

Moïsé, E. (2011), "Transparency Mechanisms and Non-Tariff Measures: Case Studies", *OECD Trade Policy Papers*, No. 111, OECD Publishing, Paris.  
<http://dx.doi.org/10.1787/5kgf0rzzwfq3-en>



## OECD Trade Policy Papers No. 111

# Transparency Mechanisms and Non-Tariff Measures

### CASE STUDIES

Evdokia Moïsé

JEL Classification: F13, F14, H83, L51

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This document has been declassified under the responsibility of the Working Party of the Trade Committee under the OECD reference number TAD/TC/WP(2010)4/FINAL.

This study has been prepared with financing from the government of Japan.

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## **Abstract**

### **TRANSPARENCY MECHANISMS AND NON-TARIFF MEASURES: CASE STUDIES**

*by*

Evdokia Möisé, OECD Trade and Agriculture Directorate

Lack of regulatory transparency is a major and recurrent obstacle for businesses seeking to trade internationally. This study finds that transparency mechanisms applied at different stages of the design, finalisation and implementation of domestic regulation have allowed countries to reduce administrative burdens, generate savings both for the administration and for the private sector and maintain a relation of confidence conducive to a smoother enforcement of related policies. They have also helped them enhance the readability of laws and regulations and the predictability of their enforcement (thus further reducing indirect business costs), and prevent potential frictions with trading partners. The resulting improvements in terms of potential business costs can strongly influence the attractiveness of the country for foreign investors.

This paper features four case studies:

- The UK review of the Insurance Premium Tax (IPT) provisions
- Two European directives relating to electrical and electronic equipment
- A review of Australia's quarantine and biosecurity systems
- The review of the Drug and Alcohol Testing rules of the United States Department of Transportation

#### *Acknowledgements*

The author wishes to thank Lars Bruckner of NEC Europe; Thorsten Brunzema and Madalina Caprusu of the European Commission; John Cooke, of International Financial Services London; Fran Freeman and Tim Crowe from the Australian Department of Agriculture, Fisheries and Forestry; Toshihiko Fujii and Tomoko Ota, from the Japanese Ministry of Economy, Trade and Industry; Takuya Fukumoto of the Japan Business Council in Europe; Alex Hunt from the US Office of Management and Budget, as well as Dale Andrew, Head of the TPLS Division and Frank Van Tongeren, Head of the Policies in Trade and Agriculture Division in the OECD Trade and Agriculture Directorate, for information, helpful comments and suggestions.

*JEL Classifications:* F13, F14, H83, L51

*Keywords:* transparency, non-tariff measures, regulation, market access, administrative burdens, regulatory impact assessment, public consultation

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## Executive summary

This work is part of the Trade Committee's 2009-10 PWB project on the "Design and Effectiveness of Non-Tariff Measures" aiming to provide key elements necessary to design NTMs in the least trade-distorting way. The project was laid out in the OECD internal document, "Preliminary Thoughts on the Trade-Related Regulatory Transparency: Project Proposal", presented at the June 2009 Working Party meeting. During that meeting, the Working Party decided to explore how transparent design and implementation of non-tariff measures can impact on fixed and variable trade costs by reviewing international commitments to regulatory transparency and domestic provisions in favour of transparent rule-making.<sup>1</sup>

Fact-finding and analysis for this report is drawn and illustrated through case studies of non-tariff measures in Member countries whose potential for generating unnecessary obstacles to trade has been highlighted and dealt with through domestic and international transparency mechanisms in the countries concerned.

The transparency of the regulatory process not only ensures the predictability of the business environment, but is also a valuable tool for identifying and addressing unintended obstacles to trade which can also serve as a check against subtle forms of protectionism. Foreign traders and investors seeking access to a market as much as domestic market players need to base economic decisions on accurate assessments of potential costs, risks, and market opportunities, but have greater difficulties in obtaining information when the regulatory environment is opaque.

International commitments to design and implement non-tariff measures in a transparent manner can be found in several World Trade Organization (WTO) agreements. Although these WTO provisions do not impose higher levels of transparency commitments to the already sophisticated transparency frameworks established in several OECD member countries, they provide trading partners an additional opportunity to get involved in the concerned country's rule-making process. This is particularly valuable where highly technical regulations, such as those covered by the Technical Barriers to Trade (TBT) agreement, are at stake. Still, the implementation of such provisions varies greatly across countries, including through the special and differential treatment provisions granted to developing country members. Ongoing discussions in the WTO show a growing tendency to reinforce, expand and make multilateral transparency disciplines more sophisticated in areas such as TBT, Non-Agricultural Market Access (NAMA) or trade facilitation.

Regional Trade Agreements (RTAs) increasingly include transparency-related provisions, and an overview of existing provisions shows that, under the impetus of a

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1. The OECD internal document, "Transparency in the design of non-tariff measures and the cost of market entry: conceptual framework", presented at the December 2009 Working Party meeting, is also relevant to work on this project.

domestic transparency culture, there is a clear tendency to gradually expand and render more sophisticated the transparency provisions in recent RTAs. The case studies provided no evidence that transparency mechanisms of applicable RTAs made any difference with respect to the domestic mechanisms already prevalent in the reviewed OECD member countries. There seems however to have been an impetus to strengthen the domestic framework in countries where public stakeholder involvement is less prevalent. Public consultation provisions in RTAs are generally more far-reaching as regards TBT issues, presumably on account of their highly technical nature, and provide a push for moving beyond what is expected in the multilateral context.

At the domestic level, case studies of regulation in Australia, the European Union, the United Kingdom and the United States illustrate a number of good transparency practices in the elaboration, adoption and implementation phases of rule-making. These practices are more generally applied among OECD member countries, where governments commonly make information available to the public, listen to a wide range of interests, are generally responsive to what is heard and apply such transparency mechanisms in an inclusive and non-discriminatory manner, benefitting domestic and foreign economic operators equally. Such good transparency practices considerably improve the prospect of domestic regulatory measures to achieve efficiently their intended objective without creating unnecessary barriers to trade. In particular they improve the availability of information to small and medium size enterprises (SMEs) and foreign stakeholders; contribute to reducing the opaqueness of regulation and the complexity of regulatory frameworks; and enhance the capacity of stakeholders to check the accuracy impact assessments on domestic economic activity, international trade and investment.

The reviewed cases illustrated how the use of information technologies helped reach audiences at a distance from the decision centre and provided faster and cheaper access to trading partners and foreign businesses. At the same time, the open-ended manner for carrying out consultations not only ensured more efficient formulation of government policies but also improved the prospects of more constructive relations between the administration and economic operators. Since involvement in the rule-making process is not costless for the concerned stakeholders, intelligible and comprehensive information is necessary in order to secure meaningful participation. On the other hand, the resources engaged in operating transparency mechanisms appear to be fully compensated by the benefits they help to generate.

In all reviewed cases, stakeholder involvement has significantly contributed to identifying ways to reduce administrative burdens and generate considerable savings, which in the case of one of the regulations studied was estimated at EUR 41 million. Transparency mechanisms have also served to build trust among participants. This paved the way for a smoother enforcement of related policies; it also enhanced the readability of laws and regulations and the predictability of their enforcement, thus further reducing indirect business costs. On the whole, transparency mechanisms appear to be a particularly cost-effective tool for avoiding unnecessary obstacles to trade.

## I. Introduction

The transparency of the regulatory process is a significant governance element not only from the perspective of the government's accountability to its domestic constituencies but also as an important factor to foster a freer flow of goods and services across borders. Lack of regulatory transparency is a major and recurrent non-tariff-related complaint of businesses seeking to trade internationally. Beyond its importance in ensuring the predictability of the business environment, transparency is a valuable tool for identifying and addressing unintended obstacles to trade and could also serve as a check against subtle forms of protectionism. Accordingly, regulatory transparency has been at the forefront of the international trade agenda both at the multilateral and at the bilateral/regional level. It appears even more topical in the current context of the economic crisis, when pressing calls for emergency action can lead to intended or unintended protectionist measures without the scrutiny and accountability provided by transparent rule-making processes.

The OECD has explored trade-related regulatory transparency from several different perspectives, including from the perspective of international investment,<sup>2</sup> environmental provisions in RTAs,<sup>3</sup> domestic regulation for services trade,<sup>4</sup> trade facilitation<sup>5</sup> and TBT good regulatory practice.<sup>6</sup> The Working Party has now decided to explore how transparent design and implementation of non-tariff measures can impact on fixed and variable trade costs by reviewing international commitments to regulatory transparency and domestic provisions in favour of transparent rule-making. The section that follows examines international commitments (multilateral and regional) to design and implement non-tariff measures in a transparent manner. Section III presents the case studies that were used to identify and illustrate the operation of transparency mechanisms at the domestic level. Section IV highlights good governance practices that can be found in domestic provisions favouring the transparent design and implementation of non-tariff measures.

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2. *Public Sector Transparency and the International Investor*, OECD 2003.
  3. *Environment and Regional Trade Agreements*, OECD 2007.
  4. Iida, Keiyo and Julia Nielson "Transparency in Domestic Regulation: Prior Consultation" in *Trade in Services: Negotiating Issues and Approaches*, OECD 2001 and "Transparency in Domestic Regulation: Practices and Possibilities", TD/TC/WP(2001)31/FINAL.
  5. Moise, Evdokia "Transparency and Simplification Approaches to Border Procedures" TD/TC/WP(2002)36/FINAL, TD/TC/WP(2002)50/FINAL, TD/TC/WP(2002)51/FINAL.
  6. Lesser (2007), *Do Bilateral and Regional Approaches for Reducing Technical Barriers to Trade converge Towards the Multilateral Trading System?*, OECD Trade Policy Working Paper no 58, and OECD (2004) "Good Regulatory Practice for the Preparation, Adoption and Application of Technical Regulations", OECD internal document.

## II. International commitments to design and implement non-tariff measures in a transparent manner

### *Transparency-related provisions in the multilateral trading system<sup>7</sup>*

Many WTO agreements require governments to disclose their policies and practices publicly within the country and/or by notifying the WTO. The General Agreement on Tariffs and Trade (GATT) disciplines, mainly found in GATT Article X, include an obligation to publish all regulations and subordinate measures, including judicial decisions, administrative guidelines and rulings of *general application* that *affect trade* in a *prompt* manner so as to enable relevant parties to become *acquainted* with them. Publication requirements are reiterated in General Agreement on Trade in Services (GATS) Article III, TBT Article 2.11 and Annex B of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement). The TBT and SPS provisions specifically mention a “reasonable interval” between the publication of measures and their entry into force in order to allow producers in exporting Members to adapt their products or methods of production to the requirements of the importing country.

Notification and comment procedures following a notification to the WTO are found in both the TBT and SPS Agreements (TBT article 2.9 and articles 5 and 7 to 10 of the SPS Annex B), with exceptions for emergency situations (TBT 2.10, SPS Annex B art.6). Notifications should include a brief indication of the objective and the rationale of the regulation. Notification and comment procedures are triggered when a technical regulation or sanitary or phytosanitary measure is not based on a relevant international standard or where no such standard exists, and may have a significant effect on the trade of other Members.<sup>8</sup> GATS Art.III also includes an annual notification requirement to the Council for Trade in Services on new or changed measures.

Furthermore, GATT Art.X and GATS Art.VI introduce disciplines on the administration of the Members’ regulatory framework, requiring uniformity, impartiality and reasonable administration, as well as the availability of an appeal or review mechanism.

The case studies show that WTO publication and due process provisions do not impose higher levels of transparency commitments to the already sophisticated transparency frameworks established in several OECD member countries – although this is most likely different in countries lacking a well-rooted tradition of regulatory transparency. However, even where domestic transparency mechanisms work quite effectively, WTO notification and comment procedures provide trading partners an additional opportunity to get involved in the concerned country’s rule-making process. This is particularly valuable where highly technical regulations, such as those covered by the TBT agreement, are at stake. This is clearly demonstrated in the case of the consultation process undertaken by the European Commission on the Waste Electric and Electronic Equipment, Directive 2002/95/EC (WEEE directive) and the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment, Directive

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7. Transparency-related provisions in the WTO system are well known and have been largely analysed. This section only provides a brief reminder of these provisions.

8. Complementing the notification obligation of the TBT agreement, the Committee on TBT has put in place detailed procedures for notification which have been refined over the years. For example, the Committee has recommended a time limit of at least 60 days for comments on notifications of technical regulations and conformity assessment procedures.



2002/96/EC (RoHS directive). Although the consultations were quite productive and allowed a wide array of stakeholders' concerns to be taken into account already at the initial development stage, the additional feedback and ensuing dialogue triggered by the TBT notification process demonstrate the added value of the multilateral transparency obligations.

In the WTO, the tendency is clearly towards a further strengthening of the concept of transparency. Several provisions under negotiation in the Negotiating Group on Trade Facilitation (NGTF) go beyond the mere exchange of information between WTO Members, pledging for transparency measures directly benefitting the economic operators. It could be argued that these proposals translate and seek to further expand good governance practices already common in the OECD area. However, it is important to note that there is considerable acceptance of these provisions beyond the OECD membership. Articles 1 and 2 of the NGTF Draft Consolidated Negotiating Text<sup>9</sup> introduce sophisticated transparency commitments directed not only at governments but also at traders. They call for prompt, convenient and non-discriminatory publication of information and promote internet publication and dedicated enquiry points to help improve the accessibility and user-friendliness of trade-related information. They also call for reasonable and timely opportunities for stakeholder comments, seeking to secure sufficient comment time and to avoid arbitrary exceptions to those opportunities.

Enhanced transparency provisions are also under discussion in the NAMA negotiations. A number of WTO Members favour an extension of such provisions to economic operators. NAMA proposals on electrical safety and electromagnetic compatibility of electronic goods,<sup>10</sup> on standards, technical regulations and conformity assessment procedures for automotive products,<sup>11</sup> on labelling of textiles, clothing footwear and travel goods,<sup>12</sup> and on a framework for industry-specific non tariff barrier (NTB) proposals<sup>13</sup> include several provisions going beyond what is provided in the TBT agreement. In addition to commitments for advance publication of proposed regulations

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9. TN/TF/W/165.Rev6 of 22 December 2010.
  10. *Agreement on Non-Tariff Barriers Pertaining to the Electrical Safety and Electromagnetic Compatibility (EMC) of Electronic Goods*. See three communications from the United States : document TN/MA/W/105/Rev.3 of 26 November 2010; document TN/MA/W/125 of 4 December 2009 and document TN/MA/W/133 of 22 January 2010
  11. *Agreement on Non-Tariff Barriers Pertaining to Standards, Technical Regulations and Conformity Assessment Procedures for Automotive Products*. See four communications from the United States : document TN/MA/W/120 of 15 September 2009; document TN/MA/W/121 of 23 November 2009; document TN/MA/W/126 of 4 December 2009; and document TN/MA/W/131 of 22 January 2010. *Understanding on Non-Tariff Barriers Pertaining to Standards, Technical Regulations and Conformity Assessment Procedures for Automotive Products*. See communication from Canada and the United States, document TN/MA/W/139 of 9 July 2010.
  12. *Understanding on the Interpretation of the Agreement on Technical Barriers to Trade with respect to the Labelling of Textiles, Clothing, Footwear, and Travel Goods*. See two communications from the European Communities, Mauritius, Sri Lanka, Ukraine and the United States : document TN/MA/W/93/Rev.2 of 8 November 2010 and document TN/MA/W/123 of 27 November 2009.
  13. *Market Access for Non-Agricultural Products, Framework for Industry-specific NTB Proposals*. Communication from Brazil, the European Union and India, document TN/MA/W/136 of 15 March 2010.

and for reasonable and timely opportunities for feedback from concerned stakeholders, those negotiating proposals aim to improve the predictability and accessibility of proposed regulation by requiring publication of their objectives and rationale and to enhance the accountability of relevant authorities as to the way stakeholder concerns have been addressed. In particular, they call on Members to provide information on the way available regulatory and non-regulatory alternatives have been assessed and taken into account in the policy making process, the reasons for modelling proposed regulations on other Members' regulations, and the reasons why it was considered that relevant international standards were not an appropriate basis for their proposed regulation. Some of the above proposals also suggest allowing comment time of no less than 60 days for both Members (governments) and other interested parties (individuals and firms), unless urgent problems of safety, health, environmental protection, or national security arise or risk to arise. The proposals on electrical safety and electromagnetic compatibility and on automotive products call for transparency commitments to apply "*regardless of whether relevant international standards (..) exist or the technical content of the proposed (regulations) is in accordance with (them)*". However, developing countries mostly support limiting the coverage of transparency provisions to technical regulations which deviate from relevant international standards and this approach is also adopted in the proposed framework for industry-specific NTB proposals.

The adoption of these provisions in the future would greatly improve the predictability and openness of the trading environment in all WTO Members, although discussions in the WTO have highlighted the challenges transparency obligations could bring to developing country administrations. These concern not only the financial and human resource costs for establishing and running efficient transparency and public consultation mechanisms, but also the problems of ensuring accessibility for all concerned stakeholders. Implementation and capacity building action plans will have to address these challenges in close cooperation between developing countries and donors.

### ***Transparency-related provisions of existing RTAs***

Regional Trade Agreements (RTAs) increasingly include transparency-related provisions, and an overview of existing provisions shows that there is a clear tendency to gradually expand and render more sophisticated the transparency provisions in recent RTAs. These provisions can broadly be classified in three categories: a) general transparency provisions that call for the transparent administration of laws and regulations as regards all matters covered by the agreement b) specific transparency provisions on goods-related requirements, mainly TBT-type requirements, but also SPS-type requirements in some agreements, and c) specific transparency provisions as regards domestic regulation affecting services trade. The case studies provided no evidence that transparency provisions of applicable RTAs made any difference with respect to the domestic mechanisms already prevalent in the reviewed countries.<sup>14</sup>

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14. It should however be kept in mind that the case studies were cast so as to highlight good practices among OECD countries. The impact of RTA transparency provisions could be different in other regulatory environments.

Table 1. RTA transparency provisions

Participants and date of entry into force	General transparency provisions			Related to TBT or SPS		Related to Services Domestic Regulation	
	Information availability	Public consultations	Due process	Information to authorities	Involvement of public	Rules development	Individual decisions
Australia-Chile 2009	√	√	√	√	√		√
Australia-Singapore 2003	√			√		√	√
Australia-Thailand 2005	√	√	√	√			
Australia-US 2005	√	√	√	√	√	√	√
Canada-Costa Rica 2002	√	√	√	n.a.	n.a.		
Canada-EFTA 2009	√			√			
Canada-Peru 2009	√	√	√	√	√		√
Chile-Colombia 2009	√	√	√	√	√	√	√
Chile-EC 2002	√			√			√
Chile-Japan 2007	√	√	√	√			√
Chile-Mexico 1999	√	√	√	√	√		√
Chile-Panama 2008	√	√	√	√	√		
Japan-Malaysia 2006	√	√	√	√			√
Japan-Mexico 2005	√	√	√	√			√
Korea-Singapore 2006	√	√	√	√ ?			√
Mexico-Guatemala-El Salvador-Honduras 2001	√		√	√	√		
New Zealand-China 2008	√	√	√	√	√	√	√
New Zealand-Malaysia 2010	√	√	√	√	√	√	√
US-DR-CAFTA 2004	√	√	√	√	√	√	√
US-Singapore 2004	√	√	√	√	√	√	√
US-Morocco 2004	√	√	√	√	√	√	√

### *General transparency provisions*

Notification requirements covering proposed or actual measures that might materially affect the operation of the agreement or otherwise substantially affect other parties' interests under the agreement, are the most basic transparency provisions included in RTAs. Such notification provisions allow avoiding unintended effects that could hamper the smooth operation of the agreement. They can be found in RTAs as early as the 1983

agreement between Australia and New Zealand (ANZCERTA), the US-Israel 1985 agreement, or the EC-Chile 2002 agreement. In more recent RTAs these provisions go beyond corresponding provisions in the WTO TBT agreement, not only in terms of scope, but also because they are not limited to measures not in accordance with international standards, as in TBT Art.2.9, and are independent of any judgement as to whether the measure is consistent with the agreement. The notification requirement is supported by the designation of contact points to facilitate communication and includes responding to questions on proposed or actual measures by the other party, whether notified or not.

With the exception of early agreements, RTAs also commonly include general transparency provisions applying to all matters covered by the agreement. The central provision, to be found in all reviewed agreements, is a requirement to publish laws, regulations, and administrative rulings of general application relating to matters covered by the agreement, while in some agreements (e.g. Japan-Chile, Japan-Mexico) this also covers judicial decisions of general application and other international agreements concluded by the parties. This provision generally mirrors corresponding provisions of GATT Article X, calling for prompt publication of trade-related regulations so as to enable interested persons and the other party to become acquainted with them. Publication requirements are not just a tool for ensuring the smooth application of bilateral trade relations as are the notification provisions, but also promote a more open and predictable regulatory environment for the private sector. Although they do not add any further obligations to the WTO framework, they may be seen as offering renewed momentum to these provisions.

In RTAs involving OECD member countries the publication requirement is generally complemented by a best endeavours call for public consultations: to the extent possible laws and regulations should be published in advance of their adoption and interested persons provided a reasonable opportunity to comment. The Japan-Mexico Economic Partnership Agreement further specifies that public comment opportunities should be maintained except in cases of emergency (including imminent danger to health, safety or the environment), should be supported by an explanation of the draft regulation's rationale and potential effects and followed by an account of submitted comments and the government's views on them. On the other hand, this type of provision is less common among non-OECD RTAs. Typically, public consultation provisions in these RTAs directly reflect domestic public consultation mechanisms existing in one or both of the RTA Members. This means that, at least in the case of OECD member countries, RTA provisions do not provide foreign stakeholders from the other RTA party any additional opportunities to get involved in the rule-making process than what is offered by the domestic framework. The case studies offer no evidence that foreign stakeholders' views would be less considered without applicable RTAs. However, in RTAs between OECD member countries with a long tradition in public stakeholder involvement and countries where these practices are less prevalent, it can be argued that RTA provisions on public consultation may bring welcome impetus to reinforce the domestic framework.

Finally, RTAs involving OECD member countries commonly include due process provisions concerning the application of laws, regulations, procedures, and administrative rulings of general application falling under the scope of the agreement, on particular persons, goods or services of the other party. Due process provisions require authorities to provide affected persons with information about the legal background of the cases, the issues at stake and current status; and with the possibility to present facts and arguments and defend their position both with the administration and before administrative or judicial tribunals. Due process requirements do not introduce additional review and

appeal commitments but call for administrative and judicial processes to follow the parties' domestic legislation and be applied in a consistent and impartial manner. On the other hand, in most RTAs dispute settlement provisions are limited to the Parties themselves and do not provide private parties, individuals or companies a direct right of action under the agreement.

### *TBT and SPS related transparency provisions*

RTAs including TBT and SPS sections start by reaffirming the parties' existing rights and obligations with respect to each other under the WTO TBT and SPS Agreements. This obviously includes transparency rights and obligations under TBT articles 2 (paragraphs 5 to 12) and 10 and SPS articles 5.8, 7 and Annex B. They commonly further require parties to designate an enquiry point, or use the one established under TBT article 10 to transmit information related to measures it has adopted or is proposing to adopt and answer related enquiries by the other party.<sup>15</sup> These notification requirements apply to new technical regulations and conformity assessment procedures or modifications to existing regulations and procedures when these differ from international standards or are likely to affect trade. Some RTAs (Japan-Mexico, Canada-Peru, Australia-Chile) establish committees for exchanging information on the application of their technical regulations and SPS-related regulations, SPS incidents and potential SPS risks. Some RTAs explicitly call for information describing the objective of the proposed technical regulation or conformity assessment procedure and the rationale for the proposed approach. Like general transparency provisions described above, notification and enquiry point commitments do not add any further obligations to the applicable TBT framework, but the establishment of an institutionalised dialogue arguably facilitates the flow of information between concerned authorities. The Chile-Mexico agreement in addition provides for an annual advance notice of the parties' standardization plans and programs to each other, so as to ease overview and planning for both parties. The New Zealand-China Free Trade Agreement (FTA) requires the parties to explain the reasons for not accepting comments by the other party and to transmit an electronic copy of the final proposal.

A more limited number of agreements introduce more specific provisions to enhance transparency of standards, technical regulations and conformity assessment procedures, in particular as regards private stakeholders. The most important is the requirement by some RTAs for parties to allow the participation of persons from the other party in the development of standards, technical regulations and conformity assessment procedures where such participation is also allowed to their nationals. A few, such as the US-Morocco agreement, go further by requiring each party "*to allow its own persons and the persons of the other party to participate*". In all these agreements nationals of the other party should be allowed to participate on terms no less favourable than those accorded to the concerned party's own nationals. According to Australia-US Free Trade Agreement (AUSFTA) or Canada-Peru, the public should be provided a meaningful opportunity and allowed sufficient time to comment on proposed technical regulations

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15. Lesser (2007) found that an average 80% of RTAs reviewed in the study contained commitments on transparency and almost one third required the establishment of a system for the exchange of information regarding technical regulations and conformity assessment procedures within the RTA (e.g., regional enquiry points). The author quotes studies by Piermartini and Budetta (2006) and by Kotschwar (2001) as having found respectively 52% and 66% of RTAs containing TBT-related commitments on transparency.

and conformity assessment procedures (most agreements introduce a 60-day period), while the government should publicize its responses to significant comments received from the public or the other party.

It should be noted that RTA public consultation provisions relating to TBT issues are generally more far-reaching than the corresponding RTA general provisions on public consultation that remain on a best endeavours basis. They also introduce a higher level of transparency disciplines than corresponding WTO TBT or SPS provisions and could thus provide a drive for moving beyond what is expected in the multilateral context. Such public consultation disciplines seem to reflect quite closely domestic mechanisms already applied in OECD member countries, but in the case of non-OECD country parties they clearly offer an incentive to reinforce transparency rules at the domestic level. In the absence of a wide-ranging survey of businesses operating in these countries, it is difficult to assess whether the operation of the RTA transparency provisions has not only reinforced the previously applicable framework but also improved regulatory transparency in practice.

### *Services related transparency provisions*

Services-related sections in RTAs commonly reiterate GATS provisions concerning the administration of domestic regulations affecting services trade: in particular they call for reasonable, objective and impartial administration and the establishment of qualification and licensing requirements, procedures and technical standards on the basis of objective and transparent criteria in order to ensure that they do not constitute unnecessary barriers to services trade. Provisions governing the treatment of applications for authorization often mirror corresponding provisions of GATS Article VI.3, requiring parties to inform the applicant of the decision concerning the application or of the status of the application. In addition to the horizontal disciplines, RTAs covering services trade generally develop more specific and detailed disciplines for specific sectors such as telecommunications and financial services.

Relatively few RTAs however contain specific provisions for transparent rule-making in the area of services, although services related disciplines in the agreement are clearly covered by general transparency provisions where such exist. Some agreements such as the AUSFTA, US-Morocco or Chile-Colombia go beyond the requirements of GATS Article III by requiring the parties to establish mechanisms to respond to enquiries from any interested person regarding services-related regulations and to address in writing comments received on their draft regulations to the extent possible. These provisions also include a best endeavours call for allowing reasonable time between the publication of final regulations and their effective date. As with TBT-related provisions, these requirements seem to offer a valuable drive for reinforcing transparency practices at the domestic level in non-OECD member countries.

## **III. Selected case studies**

The case studies described below showcase a number of good transparency practices in the elaboration, adoption and implementation phases of rule-making. They were selected from examples volunteered by Member countries, suggestions by the Business and Industry Advisory Committee to the OECD (BIAC) and information accessible to the Secretariat, as agreed at the June Working Party meeting. They are based on information available in WTO and OECD documents, documents available online regarding the

reviewed regulation and interviews with businesses and Member country officials. They should not be viewed as the best examples of regulatory transparency in the OECD area, but rather as informative illustrations of the effects of such practices on the design of non-tariff measures. Far from being isolated, they demonstrate approaches more generally applied among OECD member countries, although some OECD members' practices do stand out in terms of domestic regulatory transparency, as shown by the OECD country reviews of regulatory reform.<sup>16</sup>

### **Case study 1: The UK review of the Insurance Premium Tax (IPT) provisions<sup>17</sup>**

The review of the UK Insurance Premium Tax (IPT) provisions relating to overseas insurers is an interesting case of reform undertaken specifically to address potential non-tariff barriers to trade, based on domestic provisions in favour of transparent rule-making.

#### ***Background***

Insurance Premium Tax (IPT) is a tax payable by insurers on premiums received under taxable insurance contracts in respect of risks located in the United Kingdom. IPT applies to both UK-based and overseas insurers. Since the tax was introduced in 1994, insurers with no business establishment in the United Kingdom were required to appoint a tax representative in order to eliminate the risk of tax loss from overseas insurers. Such tax representatives were, by law, jointly and severally liable with the insurer for the payment of unpaid tax.

Following the adoption among EU Members of Mutual Assistance provisions on exchange of information and recovery of debt, the insurance sector raised questions around the continued need for the appointment of an IPT tax representative, arguing that resident tax representative requirements increased compliance costs for overseas insurers and led to non-compliance. These private sector concerns and a European Court judgment (C-522/04 *Commission v. Belgium*) which found that provisions imposing the appointment of fiscal representatives with personal liability contravened Treaty provisions on the freedom to provide services and freedom of establishment, have incited the UK administration to reconsider IPT requirements for overseas insurers.

#### ***The pre-establishment phase of the regulation***

In response to private sector concerns and in order to identify and address unnecessary and burdensome requirements on businesses, HM Revenue and Customs (HMRC), as the UK Department in charge of tax administration, carried out a formal consultation which ran from 26 July to 19 October 2007 and included a seminar for industry representatives at which possible options for change were discussed. The objective of the consultation was to explore the issues raised by the industry, including possible options for change, and to gather evidence to assist in analysing and quantifying

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16. All reviews can be found on [www.oecd.org/countrylist/0,3349,en\\_2649\\_37421\\_1794487\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/countrylist/0,3349,en_2649_37421_1794487_1_1_1_1,00.html)

17. Mr. John Cooke, Chairman of the LOTIS (Liberalisation of Trade in Services) Committee of International Financial Services London (IFSL) provided valuable information concerning this review.

the administrative burden imposed by the IPT tax representative requirements and any effect they may have on competition and compliance.

The consultation was conducted in accordance with the UK government's *Code of practice on written consultations*,<sup>18</sup> i.e. taking into account the following consultation criteria: 1) organise consultation *at a stage when there is scope to influence the policy outcome*; and 2) lasting *at least 12 weeks*; 3) offering clarity *about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals*; 4) *accessible and clearly targeted*; 5) *keeping the burden of consultation to a minimum*; 6) providing careful analysis of the responses and clear feedback to participants following the consultation.<sup>19</sup>

The consultation was announced in Budget 2007. It was supported by a consultation document reviewing the tax representative requirements and a partial impact assessment of the upcoming reform, so as to inform stakeholders' positions. The consultation document included possible policy options, envisaged by HMRC in order to address the concerns expressed, including a) the removal of the requirement for a resident tax representative, b) the removal of the requirement for joint and several liability, c) the introduction of an IPT registration threshold, and d) the introduction of an IPT *de minimis* concession. The document proposed questions to help understand the sectors' current practice offer them the opportunity to provide evidence on the administrative burdens and compliance costs associated with the requirements and collect their views on the best policy approach. The impact assessment undertaken by HMRC spelled out the policy objectives and in particular the need to ensure that domestic insurers do not face unfair competition from non compliant overseas insurers, while at the same time reducing the barriers to cross border trade. It also offered first estimates of the administrative burden linked with the current framework, including the burden per business of IPT registration, the burden of submitting IPT return and the burden of requesting approval for appointment of a tax representative.

A total of 15 written responses were received from insurers, brokers, tax representatives, industry bodies, professional bodies and tax advisers. Following the consultation and the seminar which was held with participation from both HMRC and industry, HMRC analysed and compiled the responses to the consultation document and published a summary of these responses broken down by policy option considered, as well as the government response to the stakeholders' inputs. The list of respondents and seminar attendees was published by the administration.

### ***The influence of stakeholders' input on the design of the regulation***

Consulted stakeholders overwhelmingly preferred the option of removing the requirement to appoint a tax representative in its entirety. The removal of the joint and several liability requirements appeared an interesting alternative option, since this requirement emerged from the responses to the consultation as the main element causing difficulties for overseas insurers. Respondents suggested that non-UK based insurers should be able to choose either to manage their IPT affairs directly with HMRC, or to appoint a tax agent without joint and several liabilities to act on their behalf. Although the

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18. Now superceded by the *Code of Practice on Consultation* of July 2008.

19. The Code includes a seventh criterion meant to improve the capacity to consult, requiring officials running consultations to seek guidance and to share what they have learned.



consultation failed to produce any information on the cost of appointing a joint and severally liable tax representative, information on the annual cost of a tax representative without joint and several liability allowed HMRC to calculate that the total benefit to the industry from the removal of the requirement was in the range of GBR 1.4 million to GBR 3.5 million. It was also expected that this reduction in real and administrative burden costs should encourage currently non-compliant foreign insurers to register for IPT in the United Kingdom and pay the tax due, thus removing unfair competition to compliant insurers.

Following this reform, the administrative costs of HMRC were expected to increase on account of the increase in the number of companies on the IPT register. However, the additional burden, estimated to be in the range of GBR 6 000 to GBR 14 000, would be compensated by the favourable fiscal effect. At the same time, respondents highlighted the difficulties linked to the actual payment of the tax due and invited HMRC to make it easier for insurers or their representatives to pay any tax due by the introduction of a facility to accept one-off payments and the introduction of web access to the required forms with added facilities for on-line filing and payment.

The consultation also produced information about the anticipated drawbacks of the other considered options. The removal of the tax representative requirement just for EU insurers would have meant adding to the current tax legislation, arguably making the full tax representative provision disproportionate for a non-EU insurer. The restricted numbers of tax representatives in the market also made it difficult for HMRC to impose a joint and severally liable tax representative upon each non-EU based insurer who is not covered by mutual assistance arrangements. The additional complexity required to target a very small trader population (approximately 500 IPT registered non-EU insurers) made this option clearly unattractive. The responses to the consultation also made it clear that the introduction of an IPT registration threshold for insurers writing small amounts of UK insurance was not a solution to the burdens incurred by the insurance industry overall, thus distorting business. The threshold would also generate problems of ongoing monitoring requirements, additional complications for co-insurance and of interaction with the current extra-statutory *de minimis* concession.<sup>20</sup>

### ***The adoption phase of the regulation***

Following the consultations, the UK government announced in Budget 2008, published on 12 May 2008 the removal of the requirement for overseas insurers with no business or fixed establishment in the United Kingdom, to appoint a tax representative and the update of HMRC's powers to recover tax from the insured party in the case of a non compliant non-EU insurer. Overseas insurers, whilst still needing to register for IPT, will now be able to choose whether or not to appoint an agent to act for them in the United Kingdom. This agent will not need to be jointly and severally liable for the tax due by the insurer. Additionally, subject to certain conditions, an agent will not necessarily have to be located in the United Kingdom and it will be possible for an agent to be based elsewhere in the European Union. The recovery of IPT from an insured party will be restricted to circumstances where the non compliant insurer is based in a country with no Mutual Assistance, or similar, arrangements with the United Kingdom. The government

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20. Payment relief provided by the Department for premium taxes below certain limits when strict application of the law would create an unintended disadvantage

has decided not to carry out any further work in relation to the introduction of a registration threshold and a reform of the *de minimis* concession.

### ***The application phase of the regulation***

Furthermore, the administration announced that HMRC will contact all participants to the consultation document, including representatives from the insurance sector, advisors, and tax representatives themselves, to ensure they are aware of the new rules, and to give them an opportunity to comment on the revised draft guidance. Related public notices and guidance documents have been updated to reflect the changes and posted on the HMRC website. Contact details in the National Advice Service were also published for users that have further questions about the changes. A number of insurance and advisor companies have expressed their satisfaction with the reforms, which “*should make compliance easier for non-UK insurers*”.

## **Case study 2: The reviews of Directive 2002/95/EC on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE)<sup>21</sup>**

The reviews of two European Commission directives on waste electrical and electronic equipment, Directive 2002/95/EC, known as RoHS and Directive 2002/96/EC, known as WEEE, provides an illustration of transparency mechanisms applied to relatively complex regulation, involving various policy objectives and a vast array of stakeholders, domestic and foreign.

### ***Background***

The original versions of the RoHS and WEEE Directives have been adopted in 2003 and are currently implemented by all EU Member States. They are key elements of EU environmental policy on waste, because of the estimated growing volume of electric and electronic equipment waste (WEEE) and potential hazardousness following their disposal. The RoHS directive restricts the use of certain hazardous substances in electric and electronic equipment so as to protect human health and facilitate the environmentally sound recovery and disposal of WEEE. The WEEE directive requires Member States to promote the collection of WEEE separately from other forms of waste, to ensure they are treated in a specific way and to achieve significant re-use, recycling and recovery. It makes electric and electronic equipment (EEE) producers responsible for financing the collection, treatment, recovery and disposal of WEEE and aims to induce industry modifications allowing easier dismantling, recycling and recovery, so as to reduce the dispersion of hazardous substances throughout the waste management operations. The

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21. This case study would not have been possible without the valuable contributions of the Japan Business Council in Europe (JBCE), Japan Electronics and Information Technology Industries Association (JEITA), Japan Electrical Manufacturers Association (JEMA), Japan Business Machine and Information System Industries Association (JBMA), Communications and Information Network Association of Japan (CIAJ) and the Association for Electric Home Appliances (AEHA). We particularly acknowledge the contributions of MM. Takuya Fukumoto, JBCE Secretary General and Lars Brückner, NEC Europe, as well as MM. Thorsten Brunzema and Madalina Caprusu, DG Environment policy officers for WEEE and RoHS.

original texts of the Directives foresaw the review of their operation, continuing relevance, effectiveness and efficiency before February 2005 for RoHS and five years after its entry into force for the WEEE Directive.

On the basis of the review provisions built into the original text, the reviews were meant to increase the efficiency and effectiveness of the Directives in achieving their environmental goals, while eliminating any unnecessary costs to business, consumers, non-governmental organisations (NGOs) and public authorities arising from their implementation. However, in addition to their built-in review provisions, both the RoHS and the WEEE Directives were among the regulations targeted by the 2005 Community strategy on the simplification of the regulatory environment<sup>22</sup> aiming to make legislation less burdensome, easier to apply and thereby more effective in achieving its goals. In 2007, the WEEE Directive was also included in the scope of the Action Programme for Reducing Administrative Burdens in the European Union,<sup>23</sup> directed at reducing administrative costs, notably with respect to registration and labelling requirements. In addition, since the adoption of the original texts, concerned industries have been in constant interaction both with Commission services (DG Environment and DG Enterprise) and with Member State administrations as regards the implementation of the Directives provisions. For instance the UK Department for Business, Innovation and Skills (DTI at the time) organised several consultations on its proposals to implement the Directives, covering draft regulations, non-statutory guidance and a regulatory impact assessment.

### ***Information to support the simplification process***

The formulation of the Commission's review proposal in co-operation with concerned stakeholders roughly followed four steps: A first internal study describing the main benefits and problems in the implementation of the WEEE Directive, identifying WEEE regulatory and management approaches at worldwide level and suggesting implemented improvements, was published in 2006. It was followed by a first call for inputs and information announced online, and opened to all stakeholders over two-month periods (in 2006 for WEEE and in 2007 for RoHS). Contributions made by various stakeholders were published online unless their contributors indicated that they should be considered confidential. Additional technical studies were commissioned to support the development of options on the identified topics for the review of the two Directives. These studies, carried out between 2005 and 2007, were among others based on inputs from industry and published for consultation on the Commission website <http://ec.europa.eu>. In parallel an information and consultation workshop on the WEEE Directive was organised in 2007, open by invitation to expert stakeholders. Finally, wide-ranging public consultations were launched in 2008 over two month periods, using as background the above technical documents and in accordance with the Commission Impact Assessment Guidelines.<sup>24</sup>

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22. Commission Communication of 25 October 2005 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, implementing the Community Lisbon Programme "A strategy for the simplification of the regulatory environment".

23. COM(2007)23, adopted by the European Commission in January 2007.

24. Impact Assessment Guidelines, SEC(2009)92, as amended in 15 January 2009, initially published in June 2005. The Guidelines indicate the consultation of interested parties is an

The various supporting pieces were meant to inform stakeholders' positions as well as solicit their opinions on the various policy options. Comments were invited on a number of issues, so as to clearly structure problem understanding and feedback, but were also invited to propose additional options that the review should consider. Concerns raised by trading partners in the TBT Committee (concerning the original versions of the Directives), such as the withdrawal of the Deca-BDE exemption from RoHS,<sup>25</sup> the relation between RoHS and Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), or the coverage of medical devices, were also assessed in the formulation of the Commission's review proposals. The WEEE review focussed in particular on:

- the Directive's collection and recycling targets (including fixed or variable mandatory collection targets, environmental weight-based collection targets, or obligatory give-back; general, category-specific or material-based recycling targets; and targets for reuse of whole appliances);
- the clarification and width of the product scope and the possibility for Member States to go beyond the Directive's provisions (including formalisation of criteria, establishing fixed lists, specifically excluding certain types of products from the scope);
- specific treatment requirements (including the introduction of treatment standards, or a better alignment between WEEE and RoHS provisions) and
- the operation of producer responsibility provisions, applied in a variable manner by different Member States (including aligning the legal basis of producer responsibility provisions, harmonising the implementation, or providing incentives for eco-design).

The RoHS review focussed in particular on:

- improving the Directive's effectiveness and implementation, by clarifying the scope and definitions of the Directive and in particular the relationship between WEEE and RoHS scope, taking into account the different legal basis of the two Directives (RoHS basis calling for harmonization of requirements, while WEEE basis leaves more latitude to Member States);
- the harmonization of enforcement practices to overcome the trade and competition distortions generated by diverging national interpretations (including the possibility of a uniform mechanism for demonstrating compliance and the procedure and criteria for granting exemptions);
- enhancing the complementarity and coherence with other EU legislation, such as the EU framework legislation for the marketing of products (regarding definitions and enforcement) and REACH (regarding substance restrictions).

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obligation for every impact assessment, in order to produce *high quality and credible policy proposals*

25. Deca-BDE is a brominated flame retardant which had been exempted from the original RoHS Directive on the basis of a risk assessment concluding it did not represent any significant risk to health or the environment. Following a ruling from the European Court of Justice annulling this exemption, Deca-BDE was brought back in the list of banned substances and was included in the review of RoHS.

### *The influence of stakeholders' input on the design of the regulation*

The consultation process produced more than 170 inputs for WEEE and over 110 inputs for RoHS from various stakeholders, including Member States, municipalities, EU and non-EU producers of electrical and electronic equipment such as Electrolux or Microsoft and business associations, such as AMCHAM or EUROMETAUX (the majority of respondents), retail and distribution companies, treatment, recycling and recovery operators, standardisation and certification organisations and environmental or consumer NGOs. Outside Europe, most concerned companies got information and provided comments through their umbrella industrial associations and the commercial service of their home country embassies. In general stakeholders commented on the topics suggested in the consultation document but proposed very few additional topics for discussion, pointing to a rather comprehensive coverage of topics for review in the consultation document. Stakeholders were able to follow the progress of the review in general and of the foreseen consultation and its results, including other stakeholders' inputs, on the Europa website.

Overall, the process between initial reflections and the draft legislative proposals published by the European Commission on December 2008 took roughly two years, a length of time commensurate to the scale of the affected pieces of legislation. Stakeholders' input together with the information contained in the technical studies were taken into account by the Commission in order to perform an analysis of the policy options for the reform, although some stakeholders indicate that it is not always easy to see the correspondence between their input and the options retained in the draft legislation. At the same time frequently asked questions (FAQ) documents were issued by the Commission to help authorities in the Member States interpret the Directives and support the compliance by economic operators, even if such FAQ documents are not legally binding.

In particular, the Commission drafts:

- proposed to move from the current fixed collection target of 4kg/capita per year for all Member States to a variable collection target set in function of the EEE quantities placed on the market, thus taking into account variations in EEE consumption in individual Member States, as favoured by a significant percentage of stakeholders;
- endorsed the widely supported option to include the re-use of whole appliances in the recycling target, and proposed to increase that target as requested by Member States, municipalities and NGOs, an option industry actors did not favour;
- opted for a harmonisation of the product scope of the RoHS Directive through fixed lists, as suggested by many stakeholders and proposed updating the lists through the EU committee system ("comitology" procedure), so as to address industry concerns about the difficulty to keep regular updates of new products appearing in the market;
- called for the harmonisation of the registration and reporting obligations for producers and the interoperability of national producer registers which was generally supported by stakeholders in order to reduce the administrative burden related to the application of the WEEE Directive. The possibility for producers to only register and report in one Member State for all their activities in the EU is expected to lead to potential savings of EUR 60 million;

- included medical devices and monitoring and control instruments to the scope of the RoHS Directive, as supported by almost all stakeholders, and followed industry calls for a staged introduction so as to avoid adverse socioeconomic impacts;
- introduced binding product lists to reduce the administrative burden caused by diverging interpretations;
- aligned product conformity assessment requirements and market surveillance mechanisms to the common EU framework for the marketing of products and based conformity assessment on internal production control and self-declaration on the manufacturer's responsibility, as unanimously supported by industry stakeholders.

The Commission draft proposals, including explanatory memoranda where stakeholders' inputs were described, were published on 3 December 2008. They entered the legislative stage involving the European Parliament and Council, where the text can still be significantly amended before adoption. During that stage stakeholders still have the opportunity to seek improvements to the legislation, although the consultation process in that stage is much less systematised. In parallel to representations made to Members of the European Parliament, stakeholders generally contact the national governments of Member States. Many stakeholders find it more difficult to navigate through multiple administration contacts than the previous stage leading to the establishment of the Commission draft. However, some EU members commonly take a leading role at this stage, consulting stakeholders, explaining how comments were considered and co-ordinating with other EU governments to work towards common policy positions. This has *de facto* led non-European stakeholders to address their concerns to these EU members at the legislative stage.

### ***The influence of WTO transparency provisions***

At the same time, the draft proposals were notified to the WTO in February 2009 (G/TBT/N/EEC/247 and G/TBT/N/EEC/248). They received comments by a number of WTO Members, including Canada, China, Jordan and the United States, to which the Commission replied in accordance with TBT Article 2.9. For instance, the Commission:

- indicated its readiness to give appropriate consideration to other WTO Members' classification rules for WEEE from private households (for instance US technical regulation 40 CFR 261.5(g) when laying down the classification of WEEE in the implementation phase with Member States and the Parliament;
- clarified that the inclusion of medical devices under the scope of RoHS would not become effective before 2014 and did not concern spare parts or implantable medical devices, for which the medical device industry had expressed concerns;
- reassured trading partners that future stakeholder consultations on adaptation to technical and scientific progress would follow the same open and transparent process and would not be limited to closed consultations risking to favour domestic industries or lead to the development of proprietary technology;
- announced its decision to maintain temporarily the restriction on the use of deca-BDE, assigning importers and manufacturers the responsibility for producing the additional evidence needed against its toxicity.

### ***Cost implications of the review***

Information obligations weighing on businesses and stemming from the WEEE Directive were mapped and measured by the *High Level Group of Independent Stakeholders on Administrative Burdens* (HLG), together with the other pieces of legislation investigated in the context of the Action Programme to Reduce Administrative Burdens. The HLG concluded that the WEEE Directive generated EUR 186 million administrative costs (avoidable and unavoidable), of which 62% or EUR 116 million classified as administrative burdens (i.e. that could be avoided) and EUR 19 million considered as resulting from national obligations going beyond EU requirements (often referred to as “gold-plating”). Commission estimates presented to the HLG expect the proposed harmonisation of reporting obligations to reduce administrative burdens by EUR 41 to 66 million per year for businesses directly and for public administrations, although the initial costs for businesses for moving to the new system would reduce benefits the first year.

### **Case study 3: The review of Australia’s quarantine and biosecurity systems**

The review of Australia’s quarantine and biosecurity systems offers an example of a complex and politically sensitive regime which was reconsidered in a comprehensive and open-ended manner with a view to improving domestic efficiency without ignoring trading partners’ concerns.

#### ***Background***

In February 2008, Australia launched a major review of its quarantine and biosecurity systems. The Australian government sought to assess whether the current arrangements were appropriate, effective and efficient in minimising the risk of entry, establishment or spread of potentially harmful exotic pests and diseases in a changing operating environment (a globalised economy, increasing and expanding passenger, cargo and genetic material movements, population spread into new habitats, and climate change). The review was thus meant as an advance preparation for government reflection, taking into account all relevant developments in the domestic and international environment, including physical and financial constraints regarding an efficient government intervention, but also criticisms, expressed at home and abroad concerning the perceived shortcomings of the system. The Minister for Agriculture, Fisheries and Forestry appointed an independent Panel of experts and asked it to review Australia’s quarantine and biosecurity system, including public communication processes and governance and institutional arrangements, and to produce a report (*One biosecurity: A Working Partnership*, also known as the *Beale report*, from the name of the Panel’s Chair), consulting in the process with relevant domestic and international stakeholders and benchmarking Australia’s arrangements in an international context.

#### ***An open-ended mandate and an inclusive consultation process***

The Panel was requested to focus its reviews on whether current arrangements achieved effectively and efficiently Australia’s *Appropriate Level of Protection*<sup>26</sup>

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26. In the sense of SPS Annex A(5), “the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or

(ALOP), set as “very low but not zero” and its continuum of intervention, meant to progressively reduce risk through pre-border, border and post-border activities; whether public communication, consultation and research and review processes were appropriate; and whether resources, systems and institutional arrangements were properly aligned to the requirements of delivering the expected biosecurity, quarantine and export certification services.

The Panel first prepared and released in March 2008 an Issues Paper in order to prompt discussion and attract submissions and comments from all interested stakeholders. Submissions were invited over a one month period, and in accordance with the *Freedom of Information Act 1982* and the *Privacy Act 1988*. Although the paper set the scene for the review, highlighted a number of issues for further consideration and posed specific questions, stakeholders were encouraged to raise any other matters they considered relevant. On the other hand, the Panel specified that the review would not discuss or review Australia’s ALOP, which was already determined by the government<sup>27</sup> at a “very low level but not zero”, or Australia’s rights and obligations as a signatory to the WTO SPS Agreement. Some of the issues raised by the Panel, which were particularly relevant from a trade-related point of view, were:

- whether applied risk analysis is appropriate in maintaining the defined ALOP, understood and applied in a consistent way, comprehensive and timely, and achieved in a way that is not more trade restrictive than necessary;
- the implications of the current system on exporters, consumers and the economy, on market access requests and import applications and their consistency with Australia’s international obligations;
- the potential of jurisdictional and institutional arrangements (including commonwealth and state responsibility and cost sharing) to frustrate actions to implement SPS commitments;
- whether communication mechanisms on biosecurity policy are effective, including with Australia’s trading partners.

The Panel received around 220 written submissions from a wide range of interested parties, including overseas submissions, and subsequently organized over 170 meetings with domestic and international stakeholders, both individuals and representatives of organizations to discuss submissions. The Panel also sought information from Australia’s trading partners on their arrangements for managing biosecurity risks and held discussions with government officials and business representatives in New Zealand, North America, Europe, and representatives from other WTO Members. A dedicated website ([www.quarantinebiosecurityreview.gov.au](http://www.quarantinebiosecurityreview.gov.au)) offered online support to the process: reference documents used during the review were made available on the site, alongside with copies of all the submissions received. Stakeholders highlighted *inter alia* problems with variable state biosecurity requirements imposing a significant burden on businesses and perceptions of political interference resulting in slow resolution of market access issues; uneven consultation mechanisms that work better at the central level than on the ground; clear requests for incentives to improve private sector compliance and to improve

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*health within its territory*”. According to SPS Article 5.4, when determining ALOP, countries should “take into account the objective of minimizing negative trade effects.”

27. As is the government’s prerogative and responsibility by virtue of the SPS Agreement.



and expand co-regulation; and strongly criticized mandated inspection targets that were not based on risk assessment.

At the completion of the consultation process, the Beale Report, submitted to the Australian Government, described the current situation, summarized comments received and presented specific recommendations. In particular and as far as trade-related issues are concerned, it recommended to:

- establish a National Biosecurity Authority and a corresponding Commission to provide independent, science-based decision making; as well as clear Guidelines on how to assess the economic impact of potential biosecurity threats;
- move away from mandated inspection targets in favour of a comprehensive risk-return approach to allocating inspection resources;
- eliminate to the extent feasible paperwork burdening businesses through electronic interfaces, on-line approval systems and electronic certification;
- conclude compliance agreements, including audit, to recognise formally the food safety management systems of importing businesses and grant reduced regulatory burdens for businesses with good compliance records;
- extend the reach of Commonwealth biosecurity legislation to the exclusion of any state or territory law, increase Commonwealth resources to support monitoring, surveillance, investigation and prosecution and establish a national biosecurity agreement to underpin the partnership between Commonwealth and the states.

The Australian Government released its Preliminary Response to the report in December 2008, agreeing in principle with all 84 recommendations subject to budget processes, and outlining the actions the government intends to take in order to put the recommendations into practice. The response is publicly available on the Department of Agriculture, Fisheries and Forestry (DAFF) website along with updates of progress with reform.<sup>28</sup> Changes to Australia's quarantine and biosecurity system based on the Beale Report have and will continue to be notified through the SPS notification system, whereby the normal comment and consideration process will occur.

#### **Case study 4: The review of the Drug and Alcohol Testing rules of the United States Department of Transportation**

The review of the Drug and Alcohol Testing rules of the US Department of Transportation (DOT) showcases the importance of an extensive and comprehensive discussion of stakeholder concerns in order to explain the administration's policy choices, reinforce the accountability of policy makers and improve the prospects for efficient implementation of the final regulation.

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28. [www.daff.gov.au/about/publications/quarantine-biosecurity-report-and-preliminary-response](http://www.daff.gov.au/about/publications/quarantine-biosecurity-report-and-preliminary-response)

## ***Background***

US DOT established drug and alcohol testing procedures in 1994,<sup>29</sup> responding to the 1991 Omnibus Transportation Employee Testing Act requirement that safety-sensitive transportation employees in aviation, trucking, railroads, mass transit, pipelines, and other transportation industries be drug and alcohol tested. The DOT regulation established rules on who must conduct drug and alcohol tests, how to conduct those tests, and what procedures to use when testing. These rules cover all transportation employers, safety-sensitive transportation employees, and service agents – roughly 10 million people. Since that date, DOT amended a number of specific provisions and issued a large volume of guidance and over 100 written interpretations, as well as a significant amount of informal advice. However, most of this material was not incorporated into the rule text. In addition, changes in testing technology, the structure of the drug and alcohol testing business, and the functioning of the department’s drug and alcohol testing programs persuaded the DOT to update the provisions.

In 1996 DOT launched a revision of the drug and alcohol testing procedures regulation in order to incorporate guidance and interpretations of the rule into its text, and update the rule to address changes that had taken place. The department also sought to make the organization and language of the regulation clearer in order to meet the objectives of applicable “Plain Language” policies and to assess the effects of the provisions on small businesses and other small entities as required under section 610 of the Regulatory Flexibility Act.

## ***The pre-establishment phase of the regulation***

In order to gather information necessary for the rulemaking process, the DOT started by issuing an Advance Notice of Proposed Rulemaking (ANPRM)<sup>30</sup> in April 1996, asking for suggestions for change in the rule. The DOT received 30 stakeholder comments in response to the ANPRM. On the basis of information collected through the ANPRM process and directly by the DOT, the department elaborated a comprehensive revision to rule 49 CFR Part 40 and publicized it by means of a Notice of Proposed Rulemaking (NPRM) in December 1999.

The NPRM procedure is an important tool for ensuring stakeholder involvement in the rulemaking process. It is required by the Administrative Procedure Act in order to impose regulatory agencies to listen to comments and concerns of people whom the regulation will likely affect. The Administrative Procedures Act requires the publication in the Federal Register of a general notice, including a statement of the time, place and nature of public rule making proceedings; reference to the legal authority under which the rule is proposed; and the terms or substance of the proposed rule, or at least a description

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29. A first interim rule on drug testing drawing on Department of Health and Human Services (HHS) guidelines for Federal agency employee drug testing was published by DOT in 1988 and finalized in 1999 responding to stakeholder comments (49 CFR -Code of Federal Regulations- part 40). Alcohol testing was added in the 1994 rule

30. An ANPRM is a preliminary notice, published in the Federal Register, announcing that a US government agency is considering a regulatory action and seeking to help the concerned agency gather information necessary for the rulemaking process. The ANPRM could be viewed as an advance version of the NPRM (see below), where the concerned agency considers an earlier stakeholder involvement could assist information collection.

of the subjects and issues involved. A NPRM is not required for military or foreign affairs issues, internal agency management issues, interpretative rules, or rules affecting specific persons, which have all been named and personally served with a copy of the relevant information. Furthermore, emergency rulemaking is allowed to bypass the NPRM process. The NPRM typically gives 60 days for public comment from any interested party, in the form of written data, views or arguments and possibly oral presentations. The final version of the rule, after taking into account the comments made, has to be published not less than 30 days before its effective date, except for interpretative rules, rules granting or recognizing an exemption or relieving a restriction, and in cases where the agency has a good reason to proceed otherwise and duly substantiates this in the rule.

An open-ended and wide-ranging process as regards potential participants, the NPRM secures at the same time an efficient stakeholder input thanks to the structured and detailed supporting material provided by the concerned administration to trigger specific and constructive comments. In order to further ensure wide accessibility of the notice, the NPRM is also made available on the regulations.gov site, which is the online source for U.S. government regulations from nearly 300 federal agencies ([www.regulations.gov/search/Regs/home.html](http://www.regulations.gov/search/Regs/home.html) - aboutUs). The regulation.gov site allows stakeholders to search for Federal Register (FR) notices, proposed rules or final rules and submit comments on a regulation or on comments submitted by other stakeholders. To improve its user-friendliness, the site offers the possibility to sign up for e-mail alerts about a specific regulation, quickly access regulations that are popular, newly posted or closing soon, and to subscribe to RSS feeds by agency of newly posted FR notices.

### ***The influence of stakeholders' input on the design of the regulation***

In response to the NPRM on the drug and alcohol testing procedures, DOT received letters from over 400 commentators, making around 4 000 individual suggestions concerning the rule. DOT also held three public listening sessions, as well as an internet forum, at which numerous interested parties commented further on the department's proposals. In addition to US nationals, Canadian and Mexican stakeholders were also extensively involved in the consultation process, representing both employer and employee interests in the transportation industry, as well as laboratories, medical offices and other testing companies. The major policy issues which were the subject of detailed stakeholder comments included:

- the admissibility of relieving employers in safety-sensitive positions from duty while waiting for the confirmation of drug and alcohol testing results;
- issues related to the verification of test results;
- the process for returning to duty for employees that were tested positive;
- the provisions regarding the laboratories, medical officers and other testing companies, including the applicable qualification requirements, the respective roles of the various entities in the testing process, confidentiality issues and conflicts of interest issues;
- the challenges and necessary safeguards regarding reporting and storing information through electronic means;
- and the process of reporting violations to DOT agencies.

Issues potentially raising trade concerns included training and qualification requirements for testing officers and entities; as well as possible conflicts between divergent regulation in the United States and its North American Free Trade Agreement (NAFTA) trading partners. Training and qualification of medical officers, testing officers and laboratories were viewed as essential factors for guaranteeing fairness, efficiency and accuracy of the testing program. DOT formulated proposals for ensuring that medical review officers are properly qualified and commentators offered numerous comments and suggestions on the topic. There was extensive debate as to whether medical officers should be submitted to regular training or allowed to self-certify, and the impact this choice could have on the quality of the service and on the cost and supply of the service to regulated employers. Furthermore, concerns were expressed that training and qualification requirements have the potential of raising obstacles for service providers across state lines and across the US border for trading partners such as Canada and Mexico.

On the other hand, foreign stakeholders raised the issue of diverging approaches in labour and workplace regulation between the United States and third countries. The interpretation of test results revealing the use of substances that are legally available in a third country but not in the United States could raise difficulties as regards the position of the employee tested positive. It was suggested, in accordance with DOT's own interpretation of the rule, that the burden of proof relates to the existence of a legitimate medical explanation for using a given substance: even if the substance is legally available for instance in Canada, it has to be used for its appropriate purpose and in keeping with the medical instructions for its use.

### *The follow-up to the consultation process*

The final rule, published in the Federal Register, provides an extensive record of commentators' inputs, comments, concerns and recommendations and a point-by-point response to all the comments. It goes on to make significant alterations to the existing rules governing the Department's drug and alcohol testing programs. In responding to stakeholders' comments the Department focused on the substance of the comments, rather than the number of submissions favoring or opposing a particular proposal, and sought to explain why they did or did not make changes in response to various comments. In particular, DOT:

- acknowledged concerns about the testing and qualification requirements for medical officers and decided to drop self-certification proposals, considering that training costs and time commitment bore little risk of drying up the supply of medical officers. At the same time, sharing concerns about potential trade barriers to service supply across state and national borders lines, the DOT specifically provided that a physician licensed to practice in any jurisdiction (a state or province of the United States, Canada or Mexico, consistent with NAFTA requirements) and meeting medical review officer requirements of the regulation is authorized to act as a medical officer with respect to employees located in any jurisdiction. Any attempt by a state medical regulatory organization to limit the geographical scope of medical officers' work would be pre-empted under DOT agency rules;
- tailored application of the rules to Canadian truckers in order to avoid potential conflicts with Canadian human rights laws and worked on implementation in close co-operation with the Canadian Trucking Association.

DOT has thoroughly restructured Part 40, with subparts organized by subject matter area. Like the NPRM, and in contrast to the existing rule, the text was divided into many more sections, with fewer paragraphs each on average, to make it easier to find regulatory provisions. The new rule used a question/answer format, with language specifically directing particular parties to take particular actions (e.g. “As an employer, you must \* \* \*”). DOT also tried to express the requirements of the rule in plain language. Commentators were very complimentary about the reorganization of the rule, generally praising it as much clearer and easier to follow than the existing rule. The Department received a plain language award, known as the “No Gobbledygook Award,” from Vice President Gore’s National Partnership for Reinventing Government in recognition of the improved clarity of the regulation.

The Department decided to establish a 1 August 2001 effective date for the revised Part 40 (more than seven months after the publication of the final rule), in order to give stakeholders time to address and adapt to the difficulties involved in the transition between the existing rule and the new rule. During that period, program participants were given the opportunity to learn about new provisions before having to implement them and the Department developed and issued guidance (e.g. a revised medical review officer (MRO) manual) and made presentations at a significant number of conferences and training sessions.

#### IV. Domestic transparency mechanisms for regulations affecting international trade

Regulatory transparency at the domestic level, understood as *the capacity of regulated entities to express views on, identify, and understand their obligations under the rule of law* (OECD 2001) is extensively used in OECD member countries as a basic tool of regulatory quality. For the administration it offers a remedy against inadequate information in the public sector and reinforces the capacities of governments to implement policy effectively, with the support of an informed public. For the regulated entities it provides the means for improving compliance prospects, accurately assessing potential costs, risks, and market opportunities and possibly fending off unnecessary burdens on their activities.

The importance of domestic transparency mechanisms in ensuring the openness of affected markets and the effective participation of economic operators, including foreign ones has been highlighted in the 1997 OECD *Market Openness Principles*,<sup>31</sup> and re-affirmed in the 2005 *OECD Guiding Principles for Regulatory Quality and Performance*. The 2005 *Guiding Principles* highlight the importance of “consult(ing) with **all** significantly affected and potentially interested parties, **whether domestic or foreign**, where appropriate at the **earliest possible stage** while developing or reviewing regulations, ensuring that the consultation itself is **timely and transparent** and that its **scope is clearly understood**” (emphasis added). Foreign traders and investors seeking access to a market need as much as domestic market players to base economic decisions on accurate assessments of potential costs, risks, and market opportunities, but have greater difficulties than the latter in obtaining information in an opaque regulatory environment.

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31. 1997 OECD report on regulatory reform

The OECD country reviews on regulatory reform<sup>32</sup> have shown that regulatory transparency had greatly improved in the OECD area since the 1990s, due to the increasing use of a range of public consultation and information availability tools. OECD member countries make more information available to the public, listen to a wider range of interests, are more responsive to what is heard and this is no longer limited to some Members only. Importantly, transparency mechanisms are generally applied in an inclusive and non-discriminatory manner, benefitting equally domestic and foreign economic operators. It would be difficult to assert what may have been the impact of multilateral and bilateral transparency provisions on these developments in the OECD area, but the globalisation of economic activity clearly has provided momentum. On the other hand it is obvious that the evolving regulatory transparency culture among OECD member countries strongly influenced their negotiating stance in the RTA arena, bringing about increasingly sophisticated transparency provisions in RTAs, as described above.

Good transparency practices illustrated in the case studies included in this paper considerably improve the prospect of regulatory measures that efficiently achieve their intended objective without creating unnecessary barriers to trade. They seem to address to a significant extent some of the major transparency problems affecting trade and investment identified in the early OECD reviews,<sup>33</sup> namely:

- poor information availability to SMEs and foreign stakeholders;
- arcane regulation;
- complexity of regulatory frameworks;
- complex interactions between levels of government;
- random organisation and unclear accessibility of public consultations;
- exclusion of less influential stakeholders, such as new market entrants from public consultations;
- lack of supporting information to allow informed choices in consultations;
- excessive discretion in implementation.

### *Transparency in the pre-establishment phase of laws and regulations*

The first step in improving regulatory transparency in the pre-establishment phase of laws and regulations is clearly the timely announcement of planned legislative and regulatory initiatives. Publication of draft laws and regulations as a means of providing regulated entities **advance notice** of forthcoming requirements in the market is valuable *per se* and independently from any associated public consultation because it allows firms more time and flexibility to **adjust** to regulatory changes. This is particularly important in the case of highly technical regulations which may entail significant adjustment costs on behalf of the private sector. In the case studies the administration published information on the upcoming regulation between one and two years before establishing a formal text

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32. The influence of the regulatory environment on market openness has been reviewed in 23 OECD Members since 1998. The latest review, of Australia, took place in 2009.

33. OECD (2001). See also Fliess, B. and C. Busquets, “The Role of Trade Barriers in SME internationalisation”, OECD Trade Policy Working Paper no 45

(which, in the case of EU regulation, is expected to undergo roughly a further year before adoption). In the Australian and US cases an open-ended process meant to collect stakeholder input and comments was launched even before any specific legislative or regulatory initiatives were envisaged.

The publication of draft laws and regulations is even more critical as the basis for launching a dialogue with concerned stakeholders. **Timeliness** in that case is directly defined by the needs of a meaningful interaction. Information is made available when the administration's reflection is sufficiently mature to provide preliminary analysis and enable an effective and informed dialogue on the issues being consulted on. At the same time, it has to intervene at a sufficiently early stage as to be able to **influence** the administration's policy choices. In the case studies, the consultation process was launched once a series of technical studies or partial impact assessment were ready to share with concerned stakeholders. However, consulting authorities were pretty open to consider all possible policy options, including new options suggested by stakeholders.

The **accessibility** of information on planned legislative and regulatory initiatives has been considerably improved through the use of information technology. The wide use of information technology (IT) channels in all case studies, allowed administrations to provide faster and cheaper access to draft regulations and supporting material, as well as to reach audiences further removed from the decision centre, in particular foreign stakeholders and SMEs. It consequently broadened the basis on which consulting administrations sought to identify and reconcile conflicting interests and goals.

However, even if information available online improves accessibility for foreign stakeholders and SMEs, involvement in the rule-making process is not costless and an overload of information or calls for contributions can practically exclude all but the most resource-rich economic actors. For this reason, it is important to provide **structured and comprehensive** information and help stakeholders navigate through the consultation process. IT provides a valuable platform for integrating data and facts in an intelligible form: assessments on compliance costs, trade and investment impacts, and human health and environmental impacts were all included in the consultation packages proposed for review. Finally, IT offers new information management capacities permitting the establishment of centralized databases of the rules and formalities under review, with search engines and electronic filing.

On the other hand, IT not only enhanced information accessibility and intelligibility, but also information sharing among stakeholders, **interactivity** and the involvement of experts. On line availability of stakeholder inputs and the parallel organisation of expert seminars where concerned entities could exchange views greatly enriched reflections on the two EU Directives and the US drug and alcohol testing rules. The possibility for all stakeholders to review other stakeholders' views and get an overview of the conflicting positions and goals the administration seeks to address also reinforces the accountability of the administration as regards policy choices and reduces the risk of capture.

Although frequent informal contacts between the administration and concerned stakeholders have taken place before and throughout the consultation period, allowing to maintain an ongoing, confidence-building dialogue, **formalized and systematic** public consultations are nevertheless important for ensuring comprehensive, productive and targeted public-private interactions. Administrations in the UK, the US and the EU case studies extensively used *notice-and-comment* procedures based on minimum adopted standards, with clear rules of the game, procedures, and participation criteria, applicable to all bodies with regulatory powers, such as the UK Code of Practice on Consultation,

the US Administrative Procedure Act, or the European Commission Impact Assessment Guidelines. The independent experts' panel in charge of the Australian review followed the same rules and procedures as would have been applicable to government authorities undertaking consultations. The applicable consultation rules and guidelines were in all cases not only accessible to the public, but clearly cross-referenced in consultation documents.

The intelligibility of planned regulation is reinforced by publicizing, alongside with the policy proposals, the accompanying impact assessments, including assessments of expected international trade and investment issues. Relevant underlying technical analysis and data were also conducted on the basis of the same transparency standards and published. Sharing with consulted entities the **impact assessment** undertaken by the administration on the basis of expert information and previous stakeholder feedback enhanced their capability to understand issues at stake and start preparing for compliance. At the same time it gave stakeholders the opportunity to rectify possible information and analysis deficiencies, voice solicited or unsolicited comments on the texts and highlight potential barriers to trade, so that the publication of impact assessments serves as an additional quality control system along with institutionalized controls within the government.

Finally, an essential safeguard for transparent and accountable rule-making lies with the publication of the administration responses to stakeholder input. This mechanism ensures that comments have been given due consideration prior to the adoption of a final regulation but also improves stakeholder confidence in the **responsiveness** of the administration and provides them incentives for future participation in the rule-making process. The scrupulous, point-by-point response of the US DOT administration to stakeholder comments and concerns helped to double-check the quality and thoroughness of the administration's policy making process, as well as avoiding capture or suspicions about capture. Likewise, the publication by the Australian government of its policy stance and preliminary response to the issues raised by the Beale review offers clarity and predictability to the regulatory environment that businesses can expect on biosecurity issues in the coming years.

### *Transparency in final laws and regulations*

Although the principle of plain language drafting seems to have made significant progress in the OECD area, the growing complexity and technical nature of regulation is steadily increasing costs and reducing accessibility. The publication in three of the reviewed cases of FAQ and interpretation documents as well as policy statements accompanying the final law and regulations helps partially address this problem. The increasing focus on "plain language" programs should also contribute to reducing the number of documents that may be difficult to understand without recourse to professional help.

## **V. Conclusion**

Transparency mechanisms are extensively used in OECD member countries as a tool of regulatory quality, allowing to enhance regulatory design and implementation and to improve compliance prospects for the private sector. OECD member countries largely subscribe to international commitments in favour of regulatory transparency, both at the multilateral and the bilateral/regional level and have been actively pursuing further



expansion and strengthening of those commitments both geographically and thematically. There is a noteworthy two-way influence between domestic and international mechanisms. It offers renewed momentum to reinforce the domestic openness and transparency culture, provides trading partners additional opportunities to get involved in the domestic rule-making process and influences the negotiating stance in the RTA arena, bringing about increasingly sophisticated transparency provisions.

The case studies presented above clearly show that transparency mechanisms applied at different stages of the design, finalisation and implementation of domestic regulation significantly contribute in identifying and addressing potential barriers to domestic economic activity and international trade and investment. In all cases they have allowed concerned countries to reduce administrative burdens, generate savings both for the administration and for the private sector and maintain a relation of confidence conducive to a smoother enforcement of related policies. They have also helped them enhance the readability of laws and regulations and the predictability of their enforcement (thus further reducing indirect business costs), and prevent potential frictions with trading partners. The resulting improvements in terms of potential business costs can strongly influence the attractiveness of the country for foreign investors.

The success of these mechanisms in mobilizing domestic and foreign stakeholders' contributions is critically linked to their timeliness, accessibility and comprehensiveness, and is reinforced through the use of information technology. A critical element in the use of transparency as a tool against unintended barriers is to meaningfully involve the private sector in the impact assessment undertaken by the administration. Information on compliance costs and other potential impacts on economic activity is often more readily available to the economic operators than the administration, especially as regards highly technical regulation. Such involvement can be a valuable tool in enhancing the capacity of the administration to make informed and efficient policy choices, as long as these choices are also shaped in a transparent and accountable manner so as to improve regulatory confidence and avoid capture.

However, involvement in the rule-making process is not costless and many smaller economic actors may be excluded from resource intensive consultation mechanisms. Administrations need to present information in a digestible way if they want to secure participation from across the spectrum of concerned stakeholders. Transparency mechanisms need to be proactively pursued in order to ensure that their benefits are evenly enjoyed among economic operators.

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