source of the funds invested in the business. Grounds for refusing a TTB permit extend beyond good character of the applicant based on criminal records to include the applicant’s business experience and financial standing. Including financial criteria may be a valid way for the Parties to ensure protection of the revenue and compliance with licence conditions, such as, for example, requiring the destruction of retired equipment in a secure manner.

The TTB regime also imposes substantial reporting and record-keeping requirements on permit holders. For instance, tobacco manufacturers must maintain records of daily operations showing the amount of tobacco received (and details of the person from whom it was received), used, lost, destroyed and removed.

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\(^{14}\) Draft regulation 10.

\(^{15}\) [https://www.ttb.gov/tobacco/manufacturer_products.shtml](https://www.ttb.gov/tobacco/manufacturer_products.shtml)
A record is also required of the kind and quantity of tobacco products removed, the date of removal and the details of the person to whom they were sent. Permit holders must submit monthly reports to the TTB.

The rigorous reporting and record-keeping requirements of the TTB regime may be a good example of how jurisdictions might combine the licensing requirements under Article 6 of the Protocol with some of the due diligence requirements in Article 7 of the Protocol. However, imposing substantial information requirements on applicants for licences also has an impact on the difficulty and cost of administering and enforcing the licensing scheme which may not be appropriate or possible for all Parties, but can be an effective measure to combat illicit trade where it is implemented.

2.3. United States of America – California State Scheme

The California Cigarette and Tobacco Products Licensing Act 2003 (CCTPL Act) requires retailers, wholesalers, distributors, manufacturers, and importers of cigarettes and tobacco products to hold a licence from the California Department of Tax and Fee Administration (CDTFA).  

Licence holders are required to purchase tobacco products from other licensed parties and have an obligation to ensure other parties in the supply chain they transact with are licensed. The CCTPL Act prohibits retailers from purchasing their products from other retailers, and wholesalers are prohibited from purchasing products directly from manufacturers or importers (instead, distributors sell tobacco products to wholesalers, other distributors and retailers).

The California regime requires retailers and wholesalers to maintain “purchase invoices” for all products received from distributors and wholesalers. The purchase invoices must contain:

- contact details of the seller, including licence number
- an itemised list of the products purchased
- the sales price
- the date of purchase
- the taxes due to the CDTFA.

The requirement that licensed parties in the tobacco supply chain may only transact with other licensed parties – and also restricting the types of parties transactions can be undertaken with, such as the prohibition on retailers purchasing products from other retailers – may be a useful tool for controlling the whole supply chain. This restriction combined with the regime’s stringent record-keeping and reporting requirements may assist authorities to identify where in the supply chain products are diverted to the illicit market.

The obligation in the CCTPL Act on licence holders to maintain substantive records is similar to the requirements of the federal TTB permit regime (discussed above in Section 2.2), and may be a helpful example of how Parties to the Protocol may seek to combine licensing requirements under Article 6 with some of the due diligence requirements in Article 7, such as around customer identification.

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2.4. Kenya

In Kenya, the Excise Duty Act 2015 provides that the manufacture or importation of excisable goods, which includes tobacco products, can only be done if licensed or registered by the Commissioner to undertake that activity.17 Applications for a licence to manufacture or import tobacco products can be denied on the basis that the applicant:

- has been convicted of a relevant offence;
- is bankrupt or insolvent;
- is in liquidation or receivership;
- has specified factory, plant or equipment that is not adequate to manufacture or secure excisable goods;
- has not complied with tax law requirements; or
- is related to a person to whom any of the above grounds apply and the Commissioner is satisfied the related person will be involved in the applied for activity.

Declining applications based on characteristics of a relative of the applicant might be criticized in some jurisdictions as discriminatory or unduly restrictive. However, it may be a justifiable ground where there is evidence the relative will be involved in the applied for activity. Another way of considering the situation, which may attract less criticism, is that the application has failed to name all the people who should be applying for the undertaking and, therefore, the application may be declined based on a failure to provide all relevant information.

The Kenyan licensing regime enables the imposition of penalties including fines of double the amount of excise duty owed on the goods, or three times the value of the goods. The availability of penalties based on an economic formula, rather than a certain maximum level, may be an effective deterrent of unlawful conduct – especially where it involves large-scale operations undertaking high-value transactions.

The Kenyan licensing regime appears to have a novel element of not specifying an expiry date for licences. Instead of expiring after a set period of time, they appear to remain in force until revoked or suspended. Requiring licence-holders to apply for a new, or renewed, licence enables authorities to ensure information is kept current and that licence-holders are still complying with their obligations. Renewal also enables revenue to be collected, on an annual or other basis, where fees are charged on each application. These benefits would need to be weighed by the Parties against the increased administrative burden on authorities of receiving and determining applications.

2.5. Malaysia

The Royal Malaysian Customs Department (RMCD) issues licences to import tobacco, including cigarettes, for commercial purposes.18

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A licence application is submitted with a range of supporting documents, including:

- company registration
- legal right to business premises
- appointment as an importer/distributor from a manufacturer/supplier
- financial records.

There is a minimum capital requirement of Malaysian ringgit (RM) 350,000 to import white or clove cigarettes. This means applicants must provide confirmation of minimum paid-up capital of RM 350,000 in order to be issued a licence to import those types of cigarettes.

The requirement to provide the above documents, and the capital guarantee, may in some cases be a barrier to smugglers seeking to set up fraudulent companies in an attempt to gain an import licence.

Malaysia’s regulatory approach has similarities to the TTB permit regime in the United States of America (discussed in Section 2.2, above) in that financial information is considered in assessing the licence application. However, it appears the Malaysian regime may use this information to ascertain the legitimacy of an operation rather than a person’s competency in undertaking a business.

The requirement for applicants to show their appointment as a distributor or importer (by way of a letter from a manufacturer or supplier) may be a useful element in supply chain control by requiring participants to have a pre-existing relationship with another participant before being able to participate in the supply chain themselves. Such a requirement may also assist compliance with Article 7 due diligence requirements around customer identification.

2.6. Singapore

There are a number of licences across the tobacco supply chain in Singapore, including for tobacco products to be imported, wholesaled and retailed.

A person who intends to import or sell tobacco products in Singapore by retail must apply for a tobacco licence from the Health Products Regulation Group, Tobacco Regulation Branch.19

Tobacco retail licence holders in Singapore are prohibited from locating their business in health- or youth-related locations, such as hospitals, pharmacies, gaming arcades, and schools and other education institutions. Along with standard licence conditions (such as to comply with licence conditions and not be convicted of a relevant offence), licensees are required to be “mentally and physically fit” to comply with tobacco control legislation and the terms of the licence.

Singapore applies different fees to different tobacco licences. Retail licences incur a S$ 400 fee, whereas a new import/wholesale licence incurs a S$ 2,720 fee.20

Applications for an import licence must be accompanied by a letter of authorization from the manufacturer of the tobacco products to be imported. Applications for a wholesale licence require a letter of authorization

from the importer of the tobacco products to be wholesaled. This appears to be another example of a pre-
condition on market entry requiring an established relationship with an existing party in the tobacco supply
chain, and may be a useful consideration for Protocol Parties wishing to build some of the due diligence
requirements of Article 7 into the licensing regime.

Applications for import and wholesale licences require the provision of tar and nicotine testing results. No
other regime we looked at expressly includes such a requirement. However, other regimes may achieve the
same ends if they include a licence condition to comply with tobacco control legislation that requires the
provision of testing results. We also note that Articles 9 and 10 of the WHO FCTC provide for the testing,
measuring, and regulation of the contents and emissions of tobacco products.

Import/wholesale licences may be suspended or revoked, including on the grounds that the licensee is unfit
and improper to hold a licence if a medical practitioner provides certification of a disability impairing the
licensee’s cognitive abilities for the purposes of complying with the terms of the licence.

Similar to the TTB permit regime in the United States of America, Singapore requires an applicant to submit
proof of their right to use the premises to be licensed. However, unlike the United States of America,
Singapore does not appear to require the property owner to consent to the business being undertaken at that
property.

3. OTHER MODELS OF LICENSING SCHEMES FOR PRODUCTS AND
MANUFACTURING EQUIPMENT

We looked at seven models of licensing schemes applying to various goods other than tobacco-related
goods. The purpose of this review was to determine whether there were any useful regulatory approaches
that could be considered for inclusion in any “good practice” model for the licensing/approval of import,
export and manufacturing of tobacco products and tobacco manufacturing equipment.

The relevant elements of these licensing models are summarized in the sections below. Similar to the
summaries of jurisdictions’ tobacco licensing schemes in Section 2, we have not repeated all the ordinary
and usual features of each licensing scheme. Again, we have sought to provide a high-level overview of
what the scheme involves while drawing attention to features of it that we consider are examples of good
practice or might be of interest to the Parties.

3.1. The Australia Group – licensing controls on inputs for chemical and biological weapons

The Australia Group is an informal association of 42 states and the European Union that have introduced
licensing measures around the export of chemicals, precursors, equipment, and agents and organisms used
in the manufacture of chemical and biological weapons.21

The Group aims to limit proliferation of chemical and biological weapons through controlling their inputs.
It meets annually to assess how members’ national export licensing regimes can be made more effective,
exchange intelligence and coordinate export controls for relevant inputs to countries outside the Group in
order to prevent proliferation.

The Group is an example of jurisdictions working collectively to combat a global problem, which may
serve to reinforce the Protocol message that global solutions are needed. Parties to the Protocol may benefit

21 More information is available at this link: http://www.australiagroup.net/en/index.html
from collaboration in the design of licensing schemes and from continued cooperation to share good practice and identify opportunities to improve their domestic schemes.

The Group focuses on licensing measures that are effective in impeding the production of chemical and biological weapons, and that are also reasonably easy, economical and practical to implement while not impeding the legitimate trade of material and equipment for legitimate purposes. This focus of the Group’s licensing regime may have comparability to Protocol Parties needing to strike the right balance in controlling the tobacco supply chain. The elements of the Group’s focus of licensing may be useful for Protocol Parties to be cognisant of in designing their own licensing regimes.

Controlling inputs to the supply chain may be an effective additional tool for controlling the end product that is the source of harm. Some Protocol Parties may wish to consider at the right time whether to extend licensing to certain inputs into the tobacco supply chain (such as Ontario, Canada, has recently done with cigarette filter inputs, as discussed in Section 6 of this report) to further prevent illicit trade.

3.2. Authorised Economic Operator

The European Commission Authorised Economic Operator (AEO) programme was created to ensure a more secure end-to-end supply chain for goods entering or leaving the European Union (EU). AEO status is available to reliable traders, established in the EU, who are actively involved in the international supply chain, carry out customs-related activities in the EU and comply with strict security supply chain criteria.22

An AEO-accredited operator implies they are reliable in financial and customs terms and compliant in respect of security and safety standards. Such operators receive benefits in the form of simplified customs procedures. A supply chain where all parties are accredited as being secure will have a lower risk rating and, therefore, a lower possibility of customs intervention at the border.

If available, the benefit of increased ease of border transactions may incentivize tobacco businesses to go through an AEO-type certification process. The incentives of such a scheme may be a useful tool to encourage not only compliance with Protocol requirements but good practice in supply chain control. If customs authorities are able to trust accredited traders as secure and reliable, that may free up resources to focus interventions and compliance activity on other non-accredited traders at the border. Protocol Parties may wish, at the right time, to consider such a scheme as an additional feature beyond the licensing requirements of the Protocol whereby the Parties certify licensed operators in the tobacco supply chain as having met additional standards of compliance, competence and security, and their lower risk means there is less need for customs intervention. We note that the implications of Articles 5.3 of the WHO FCTC and Article 4.2 of the Protocol need careful consideration if such an approach was to be contemplated. The history of tobacco industry complicity with illicit trade in tobacco may also present a barrier or limitation for such an approach.

3.3. CTPAT

The Customs Trade Partnership Against Terrorism (CTPAT) is a voluntary public–private sector partnership programme involving the United States Customs and Border Protection (CBP) working with operators in the international supply chain:

• to protect the supply chain from the concealment of terrorist weapons
• to identify security gaps
• to implement security measures and best practices to improve United States border security.

In return, operators receive the benefit of simplified customs procedures. 23

Lessons from CTPAT include the need to approach the international supply chain in its totality and that supply chain best practices must be supported by senior management and incorporated into a business or corporate culture and core processes. Other lessons are that additional benefits can be gained by businesses from focusing on supply chain security, such as increasing efficiency from eliminating duplicated processes and gaining greater supply chain visibility. Businesses working with public authorities may benefit from better identifying security weaknesses and actions to mitigate those risks.

Similar to the AEO regime (discussed in Section 3.2), Protocol Parties may find interest in the CTPAT experience if considering an additional layer of supply chain control above the Protocol licensing requirements involving eased border transactions for businesses that are certified as demonstrating Protocol compliance and best practice supply chain security. Having such benefits available may incentivise tobacco businesses to increase their compliance and security measures, which would help efforts to prevent illicit trade in tobacco products and allow customs authorities to focus their resources on higher-risk operators. The same issues of concern/limitation expressed above for the AEO regime would also apply here however.

3.4. Precursor chemical licensing

The basis for precursor chemical control is found in the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. Article 12 of the United Nations Convention specifically requires countries to implement measures to control and monitor the legitimate trade in drug precursors as an essential way to prevent their diversion. 24

The United Kingdom of Great Britain and Northern Ireland has regulations on controlled drugs to give effect to the United Nations Convention. 25 The United Kingdom regime divides controlled precursor chemicals into three categories based on the sensitivity or risk of the substance. The categories result in different obligations on licence holders, such as the need to provide declarations from end-users (for Category 1 substances and Category 2 substances depending on the volume involved) as to the use of the substance and different licence/registration fees, which are charged on a cost-recovery basis.

The regime has a pre-export notification process whereby a proposed shipment is notified between competent authorities that decide whether to authorize it. Where authorities suspect the substance may be diverted, the import/export may be refused. This advanced warning to authorities affords additional time to consider proposed shipments and decide whether to authorize or refuse the import/export. Such a process may be of interest to Protocol Parties and could be considered as a feature of other collaborative efforts in addition to Protocol requirements, such as a regime similar to AEO and CTPAT (discussed in Sections 3.2 and 3.3 and in Section 6) whereby customs interventions are reduced for approved trusted operators. The


25 https://www.gov.uk/guidance/precursor-chemical-licensing
heavy administrative burden of administering such a regime, as well as substantive compliance costs for industry and the history of tobacco industry complicity with illicit trade in tobacco, are noted.

3.5. Controlled drugs

People in the United Kingdom of Great Britain and Northern Ireland need to apply for a Home Office Controlled Drugs Domestic Licence if they wish to produce, supply, possess, import or export controlled drugs. Controlled drugs are named in the Misuse of Drugs Regulations 2001 and grouped in schedules.26

The regime takes a hierarchical approach to licensing controlled drugs, with different requirements for different schedules of drugs. For example, travellers do not require a personal import/export licence for travelling with prescribed drugs listed in Schedule 5. However, travellers travelling for more than three months with more than three months’ supply of a Schedule 3 drug may need a personal import/export licence, while any amount of Schedule 1 drug for any length of travel will require a personal import/export licence.

The regime distinguishes between frequent and occasional exporters and has different procedures for the two. Occasional exporters (defined as less than 24 shipments in 12 months) must apply for a licence for each individual shipment. Frequent exporters (defined as 24 or more shipments in 12 months) can apply for a blanket export licence that is valid for a maximum of 12 months. Blanket export licence-holders are obligated to make a declaration for each shipment and submit a monthly return detailing the shipments.

Protocol Parties may find the differentiation in this regime of interest when considering their domestic licensing schemes. Such differentiation could respond to differing levels of harm and risk involved in an activity, such as with the schedules of different drugs in this regime). In the Protocol context, if particular types of product or machinery are easier to divert or preferred for illicit purposes, additional controls could be considered to address that problem. Differentiation in a regime may also respond to different actors in, or scale of, an activity, such as different rules for frequent and occasional exporters/importers. Protocol Parties may wish to consider having different licensing processes for frequent and occasional exporters/importers of tobacco products or machinery if there would be benefit in doing so. Such benefit might include the administrative efficiency gained by authorities not needing to determine export licence applications from a large cigarette manufacturer every month. There may also be benefit in requiring occasional traders to apply for a licence for each transaction if the operation is not stable and may involve different parties or processes which may have varying levels of compliance with the Protocol.

3.6. Alcohol retailing

As part of this review, we looked at alcohol retail licensing to see whether components could be incorporated in the discussion of best practice tobacco supply chain licensing. Though the components of a licensing scheme are similar (see Section 1.2), the difference in focus between alcohol retail licensing and tobacco supply chain licensing means there is limited benefit to reporting on alcohol retail licensing in detail here; alcohol retail licensing often focuses on harm reduction at the retailer level through controls imposed on the individual selling the products, whereas licensing under the Protocol is designed to prevent illicit tobacco from entering the supply chain. Two alcohol licensing schemes are introduced here to show the similarities between the features of any licensing regime.

26 https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns
Alcohol retail licensing is common in numerous jurisdictions. The main feature of alcohol licensing is harm reduction and normally includes a range of controls including:

- a requirement that only licensed alcohol retailers can sell alcohol;
- restrictions on who is able to apply for a licence;
- imposition of various conditions on different types of retailer depending on the perceived risk and other factors:
  - these might include features like opening and closing times, density restrictions (such as by capping the number of outlets in a specific area), or proximity restrictions (which prevent alcohol stores opening too close to sensitive sites such as schools or hospitals);
  - these conditions often (e.g. in Australia and New Zealand) include requirements that individuals have education on their legal duties when selling alcohol; and
- penalties and licensing forfeiture if conditions of the licence are breached.

These controls are consistent with the positive licensing scheme characteristics introduced in Section 1.2. The alcohol licensing schemes show the potential for tobacco supply chain licensing to have multiple classes of licensing with different restrictions depending on the risk posed to the Protocol, as well as the ability to impose stricter licence conditions on individual licence holders as long as those conditions are consistent with the wider licensing scheme. The alcohol licensing schemes introduced below also show the importance of ensuring that the process for granting or refusing licenses is robust, including a legitimate appeal process, to ensure that the licensing scheme meets its intended objective rather than being a vehicle to ban an otherwise legal activity.

**United Kingdom of Great Britain and Northern Ireland**

For example, businesses, organizations and individuals who want to sell or supply alcohol in England and Wales must have a licence or other authorization from a licensing authority, usually a local council. The following types of licence are required depending on the type of business/organization selling or supplying alcohol:

- a “premises licence” for any business or organisation that sells/supplies alcohol on a permanent basis;
- a “personal licence” for anyone who sells/supplies or authorizes the sale/supply of alcohol, (applicants must be over 18 years of age and hold an accredited licensing qualification to ensure licence holders are aware of licensing law and wider social responsibilities involved in the sale of alcohol); and
- a “club premises certificate” for qualifying members’ clubs, such as working men’s clubs and rugby clubs, which sell or supply alcohol.

Application forms and fees are sent to the local council for approval, and copies sent to the police or other responsible authorities, such authorities include the licensing authority, environmental health authority, planning authority, local trading standards, Home Office Immigration Enforcement, depending on the licence type. Licensing fees are prescribed in the Licensing Act 2003 (Fees) Regulations 2005. Fees in
relation to premises licences and club premises certificates vary depending on the rateable value band of the premises.  

*Determining an application*

The licensing authority must grant the application for an alcohol licence where an application is properly made and if no responsible authority or other person has made representations (any person or business may make representations on applications for premises licences and club premises certificates). The licence is granted subject only to conditions consistent with the operating schedule and relevant conditions in the Licensing Act 2003.

Where representations are made by a responsible authority or other person, the Licensing Authority decides whether those representations are relevant to the licensing objectives (or frivolous or vexatious) of:

- the prevention of crime and disorder
- public safety
- prevention of public nuisance
- the protection of children from harm.

If the licensing authority decides that any representations are relevant, it must hold a hearing to consider them. At the hearing, the licensing authority may:

- grant the application subject to modifying conditions that are consistent with the operating schedule in a way it considers appropriate for the promotion of the licensing objectives;
- reject one or more requested licensable activities;
- reject the application; or
- refuse to specify a person as a designated premises supervisor.

Decisions of the licensing authority can be appealed to the Magistrate’s Court.

*Mandatory conditions*

The Licensing Act 2003 (Mandatory Conditions) Order 2014:

- bans the sale of alcohol below the cost of duty plus value added tax
- bans irresponsible promotions
- provides for mandatory provision of free drinking water
- provides for adoption of an age verification policy
- sets out the mandatory provision of smaller measures (drinks available in smaller sizes).  

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27 [https://www.gov.uk/guidance/alcohol-licensing](https://www.gov.uk/guidance/alcohol-licensing)

New Zealand

In New Zealand, under the Sale and Supply of Alcohol Act 2012, territorial authorities have the power to create local alcohol policies (LAPs). The Act provides broad criteria that must be followed (such as maximum opening hours), and local councils can determine opening hours within those broad criteria and impose more or less specific restrictions according to what is appropriate in a specific area. There are three key areas that LAPs address with respect to “off-licences” (sale of alcohol in bottle stores and supermarkets):

- opening hours
- density
- proximity of off-licences to sensitive areas.

The Act sets default maximum trading hours of 08:00 to 23:00 on any day for the sale of alcohol on off-licence premises.29 Alcohol cannot be sold on Easter Friday, Easter Sunday (with some exceptions for wine), Christmas Day or before 13:00 hours on Anzac Day.30 LAPs must comply with these restrictions and may restrict opening hours further. For example, the Wellington City Council Provisional LAP would allow for the sale of alcohol for the maximum opening hours permitted in the Act. However, trading past 20:00 is subject to further conditions aimed at reducing alcohol-related violence, antisocial behaviour, and improving the amenities and good order. These restrictions involve ensuring the operation of closed-circuit television, a register of incidents that occur on the property and ensuring that litter is removed from the outside of the premises.

In other major centres, Auckland Council’s Provisional LAP restricts off-licence hours further from 09:00 to 21:00, and Christchurch’s LAP imposes maximum trading hours of 07:00 to 22:00.

Off-licence density is an issue considered by licensing inspectors. For example, under the Wellington LAP, any licence application for premises which will be next to or adjacent to a “sensitive facility” (defined as an “[e]ducational, or recreational facility or open space used by, or likely to attract, young people under the legal purchase age; community and/or health facility”)31 will be determined by way of public hearing. In Christchurch, no new off-licences are to be granted for bottle stores in residential zones as way to manage density. In Auckland there would be a temporary freeze on the issue of new off-licences for the first 24 months of the policy being in force. Following that term, there would always be a presumption against the issuing of new off-licences. There is always a presumption against issuing licences in neighbourhood centres (“commercial centres within residential areas”).32

Section 117(1) of the Act allows a District Licensing Committee (DLC) to impose further reasonable conditions so long as they are not inconsistent with the Act. For example, the Christchurch LAP allows the DLC to impose a range of discretionary conditions, which include:

- requiring additional security staff after a certain trading hour
- installation and operation of CCTV cameras

29 Sale and Supply of Alcohol Act 2012, s 43.
30 Section 48.
• effective exterior lighting.

We note that all LAPs have been challenged to the Licensing Authority.

3.7. Pharmaceutical industry licensing

As part of this review, we looked at licensing relating to pharmaceuticals, including in relation to precursor chemicals and controlled drugs as set out in Sections 3.4 and 3.5 of this report. The balance of this paper identifies and discusses key steps that require approval in the research and production process for developing a pharmaceutical. However, overall, the pharmaceutical model is of limited comparable value to licensing of the tobacco supply chain because of the experimental/research basis of pharmaceutical licensing involving a product that is not publicly available, whereas tobacco products are legal and readily available.

Licensing in the pharmaceutical industry involves two distinct aspects: 1) regulatory approval of new research/drugs; and 2) licensing arrangements among businesses for the development/marketing of new drugs.

United States Food & Drug Administration

Regulator approval of the pharmaceutical industry in the United States is the responsibility of the United States Food & Drug Administration (FDA).

Investigational New Drug Application

Federal law requires a drug to be the subject of an approved marketing application before it is transported across state boundaries. Because a drug’s sponsor will frequently want to ship the investigational drug to clinical investigators in other states, it must seek an exemption from the legal requirement to have an approved marketing application. The Investigational New Drug (IND) Application is the means by which the sponsor obtains the exemption from the FDA.

During a new drug’s preclinical development, the sponsor’s primary goal is to determine if the product is safe for initial use in humans, and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate, the sponsor collects the information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies.

FDA’s role in the development of a new drug begins when the drug’s sponsor, usually the manufacturer or potential marketer, having screened the drug for pharmacological activity and acute toxicity potential in animals, wants to test it in humans. At that point, the molecule changes in legal status under the Federal Food, Drug and Cosmetic Act and becomes a new drug subject to specific requirements of the drug regulatory system.

There are two IND categories: 1) commercial; and 2) research (non-commercial). There are three IND types:

• An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.
- **Emergency Use IND** allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND. It is also used for patients who do not meet the criteria of an existing study protocol or if an approved study protocol does not exist. and

- **Treatment IND** is submitted for experimental drugs showing promise in clinical testing for serious or life-threatening conditions while the final clinical work is conducted, and the FDA review takes place.

The IND application must contain information in three broad areas:

- **Animal Pharmacology and Toxicology Studies**: preclinical data used to assess whether the product is safe for initial testing in humans. Also included are any previous experience with the drug in humans, often foreign use.

- **Manufacturing Information**: information about the composition, manufacturer, stability and controls used for manufacturing the drug. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.

- **Clinical Protocols and Investigator Information**: detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators who oversee the administration of the experimental compound to assess whether they are qualified to fulfil their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an institutional review board and to adhere to the investigational new drug regulations.

After submitting the IND, the sponsor must wait 30 days before initiating any clinical trials. During this time, FDA reviews the IND for safety to ensure that research subjects will not be subjected to unreasonable risk.33

The IND process provides regulatory control on the use of controlled substances and allows the FDA to control the manufacturing process for new drugs.

**New Drug Application**

The regulation and control of new drugs in the United States of America is based on the New Drug Application (NDA). The NDA is the means by which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the country.

The goal of the NDA is to provide enough information for the FDA to make the following decisions:

- whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks;

- whether the proposed labelling for the drug is appropriate, and what the labelling should contain; and

- whether the manufacturing methods and controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality and purity.

The documentation required in an NDA is supposed to tell the drug’s whole story, including what happened during the clinical tests, the ingredients of the drug, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged.\textsuperscript{34}

Without approval, the NDA cannot be sold or marketed in the United States of America, meaning that the supply of the drug is controlled through the NDA approval process.

**Pharmaceutical industry licensing**

Licensing within the pharmaceutical industry appears to follow a different model from those regimes that form the remainder of those discussed in this report. It may be relevant to the licensing discussion because it illustrates how the pharmaceutical industry self-regulates its supply chain to protect its intellectual property, and how this links with the regulatory oversight of the pharmaceutical industry through the approval of potential pharmaceuticals at various stages of its development.

Generally, pharmaceutical licensing involves a contractual arrangement between two entities under which the licensor permits the licensee to make, use, sell or import the licensor’s product or property. For example, a licensing agreement may permit the licensee to use the licensor’s intellectual property, such as a brand name or patent, or other property right in exchange for licensing fees. Alongside receiving licensing fees, licensors benefit from the licensee’s market share/position, skills, capital and/or capacity.

The discovery and development of new pharmaceuticals is expensive, time-consuming and risky. Few businesses have the capability to develop products all the way from discovery of a new ingredient to delivery of an approved pharmaceutical to customers. Those businesses that do have such capability may lack the capacity to ensure provision of a smooth supply of new drugs. The high attrition of products in development and the large size of development programmes mean businesses seek to fill gaps in their development portfolios with products from companies that are proficient at drug discovery but lack the capability to bring those drugs to market.\textsuperscript{35} Further, because few drug manufacturers master new research techniques they gain access to new products through forming alliances with other businesses.\textsuperscript{36} This is where pharmaceutical licensing deals come into play.

Pharmaceutical licensing deals rarely involve a single one-off payment, but typically encompass multiple fees and royalties, and involve long-term cooperation. There is a significant component of technology transfer and often both parties are involved in research and/or development together. Licensing structures are intended to provide an allocation of the risks and rewards.\textsuperscript{37} In general, the phase of development the pharmaceutical is at will influence the price and licensing structure, which can include upfront payments, milestone payments and royalties; pharmaceuticals in early stages of development tend to cost less, but are more risky.\textsuperscript{38}

\textsuperscript{34}https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm

\textsuperscript{35}http://files.pharmadeals.net/contents/Sample_Valuation.pdf

\textsuperscript{36}https://www.researchgate.net/publication/244885066_Licensing_Agreements_in_the_Pharmaceutical_Industry

\textsuperscript{37}http://files.pharmadeals.net/contents/Sample_Valuation.pdf

\textsuperscript{38}http://www.uptakestrategies.com/wp-content/uploads/2013/06/Pharmaceutical-In-licensing-smoothing-the-path.pdf
PART C – LESSONS

4. SYNTHESIS OF GOOD PRACTICE ELEMENTS OF EFFECTIVE LICENSING SCHEMES

Section 4.1 synthesises some key lessons from the above sections on essential aspects for an effective licensing regime.

Drawing on our work reviewing a range of tobacco licensing regimes (see Section 2), other product licensing schemes (see Section 3) and previous work we have undertaken to review best practice elements of tobacco retail licensing schemes, we are able to suggest a number of more specific provisions to be included in any regulation implementing good practice licensing regimes. Section 4.2 presents some suggestions in this regard.

We note that Article 6 of the Protocol refers to the Parties providing for a “licence or equivalent approval… or control system” for specified activities in the tobacco supply chain. We emphasize that good practice involves an assessment of proportionality with the extent of, and risk of harm from, the activity to be licensed (or approved).

Some jurisdictions may be able to use existing controls as an “equivalent approval” to a bespoke licensing scheme, for example, customs controls and approvals. The appropriateness of such an approach, or what would amount to good practice, will depend on the circumstances of jurisdictions, both in terms of their existing regulatory environment and in terms of the scale of their tobacco industry. For instance, a jurisdiction where there is only one (or no) manufacturer or importer of manufacturing equipment and that enjoys strong customs controls may reach a different conclusion on what constitutes good practice as compared to another jurisdiction with several manufacturers and/or importers of manufacturing equipment and porous land borders.

4.1. Core aspects of an effective licensing scheme

The following features emerged from our review of licensing models in Sections 2 and 3 as essential to an effective licensing scheme. In addition to the mandatory provisions set out in Article 6 of the Protocol, we consider licensing schemes should:

• employ a positive licensing model (that is, people should be excluded from the regulated activity unless duly licensed);
• ensure that applications for licences contain sufficient information to establish the identity and character of the applicant(s) (including criminal records, relevant offences may include those against tobacco control, tax and customs laws, as well as fraud and dishonesty) and the nature of the activity they propose to undertake;
• exclude people from holding a licence based on previous relevant offences or non-compliance with the licensing scheme;
• ensure that application processes for licences not require the provision of extraneous or excessive information that would impose administrative burdens on authorities to process and verify (and on businesses to comply with);
• set fees for licences at a level to recover the costs of administering and enforcing the scheme;
• provide for an annual expiry date to apply to all licences and licensees should be required to apply for a renewal/new licence to continue undertaking the activity, and provide for licences being subject to review at any time;
• identify/licence an identified person to undertake a specified activity at identified premises (i.e. a “responsible” person needs to be identified);
• require corporates to provide details of a responsible natural person who would be liable in addition to the corporation for any breach undertaken in the course of the licensed activity;
• be considered in light of, and be consistent with, the existing regulatory environment in a jurisdiction (for example, not duplicate already existing licensing or registration requirements under other regulatory regimes);
• impose record-keeping and reporting requirements on licensees (including details of all transactions and identity of people transacted with);
• impose restrictions on whom licensees may transact with (e.g. only transact with other licensed operators in the supply chain – an example of this restriction might be a requirement that manufacturers of tobacco product manufacturing equipment only provide such equipment to licensed tobacco manufacturers);
• consider imposing restrictions on the location of licensed activities and requiring an applicant to be appointed by another operator in the supply chain to enter into transactions (for example, a letter by a manufacturer appointing an applicant as an importer of the manufactured products);
• provide for inspection of the licensee’s products and premises by authorities; and
• provide for enforcement of the licensing scheme and a hierarchy of penalties for breaches, including the suspension and cancellation of licences and prosecution for serious or repeated offences.

4.2. Implementation features of an effective licensing scheme

The detailed implementation aspects of Article 6 requirements as well as the features identified in Section 4.1 above are discussed in this section.

4.2.1. Application process

Applications for a licence are typically required to be:
• in writing;
• in a prescribed form;
• made by an applicant that is a registered company or other entity, or a person over 18 years of age;
• accompanied by the prescribed fee (generally set to cover the cost of administering and enforcing the licence scheme);
• determined within a set time limit (for example, 14 days); and
• accompanied by information/evidence in supporting documents.

4.2.2. Information

The Protocol sets out information requirements for licence applications in Article 6(3)(b). Information typically required to be submitted in licence applications by licensing regimes we researched include:
• the identity of the business and the people responsible for the activity applied for;
• the details of the premises where the undertaking is proposed to take place;
• a description of the products/machinery to be dealt in;
• a letter of appointment by another party in the supply chain (e.g. a manufacturer, importer, exporter, distributor or wholesaler appointing the applicant as an importer, exporter, distributor, wholesaler or retailer);
• background and character information of the applicant (e.g. criminal records and financial standing); and
• financial and banking information about the applicant to ensure they are a viable, legitimate business.

4.2.3. **Scope and categories of licence**
Licences authorize the named licence holder to undertake a specific activity generally at a location specified in the licence for a specific period of time, such as:
• manufacture a type or class of goods; or
• import a type or class of goods; or
• export a type or class of goods;
  - for an individual transaction or
  - for an open number of transactions, for a limited period of time.
Such specificity means people other than those named in the licence cannot undertake the licensed activity at the licensed location. It also means licensed people are prohibited from undertaking the licensed activity at other premises.

4.2.4. **Fees**
Fees are typically set at a level to cover the cost of administering and enforcing the licensing scheme. Such costs involve:
• the processing paperwork and undertaking background checks and verifying details contained in an application;
• enforcement of conditions and inspections; and
• provision of information and education on the scheme and how participants can comply.

4.2.5. **Licence conditions and obligations**
Conditions and obligations are typically imposed on licence holders, such as:
• the licence being non-transferable;
• the licence holder and staff complying with all applicable laws (for example, around tobacco control, customs and border control laws, and tax);
• record-keeping and reporting requirements;
• making premises and records available for inspection; and
• additional conditions on a case-by-case basis as determined by the issuing authority.

4.2.6. **Authorities**
Licensing regimes generally rely on two types of authorities (agencies) that have responsibility for aspects of the regime. These are for:
• administration of the licensing regime (often agencies with responsibilities for customs, revenue, business, health or internal affairs); and
• appeals (properly to an authority other than the one that makes the initial licensing decision, and generally to a tribunal in the first instance and then to a court).

4.2.7. Decision-making process

The Authority should have a set period of time (for example 14 days) for considering the application and making a decision to issue or decline a licence, or to seek further information from the applicant. Criteria for deciding whether to issue a licence can include:

• the provision of all relevant required information;
• that the applicant is over the age of 18 years (if a natural person);
• ensuring the applicant is a duly registered corporation with a responsible natural person identified; and
• ensuring the applicant meets good character standards, such as not being convicted of any relevant offences (relevant offences are normally those against tobacco control laws, and customs, tax, dishonesty and fraud offences).

4.2.8. Issue of a licence

Licences are issued by an authority where applicants meet the licence criteria and are provided by way of a certificate or registration stating:

• the name of the licensed business (and sometimes the natural person responsible for the business) or licensed natural person;
• the activity and/or premises licensed;
• the expiry date of the licence;
• any conditions on the licence; and
• contact details for the authority.

4.2.9. Grounds for refusal/suspension/cancellation

Good practice licencing should include explicit grounds for an authority to refuse, suspend or cancel a licence. These might include where the applicant/licence holder:

• has not provided required information, or has made a false statement or given misleading information;
• does not comply with the criteria for a licence;
• has breached the terms/conditions of the licence;
• has committed a relevant offence (typically related to the licensing scheme, tobacco control, customs/border control, tax or fraud) that renders them not suitable to hold such a licence;
• does not understand the licence obligations;
• has failed to comply with record-keeping and/or reporting requirements;
• has failed to notify the authority of a change in name, address, location or products/machinery involved in the licensed activity; and
• is bankrupt or insolvent or in liquidation or receivership.
4.2.10. Appeal process

Positive licensing schemes should make provision for an appeal process allowing for:

- an applicant or licence holder to appeal a decision of an authority;
- a time period for notice of an appeal to be lodged following the decision being appealed (for example, 14 days); and
- notice of appeal to be made in writing and in a standard form.

4.2.11. Offences and penalties

In order to effectively enforce positive licensing schemes, good practice licensing schemes should include, at a minimum, offences such as:

- an offence to undertake a specified activity without a licence; and
- an offence to continue a specified activity where a licence is suspended or cancelled.

A hierarchy of penalties for offences and breaches of licence terms/conditions include:

- warnings;
- administrative penalties;
- suspension, cancellation or disqualification from holding a licence;
- civil proceedings which result in fines (either based on an economic formula, such as a multiple of the value of the goods or tax at issue, or a specific amount); and
- criminal proceedings that result in fines and/or imprisonment.

5. BEYOND PROTOCOL LICENSING REQUIREMENTS

There are measures the Parties may be able to take to increase the effectiveness of their control of the tobacco supply chain beyond the minimum mandatory licensing requirements of the Protocol. Such measures can be based on examples and models reported on in this paper, such as:

- the licensing of inputs into the supply chain, as envisaged by Article 6(5) of the Protocol and recently applied in Ontario, Canada (discussed below in Section 5.1);
- increased international cooperation, such as the Australia Group has done to combat the diversion of inputs from the international chemical industry trade to chemical weapons programmes (discussed above in Section 3.1 and further below in Section 5.2); and
- an accreditation scheme for secure and reliable operators in the supply chain that have demonstrated high levels of compliance, such as the AEO and CTPAT schemes (discussed above in Sections 3.2 and 3.3, and below in Section 5.3).

5.1. Licensing inputs

Article 6 of the Protocol obligates the Parties to have a licensing regime in place to control part of the tobacco supply chain. Article 6 also requires that five years after the Protocol enters into force, the MOP will ensure that research is undertaken to identify and control key inputs in the tobacco supply chain. Therefore, Parties may wish to be mindful about potential further controls on the supply chain.

Some jurisdictions may already be considering controls on inputs. A recent example is Ontario, Canada, which in January 2018 adopted a new regulation on cigarette filter components, thus restricting inputs into
the supply chain. The regulation provides better control over the chemical acetate tow, as well as polypropylene tow, which is an integral ingredient in the manufacture of cigarette filters, as part of efforts to respond to unlicensed factories.\textsuperscript{39} The control comes in the form of restricting the import and possession of cigarette filter components to registered manufacturers in accordance with the regulation. The Ontario Government believes this regulation will help reduce untaxed and unregulated tobacco products in Ontario that undermines health and fiscal objectives.\textsuperscript{40}

In implementing and administering domestic licensing regimes, Protocol Parties may find benefit in keeping a “watching brief” on inputs into the tobacco supply chain which, if brought into a licensing scheme or otherwise controlled, could further strengthen supply chain controls and help efforts to eliminate illicit trade.

The licensing of inputs into the tobacco supply chain could take the form of jurisdictions restricting the import, manufacture, or possession of specified inputs into the tobacco supply chain to parties who are already licensed operators in the tobacco supply chain. Restricting the ability of non-licensed operators to access key inputs needed to manufacture tobacco products would bolster effective supply chain control and further restrict illicit manufacture as non-licensed operators will have greater difficulty obtaining the necessary ingredients. Further, jurisdictions will be able to take enforcement action against unlicensed parties in possession of specified ingredients (or attempting to possess such ingredients) without needing to show the party is, or intends to be, engaged in the manufacture or trade of tobacco products without a licence.

Inputs which Parties may wish to consider for licensing include:

- components necessary for the manufacture of cigarette filters, such as the chemical acetate tow (discussed more in Section 6 below);
- cigarette paper;
- tobacco;
- machinery for preparing or making up tobacco (including cigarette making machines); and
- other components and ingredients that are essential to manufacturing tobacco products.

### 5.2. Increased international cooperation

As seen in the experience of other licensing models for goods other than tobacco, such as the Australia Group, AEO and CTPAT, there is scope for Protocol Parties to bolster international collaboration to combat illicit trade. Such efforts could take the form of, in the example of the Australia Group, increased international cooperation to improve and enhance the consistency of licensing regimes and the placement of controls on the tobacco trade with non-member jurisdictions. Such international cooperation could involve the Parties meeting regularly, perhaps through the planned MOP session, for the purposes of:

- sharing good practices in developing and implementing licensing regimes;

\textsuperscript{39} Ontario Regulation 585/17 under the Tobacco Tax Act – the Cigarette Filter Components Regulation – which came into force on January 1 2018: \url{https://www.ontario.ca/laws/regulation/r17585}.

\textsuperscript{40} \url{https://news.ontario.ca/opo/en/2017/12/regulation-and-fee-changes-coming-into-force-january-1-2018.html}
• sharing intelligence on illicit trade and initiatives to prevent it; and
• collaborating to control exports of tobacco products and manufacturing equipment to jurisdictions which are not Parties to the Protocol.

5.3. Accreditation scheme

Other efforts along the lines of the AEO and CTPAT programmes could involve Protocol Parties working together to develop and implement an accreditation scheme for secure and reliable operators in the tobacco supply chain who have demonstrated secure processes and high levels of compliance and good practice. Such operators could receive the benefit of simplified customs procedures in return for maintaining higher standards of security. Effective implementation of such a scheme may incentivize other operators to improve their operations and achieve the same high standards, and may also enable authorities to devote more of their resources and intervention activities to other non-accredited and higher-risk operators. Such a scheme could involve authorities:

• monitoring and/or or requiring operators in the supply chain to identify security gaps in the supply chain and ensure implementation of measures to improve processes to prevent diversion of tobacco products to the illicit market;
• certifying that operators in a supply chain are compliant with Protocol requirements, have robust security and safety standards, and are reliable in financial and customs terms; and
• providing benefits to accredited operators in the form of simplified customs procedures.

5.4. State monopoly

Another option for controlling the tobacco supply chain beyond the mandatory licensing requirements of the Protocol is the use of state monopolies on the manufacture or retail sale of tobacco. One example of such a measure is the system for retailing tobacco in France.

In France, the retail sale of manufactured tobacco is entrusted by the state to tobacconists qualified as “administrative agents” and bound by a management contract. The legal basis of this scheme is the General Tax Code (Article 568).41

The French system is a state monopoly granting the right to sell tobacco, whereby people apply to be tobacconists and receive the delegated right to exclusively sell tobacco by retail for a specified period in a specific area. It has a strong focus on the retailer proving they are a fit and proper person. A licensee may not operate more than one outlet and must be the owner of all assets (tangible and intangible) of the business attached to the “debit of tobacco”. Additionally, the legal form of the business must be a sole proprietorship or a partnership.

The delegated right is governed by a management contract that runs for three years and sets out obligations for the retailer and the community purpose conditions entrusted to the retailer by the State (none of which are health related). The manager of the tobacco business, the deputy and the partners in the partnership operating the business must undergo initial professional training before signing the management contract.

41 Note: the information in this section was translated from the French so may contain issues of interpretation and accuracy.
contract. In addition, the tobacconist is required to attend a continuing vocational training session every three year within six months prior to the renewal of the management contract. The money received by French retailers from selling tobacco is the “approved rebate” that is set at a standard level nationally. The right to retail tobacco may be terminated or not renewed if the obligations in the management contract are not complied with.

Commentary on French retail regime’s contribution to good practice licensing

The French retail licencing model appears to have similarities with other positive licencing schemes, in that prior approval is required to participate in the regulated activity, a licence holder has to meet certain criteria, and obligations and conditions are imposed on the grant of a licence.

However, there is an additional element of the model, as it is a state monopoly with delegated rights. This feature limits the amount of money retailers can make from selling tobacco, although, in practice it may not be much different to regulations imposing minimum prices and/or taxes in other regimes. This model also limits a licensee to one outlet and requires the licensee to personally operate the flow of tobacco, which may again reduce the attractiveness of participating in the regulated activity.

However, short of making the sale of tobacco a state monopoly, we acknowledge that other positive licensing schemes could achieve similar aims by imposing similar limits through conditions on the grant of a licence or as a criterion for its grant. For example, where authorities consider such restriction warranted, the criteria for or conditions on the grant of a licence could restrict its application to one location and provide that a licensee may only hold one licence. The French retail model also raises an issue that Protocol Parties may wish to contemplate if considering designing and implementing a licensing scheme under the Protocol that employs a state monopoly system, that issue being that a State monopoly licensing system is being used to accommodate the sale of a product harmful to health.

6. DISCUSSION

The Protocol mandates a licensing scheme or system of equivalent approval for certain aspects of the tobacco supply chain, and it sets out certain elements required for that licensing scheme to be effective. That prescription – coupled with examples of tobacco-related positive licensing schemes from various jurisdictions and the examples of other licensing models, as set out in this paper – should assist Protocol Parties in considering, designing and implementing their licensing schemes under Article 6.

There is a spectrum of licensing schemes that range from light-touch registration of businesses and operators at one end to a positive licensing model at the other that requires would-be operators to apply for a licence and demonstrate compliance with eligibility criteria in order to gain market entry.

42 http://www.douane.gouv.fr/articles/a10942-formation-pour-la-vente-au-detail-des-tabacs-manufactures

43 http://www.douane.gouv.fr/articles/a11975-monopole-de-la-vente-au-detail-des-tabacs-manufactures-les-textes-en-vigueur

44 http://www.douane.gouv.fr/articles/a10950-principales-obligations-du-debitant-de-tabac
And: http://www.douane.gouv.fr/articles/a10934-conditions-pour-devenir-debitant-de-tabac
The more stringent and complex a licensing scheme is to comply with for businesses, the more complicated administering that system is likely to be for regulators. Striking the right balance is something Protocol Parties may wish to consider when designing licensing regimes under Article 6 of the Protocol, given the varying levels of resources they have available and the varying levels of trade in tobacco in different jurisdictions.

We consider the benefits of implementing a licensing scheme for parties in the tobacco supply chain as including:

- consistency of the message that dealing in tobacco – a dangerous product – is not an automatic right but something that may only be carried on subject to strict regulatory controls;
- a more adaptive approach to future tobacco control strategies;
- enabling enforcement agencies to focus education and information efforts on supply chain operators through the licence application process and through the development of a comprehensive list of all tobacco-related operators;
- a less costly enforcement mechanism, affording administrative enforcement options such as the imposition of conditions on licenses or the suspension or cancellation of licences, rather than legal action through the courts;
- placing extra emphasis on legal responsibilities of those wishing to participate in the tobacco trade, and through enforcement of offences of undertaking activities without a licence, providing a mechanism for deterring and ultimately removing unscrupulous operators from the market; and
- providing for participants to cover some or all of the costs of authorities monitoring and enforcing compliance with the regime.

We have identified some key features of positive licensing schemes through our research of jurisdictions with tobacco-related licensing schemes and the academic work of Hana Ross. Protocol Parties may wish to have these features in mind when assessing and designing their licensing regimes. The key features are those matters listed in Section 4 of this report as core aspects of an effective licensing scheme, as well as the following:

- ensuring regulatory scheme implementation is low cost, without undue administrative burden;
- ensuring that the regulator considers other compatible control measures as the regulatory scheme is designed and implemented;
- considering how the licensing regime will link with existing and future requirements for products to bear stamps/markings, and link with impending track and trace regimes;
- considering the hierarchy of offences and penalties available, and considering the use an economic formula for fines to be imposed at a level proportionate to the size of the business/transaction/breach, noting that some jurisdictions will have difficulties with indeterminate penalties due to the norms of their criminal law; and
- providing for the secure disposal of manufacturing equipment, which will prevent the equipment being able to be used to manufacture illicit tobacco products.

It is likely that the given elements of any licensing scheme will depend on the domestic context. For instance, jurisdictions that have a number of manufacturers of tobacco products and/or machinery and that have land borders (or a devolved or federal system) and a sizable level of trade in such goods, will likely

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come to a different conclusion on which licensing elements are fit for their purposes when compared to a jurisdiction which is an island nation where there is only one (or no) manufacturer.

Further, any licensing regime developed with regard to Article 6 will benefit from compatibility with the existing regulatory environment in a jurisdiction. As seen in the consultation in the United Kingdom of Great Britain and Northern Ireland on this point, some governments may conclude that they cannot justify the costs of an additional bespoke (or good practice) licensing scheme where the domestic industry or problem is small and existing controls, such as a registration scheme or general requirement for businesses to be licensed and/or strong border and excise controls, are perceived to be effective at responding to the extent of the problem, thus resulting in the conclusion that their public resources are better spent on other priorities.

In addition to the issue of the Parties considering how they will implement the Protocol licensing requirements, there are three related aspects that will need further consideration – or warrant further consideration in more effectively controlling the tobacco supply chain. These additional aspects are:

- licencing, or otherwise controlling), inputs into the supply chain, as anticipated by the Protocol and recently experimented with in Ontario through licensing a key input in the manufacture of cigarette filters;
- formal frameworks for international cooperation by the Parties to give rise to best practice licensing and consistent border controls, such as the Australia Group has achieved with regard to chemical and biological weapons precursors; and
- an accredited secure trader system, such as AEO and CTPAT, for accrediting trusted operators who have demonstrated high levels of compliance with exacting standards and therefore require less intervention by authorities and can gain easier passage of their goods through borders. Such accreditation would be designed to incentivize higher standards of compliance and best practices among supply chain participants, and enable customs authorities to focus their efforts on higher-risk operators and transactions.