Reports

This Appendix provides a practical guide to the transparency mechanisms established under the TRIPS Agreement concerning how countries choose to implement provisions of the Agreement. These mechanisms help the TRIPS Council to monitor the operation of the Agreement and to promote understanding of members' intellectual property (IP) policies and legal systems. This Appendix focuses only on the practical use of these mechanisms: the relevant modules of this guide should be consulted for their full background and context.

The transparency mechanisms fall into several categories:

- Formal notifications expressly required in the terms of the Agreement itself
- A checklist of members' IP enforcement measures to supplement these notifications
- Reviews of notified national IP legislation
- Questionnaires on national practices as part of the Agreement's built-in review agenda
-

- their intent to make use of certain possibilities under the Agreement relating to their substantive obligations, specifically concerning modifications to the criteria of eligibility for protection (Articles 1.3, 3.1) and exceptions to MFN treatment (Article 4(d)); and
- information concerning the use of public health flexibilities introduced by the 2017 amendment to the Agreement.

Members' IP laws, once notified, are reviewed by members in the TRIPS Council, yielding an extensive record of questions and answers.

There is also provision for notification of state emblems to be notified under Article 6*ter* of the Paris Convention, in cooperation with WIPO.

Since domestic judicial, administrative and border control measures to enforce IP rights are often not contained in IP legislation as such, the TRIPS Council agreed on a checklist to enable members to notify elements of their enforcement systems that are relevant to their obligations under Part III of the TRIPS Agreement.

Section C below sets out the details of these notification requirements.

Built-in reviews

The Agreement requires specific review processes in the TRIPS Council regarding geographical indications under Article 24.2 (see Module IV) and biotech patenting and plant variety protection under Article 27.3(b) (see Module V). To progress these reviews, the TRIPS Council established specific subject-matter questionnaires which have enabled members to report in detail on their domestic laws in these areas.

Section E below sets out details of the material provided under these reviews.

Reports

The TRIPS Council has agreed on specific processes for developed country members to report on their technology transfer measures under Article 66.2, and on their technical assistance programs under Article 67.

Section D below sets out details of the material provided through these reporting procedures.

Contact points

In addition to the enforcement contact points established under Article 69, the TRIPS Council agreed on the establishment of contact points to facilitate coordination of technical assistance under Article 67.

Section D.3 below sets out details of the information members typically provide.

How members provide this material

The different categories of transparency material – notifications, reports, contributions to review processes – are provided to the WTO Secretariat by representatives of WTO member governments. In practice, they can provide them through various channels but increasingly use the tailored online e-TRIPS Submission System (illustrated in Figure A1.1). As this platform is a means for WTO members to fulfil their formal legal obligations to notify material to the TRIPS Council, it is only accessible by member governments, unlike the notified material itself, which is publicly available (see section B below). The Secretariat's role is simply to compile and disseminate the material provided by member governments.

Figure A1.1 Screenshot of the e-

B Accessing and using transparency materials

Since 1996, these transparency requirements have yielded a useful collection, much of it unique,

and regulations dedicated to IP, such as laws on border enforcement of IP rights.

- These legal texts must be notified in one of the WTO's working languages (English, French or Spanish). Where an authentic national text of a main dedicated law or regulation is not available in one of these languages, copies of the authentic text of that law or regulation in a national language must also be notified, in addition to the translation into a WTO language.

x 'other laws and regulations' include all national laws and regulations which are not dedicated to IP rights as such but which nonetheless pertain to the availability, scope, acquisition, enforcement and prevention of abuse of intellectual property rights (notably laws and regulations in the areas of enforcement and the prevention of abusive practices) as well as those laws and regulations dedicated to intellectual property which are not considered 'main laws and regulations'.

- These legal texts can be notified in a member's national language, although members increasingly choose to provide them in translation as well.

- the text of the law itself which is now accessible via a stable and permanent URL, provided in the notification document and in the e-TRIPS Gateway.[2]

Figure A1.4 is an example of a document illustrating how the metadata and the hyperlink to the text of the law are circulated. These are readily available public documents. Figure A1.5 is a screenshot of the record of the same law as available on the online e-TRIPS Gateway.

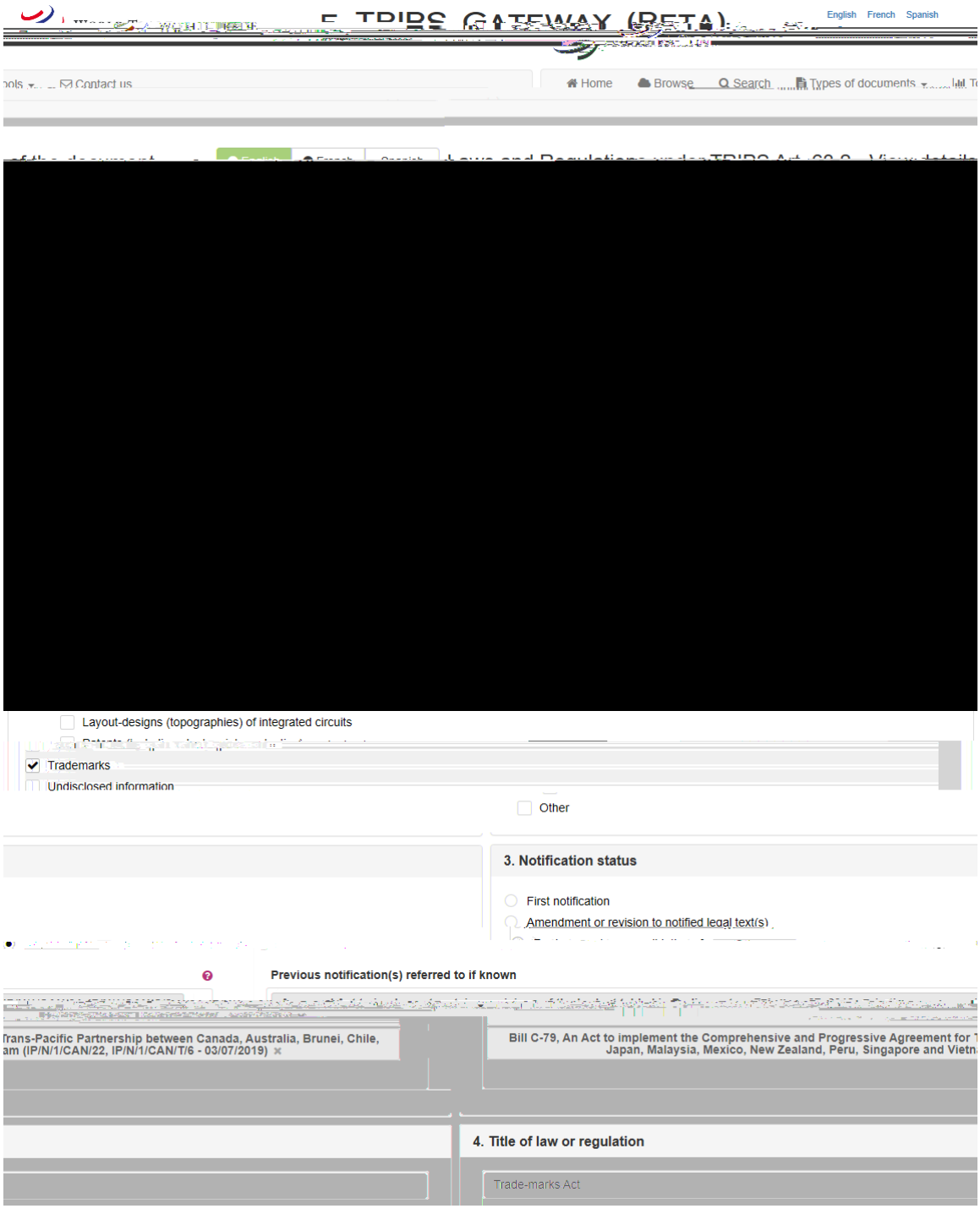
[2] The actual text of the laws was also included in WTO documents in the IP/N/1/- series until the current updated system for access was established in 2015. These legal texts are now also available on the e-TRIPS Gateway at e-trips.wto.org.

Language(s) of notified legal text	English, French
[redacted]	[redacted]
Other information	IP/N/1/CAN/T/7 (Bill C-86) amends the Trade-marks Act Bill C-86 (see subsection B of Division 7 of Part 4): Trade-marks Act (as amended):

and regulations notified under the TRIPS Agreement in the form

* Links are provided to texts of laws

Figure A1.5 Screenshot of the e-TRIPS Gateway database record of the same notification illustrated in Figure A1.4



(c) When are laws notified?

Once a member is obliged to apply a provision of the TRIPS Agreement, the corresponding laws and regulations must be notified without delay (normally within 30 days, except where otherwise provided by the TRIPS Council) (IP/C/2). Of the original members of the WTO (those which were already members when the WTO was created in 1995), developed country members had to make their initial notification of their TRIPS legislation at the end of their transition period in 1996, and developing country members when their transition period concluded in 2000. Newly-acceded members are to notify their TRIPS implementing legislation as of the time they are to start to apply the provisions of the Agreement in accordance with their accession protocol (in the course of acceding, a member will have already provided detailed information about its IP laws and regulations, so this typically facilitates the preparation of formal TRIPS notifications).

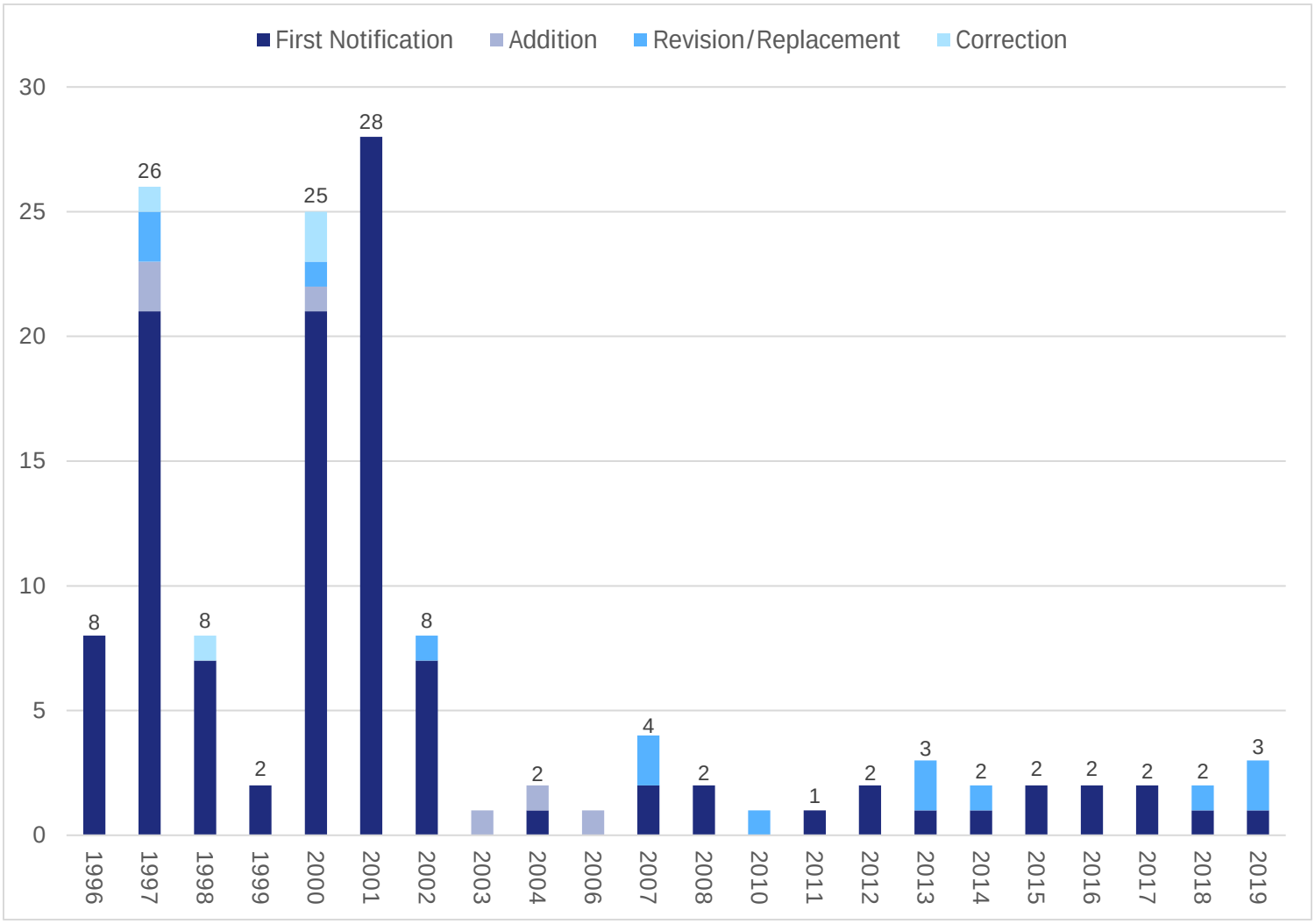
Any subsequent amendments of a member's laws and regulations must be notified without delay after their entry into force (normally within 30 days where no translation is required and within 60 days where translation is necessary).

The graph in Figure A1.6 illustrates the rate and composition of laws notified between 1995 and 2019. There is an initial spike in activity in 1996, as developed country members made their first notifications. Then, in 2000 and following years developing countries made their initial notifications. Acceding members contributed over this period depending on their date of accession. Since the mid-2000s, notifications have increasingly included updates, revisions and amendments of existing laws, as members comply with their obligation to notify ongoing developments.

Figure A1.6 Rate and composition of IP laws and regulations notified pursuant to Article 63.2, March 1995-December 2019

Figure A1.7 illustrates the pattern of notifications using the enforcement Checklist. It shows an initial spike in initial notifications by developed country members from 1996 to 1997, and by developing country members from 2000 to 2002; the pattern since then comprises initial notifications by acceding members and, inW*n1Cma2 792 t9tly,3a8 Tm

Figure A1.7 Notifications of the 'Checklist of Issues on Enforcement', 1996-2019



3 Review of national laws implementing TRIPS

information to be notified promptly. Members' notifications of contact points have generally provided the types of information presented in Table A1.2 below.

Table A1.2 Information generally provided when notifying a contact point under Article 69

Information type	Suggestion
Subject matter	For some members, the enforcement contact point differs depending on the type of IP, so there is scope to notify distinct contact points accordingly.
Competent administration	Generally the name of the responsible authority is provided – which may be the industrial property office, the copyright office, the ministry responsible for the legal system or specific authorities such as customs or police.
Job title	Specific contact points may be identified by their position, such as director of the relevant department.
Name	In some cases, individual officials' names are provided, and thus need to be updated as often as individuals move into new positions.

notifications

that it will avail itself of the faculty provided in Article II and/or Article III of the Appendix (compulsory licences for, respectively, translations and reproductions) by means of a notification. According to paragraph 2 such declarations can be made for renewable periods of ten years. Such a declaration may be renewed by means of another notification.[4] Paragraph 5 deals with the possibility for a country to make notifications in respect of territories for which it has international responsibility.

ii. **Article II(3)(b) of the Appendix** deals with the situation where a developing country member secures the agreement of all developed members, in which the same language is in general use as in that developing country member, to provide for a shorter period than the usual three years after publication for the application of compulsory licences to substitute for the exclusive right of translation. The provision requires such agreements to be notified.

iii. **Article IV(2) of the Appendix** deals with the situation where an applicant for a compulsory licence of the types provided for in Articles II and III cannot find the owner of the right in question. In such a situation, he or she must send a copy of the application to any national or international information centre which may have been designated by the member in which the publisher of the work concerned is believed to have his principal place of business. The paragraph provides that such information centres must be designated in a notification by the member concerned.

iv. **Article IV(4)(c)(iv) of the Appendix** allows developing country members to export copies of translations made under compulsory licence, provided that a number

V.

Table A1.3 Notifications associated with the special compulsory licensing system

Notification type	TRIPS provision	2003 Decision
(1) Importing member's one-off general notification of intention to use the system (not required for LDC members)	Annex, para 1(b)	para 1(b)
(2) Importing member's specific notification of the pharmaceutical products needed	Annex, para 2(a)	para 2(a)
(3) Exporting member's notification of a compulsory licence for export	Annex, para 2(c)	para 2(c)

Notification 1: importing member's one-off general notification of intention to use the system (not required for LDC members)

This one-off notification confirms in general that a member intends to use the special compulsory licensing system as an importer. LDC members are automatically entitled to import medicines under the special compulsory licensing system. Other developing countries need to file one simple notification indicating that they wish to use the system. Developed country members are excluded from using the system as importers. Suggested contents for this notification appear in the Table A1.4 below.

Table A1.4 Suggested contents for importing member's one-off general notification of intention to use the system (not required for LDC members)

[redacted]

Th73(hstes)l5951e4-3(ordn)l/ETwsVl0501t318.65 326.29 24.46 TmeW*n /P /F1 11.04 Tf1 0 0 1 294.483.91.002405.0 Gl[(T)-4(ov)-7

Information type	Suggestion
Optional information	

Table A1.5 Suggested contents for importing member's specific notification of the pharmaceutical products needed

Information type	Suggestion
List of product(s) and quantities needed	The names and expected quantities of the pharmaceutical product or products needed. The expected quantity can, for example, be a number of doses or packs (e.g. '5 million doses of medicine X'). There is no need to state the name of a supplier, nor the expected timeframe of supply and use.
Determination of no or insufficient manufacturing capacities in the pharmaceutical sector	LDCs are assumed to lack sufficient manufacturing capacity and do not need to state anything about it. Other importing members must confirm that they have established that they have insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question, following the approach set out in the Appendix to the amended TRIPS Agreement.
Information on how the lack of (sufficient) manufacturing capacity in the pharmaceutical sector was established	The Chairman's statement read out when the Protocol Amending the TRIPS Agreement was adopted mentioned that it was understood that notifications would include information on how the member had established this point (WT/GC/M/100, paragraph 29).
Is/are the product(s) needed protected by patent in the territory?	Where there is no patent for the pharmaceutical product(s) in the importing member, no mention is needed. The member may, however, choose to mention the absence of any patent.
If patent(s) in force, status of compulsory licensing	Where there is a patent for the product(s) in the importing member, the notification must advise whether a compulsory licence has been granted or is planned. Alternatively, LDCs may simply refer to their transitional period, which was last extended until 1 January 2033.
Authorized government official	Name and official position of the authorized government official submitting the notification. Notifications can be submitted by any authorized government official.

Notification 3: exporting member's notification of a compulsory licence for export

This is the exporting member's notification of the grant of a compulsory licence for export, including the conditions attached to it, as required under the special compulsory licensing system. Any member that exports under the special compulsory licensing system must make this notification for every compulsory licence that it issues under the special compulsory licensing system prior to export. A notification is not required to export pharmaceutical products under the regional mechanism (see paragraph 3 of Article 31bis of the amended TRIPS Agreement/paragraph 6 of the 2003 Decision). If the medicines to be exported form part of production under a compulsory licence that is issued predominantly for the supply of the domestic market, then there is no need to use the special compulsory licensing system at all, and consequently no notification is needed.

Suggested contents for this notification appear in Table A1.6 below.

Table A1.6 Suggested contents for exporting member's notification of a compulsory licence for export

Information type	Suggestion
Licensee information	The notification must include the name and address of the licensee.
Details of the product(s) for export	The notification must include: i. the product for which the licence has been provided ii. quantity(ies) for which the licence(s) has been granted iii. country(ies) where the product(s) is/are to be supplied iv. duration of the licence(s) v. website address where information on quantities being supplied to an importing country(ies) and distinguishing features of the product are posted.[6]
Other optional details	i. Any other licence conditions

any time prior to its first concrete use of the special compulsory licensing system as an importer, or at the same time as it first notifies specific needs under the system (see Notification 2). No notification is needed to import pharmaceutical products from another member party to a regional trade agreement under the regional mechanism (see paragraph 3 of Article 31*bis* of the amended TRIPS Agreement/paragraph 6 of the 2003 Decision).

Notification 2 - Importing member's specific notification of the pharmaceutical products needed: A member could make this notification when it wishes to signal concrete needs; for example, as part of the member's medicines procurement process. Ultimately, there would be no obligation to procure medicines under the special compulsory licensing system.

Notification 3 - Exporting member's notification of a compulsory licence for export: Any member that exports under the special compulsory licensing system must make this notification for every compulsory licence that it issues under the system prior to export.

While no specific format has been agreed, and practice varies somewhat in the actual reports submitted since establishment of this mechanism, members have generally provided the types of information presented in Table A1.7 below.

Table A1.7 Types of information generally provided in reports on incentives for technology transfer to LDC members (Article 66.2)

Information type	Suggestion
Introduction	A brief description of the general approach to providing incentives for technology transfer under Article 66.2.
Programme or project	Details of specific programme or project, such as the entity making the incentive available, the category of technology and the duration or timing.
Objective or purpose	The goal of the programme or project.
Entity making the incentive available	The government entity, or entities, in the developed country member providing the incentive.
Eligible enterprises or institutions in developed country member	Enterprises or institutions in the territory of the developed country member which are eligible for the incentive. This could be, for example, a description of the types of enterprises or institutions that are eligible for the incentive.
Beneficiary member(s) or observer(s)	The WTO member(s) or observer(s) targeted by the programme or project.
Beneficiary enterprises or institutions	The transferee enterprises or institutions, for example.
Nature of incentive measures	Identification of the type of incentive.
Financial implications	The budget of the programme or project, for example.
Field of technology	Description of the relevant sector.

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responses. Document IP/C/W/273/Rev.1 is the most recent version of the summary (available on the WTO Documents Online database).