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WORKING PAPER

Reducing regulatory trade costs: why and how?

Jacques Pelkmans

European University Institute **Robert Schuman Centre for Advanced Studies** Global Governance Programme-495

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Abstract

Regulatory trade costs matter. They consist of the costs incurred by A exporters of effective market access to B due to different regulation and enforcement, in particular of 'risk regulation' (health, safety, environment). Stronger, negotiations for 'deeper' bilateral and regional trade agreements as well as estimates of tariff equivalents of 'regulatory trade costs' have increased the awareness that lowering of regulatory trade costs is quintessential for world trade. For middle-income and developing countries, these costs are rising secularly. This paper critically reviews the three principal ways of reducing such costs to the world economy – trade agreements, international regulatory cooperation, and global technical standardisation – and discusses how to render these more effective. Key challenges are to reduce national standards setting and to promote more effectively world standards. The European Union plays a frontrunner role in this regard, including for information and communications technology standards.

Keywords

Regulatory trade costs; risk regulation; mutual recognition agreements; international regulatory cooperation; the Vienna and Frankfurt Agreements; global ICT standardization

Note from the author

A substantially shorter version of the paper is forthcoming in a special issue of the World Trade Review in honour of Alan Winters. The author gratefully acknowledges detailed comments by Rudi Bekkers from Eindhoven Technical University, in particular on section 6.

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1. Introduction

Whilst tariffs have long been in decline and are often found to be trivial or zero today, regulatory trade costs are high and on the rise. Tariffs have been reduced significantly in successive GATT Rounds. Moreover, these reduced WTO-bound tariffs often have little economic meaning in world trade for two reasons: (a) much lower 'applied' tariffs are used by almost all non-OECD countries¹; (b) even applied (or, for developed countries, bound) tariffs do not apply to a large share of world trade because FTAs or customs unions or GSP or (for the EU) EBA² imply zero or very low tariffs. For regulatory trade costs, precisely an opposite trend can be observed. When countries become more affluent, especially with a growing middle-class, the demand for what is called 'risk regulation' increases steadily. Lowering risks for citizens and workers by addressing market failures amounts to a major boost of their socio-economic welfare. However, countries regulate in different ways, be it with respect to scope, objectives, approaches, details and/or enforcement. There are also considerable 'red tape' costs, in particular in services. Such complicated differences between trading partners generate regulatory trade costs, in that access to markets becomes more costly. Risk regulation has become very important indeed, also middle-income and developing countries now utilise risk regulation routinely.

Thus, it is critical for world trade that regulatory trade costs are identified as the core problem. A simple empirical illustration to show this is offered in section 2. However, this is merely to give readers an idea of the considerable problem that these costs generate in world trade. The technical discussion of how to measure these costs properly and what approaches exist nowadays falls outside the realm of the present paper. Rather, the present contribution is essentially about taking regulatory trade costs much more serious: they need to be addressed in earnest. The TBT and SPS WTO Agreements ensure a minimum set of basic principles and disciplines encouraging 'better' risk regulation (e.g. the obligation to conduct sound risk assessment first, and e.g. encouraging the reliance on world standards) and preventing the worst forms of protectionism, as well as imposing reporting obligations. Some provisions in the GATS have similar motives as in the cases of TBT and SPS. However, the WTO does not regulate markets and hence cannot but marginally influence regulatory trading costs. With respect to lowering 'red tape' costs, in goods the WTO Trade Facilitation Agreement of 2013 has helped but in services the Reference Paper on Services Domestic Regulation was only agreed in 2021 and only by 70 economies.

Nowadays, global, regional and national trade policy is overwhelmingly about regulatory trade costs. However, there are lingering doubts about the effectiveness of current approaches. The central question I ask is how the prevailing ways of addressing regulatory trade costs can be improved.

Section 2 illustrates how high regulatory trade costs really are. It sketches important results from the recent empirical literature about regulatory trade costs, showing that such costs matter. Often, these are higher or indeed much higher than tariffs, let alone applied tariffs. Moreover, for mediumincome countries such costs are rising. For low income countries a secular rise in regulatory trade costs can be expected. Hence, the rationale for taking effective action is powerful. Section 3 offers a brief excursion to 'risk regulation', the driver behind the secular rise in such costs at world level. Risk regulation typically begins nationally and thereby almost inevitably generates differences with trading partners in ambition, approach, detail and/or enforcement. The introduction of risk regulation – if done well with sound regulatory impact assessment - amounts to an upward jump in socioeconomic welfare for citizens and workers, and is reason for satisfaction. Regrettably, however, risk regulation is almost always introduced or amended in ways distinct between trading partners, leading to a significant burden for world trade. The remainder of the paper attempts to come to grips with how regulatory trade costs are actually addressed in the world economy, outside the EU27/EEA-3

¹ Such tariff levels are autonomously decided by countries and can be changed at all times up to the bound tariff level; however, this happens relatively rarely. OECD countries usually stick to (often low) bound tariffs.

² EBA is an EU open-access system for the poorest (48) developing countries; EBA = everything but arms.

area and possibly the UK. After all, the EU/EEA is a special case as these countries have committed themselves and jointly to address such costs with the most radical – but indeed also probably most effective – approaches, by opting for economic integration in risk regulation too. All other countries in the world economy are far more reticent. The discussion focuses, in section 4, on the efforts undertaken by trade negotiators, in section 5 by risk regulators and, in section 6, by organisations, agencies and companies promoting international standardisation. Section 7 concludes. The Annex offers a detailed explanation of the approach and data behind Figure 1 in section 2.

2. How high are regulatory trade costs?

After pathbreaking work by Robert Baldwin (1970) on 'non-tariff barriers' and some occasional followups during the Tokyo and Uruguay Rounds, some early attempts of quantification of the costs were made in the 1990s. They consisted of business case-studies and of frequency indices of national regulatory measures. A perennial difficulty consisted in the absence of quantification approaches to (market) regulation. This changed with the OECD PMRs in the late 1990s. Another constraint consisted in inadequate data. The PMRs required intense and novel data collection, here for OECD countries, even though they concern less 'hard' data than plain tariff rates: the degree of restrictiveness of regulation for market players remains to some extent a matter of (expert) judgment before giving them a score between 0 and 6. PMRs are focused on domestic regulation, fairly detailed and can even be used for econometric work, within limits; they have been applied to both goods and services. For professional services, the European Commission has introduced a useful refinement (with 10 more detailed aspects included)³. More recently, both the World Bank and the OECD have introduced (different) STRIs for trade in services. For all these analyses a huge amount of country data had to be collected, from scratch. In goods and services, prompted by CGE /GTAP attempts to find out the welfare effects of reduction or removal of restrictive provisions, or, of a postulated equivalence between two or more trading partners, the common approach has become the use of tariff equivalents of the estimated costs of regulatory differences. More or less simultaneously, empirical literature has emerged about 'trade costs' in the world economy, including 'regulatory trade costs' as one element, leading contributions being Anderson & Van Wincoop (2003) and Novy (2013)⁴. The latter has been used for a massive UN-ESCAP-World-Bank project including some 160+ countries, after intense data collection⁵. For our purpose, the main problem of such massive efforts is that all types of trade costs are collected this way and precisely the regulatory costs are a weak spot⁶.

Meanwhile, a group of international economic organisations has developed the World Trade Index based on Egger, Larch, Nigai & Yotov (2018)⁷. This has led to admirable empirical work. There are five determinants of trade costs: transport & travel; information & transaction costs; ICT interconnectedness; trade policy and regulatory differences; and governance quality. With respect to 'trade policy and regulatory differences', variables include (i) being in a FTA, (ii) being part of the EU [and the eurozone], (iii) (bilateral) tariffs; (iv) whether there are ⁸ 'specific trade concerns' [STCs] in the WTO TBT and SPS committees; (iv) the OECD STRI and the heterogeneity between importer and exporter. For the regulatory part in goods – and excluding intra-EU trade – this approach significantly underplays the routine costs of regulatory differences: STCs are quite exceptional (see section 4.1) and numerous regulatory differences which cause exports from A to B to be costly, are not caught this way.

³ Called PRO-SERV, for all details including calculations for all EU Member States, see Pelkmans (1917).

⁴ Note that Chen & Novy (2022) have adapted their approach and found that trade cost proxies should not be single coefficients but variable given heterogeneity for a range of reasons. In other words, trade costs do not affect all trade flows in the same way.

⁵ World Bank (2015), in OECD /WTO, Aid for trade at a glance 2015: reducing trade costs for inclusive sustainable growth, chapter 2, see www.wto.org/english/res_e/books_p/aid4trade15_chap2_e.pdf

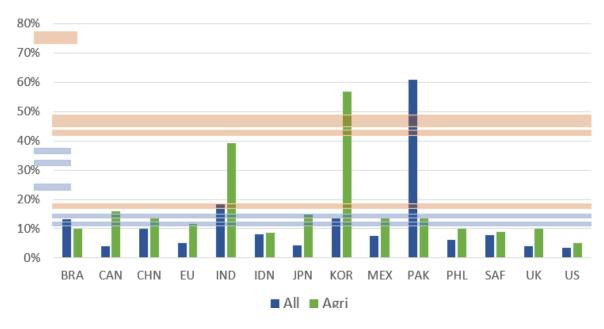
⁶ For example, on regulatory costs this is admitted by the World Bank on p. 75. The attempt to bring in the Doing Business indicators (Fig. 2.12 on p. 75) does not really measure regulatory trade costs as such.

⁷ See <u>www.wto.org/english/res_e/reser_e/ersd202102_e.pdf</u>, to be read together with an interesting empirical Background Note [www. wto.org/docs/Trade_Cost_Index_Backgroung_Note_24-03-2021.pdf] and a Staff WP by Robinova & Sebti (2021) [www.wto.org/english/res_e/reser_e/ersd202106_e.pdf].

⁸ Or even: have been; is not so clear from the text. Quite a few STCs might have been resolved.

Of course, it is not the purpose of the present paper to discuss the empirical measures and approaches of regulatory trade costs – this is a major subject on its own. However, even a cursory look at this literature – and accepting the uncertainties and disparities in the results - clarifies immediately how high these costs are, and indeed presumably higher still for developing countries. Moreover, they would seem to be higher for agricultural goods trade than for trade in manufactures.

In Figure 1 a rough attempt is presented to compare estimated regulatory trade costs (in tariff equivalents, as a % on top of the price of imports) for goods with applied tariffs in 2021 for 14 countries. This group comprises the large trading countries in the world economy and a few developing countries which are big in terms of population. The group of 14 represents 68.3 % of 2021 world trade (including intra-EU trade and excluding Hong-Kong ⁹). Figure 1 is presented for illustrative purposes. The estimated trade costs shown with horizontal bars reflect estimates of the EU and the US before TTIP ¹⁰ and more recent ones for ASEAN ¹¹.





Note: for technical explanation and sources, see text and Annex 1. All expressed in % of import prices. Applied tariffs from 2021

The main point underlined by Figure 1 is that, for the most part, estimated regulatory trade costs (several lower and higher horizontal bands) are higher than applied tariffs (vertical bars). This is a convincing rationale for trading nations to gear into more effective action addressing these costly barriers to market access. Figure 1 is a little complicated because one cannot generalise for each country and every sector, yet it is possible to convey a rather general - and indeed worrying - picture. The vertical bars are below or at the lower bands of estimated regulatory trade costs, except for India (for agri), South Korea (for agri) and Pakistan (for all goods). On the vertical axis, one finds estimated regulatory trade costs for sectoral outliers for individual countries, indicating some extreme cost levels, up to nearly 80 %¹². The overall message of Figure 1 is clear: regulatory trade costs not just matter but seriously hinder world trade, more so – on the whole - than tariffs do.

⁹ HongKong with an export value in 2021 of US \$ 672 bn has no tariffs and the notion of 'regulatory trade costs' would only apply to a small part of its trade, because most represents transit trade from/to China.

¹⁰ Based on the survey of Berden & Francois (2015).

¹¹ See in particular Ing & Cadot (2019).

¹² Of course, if one would disaggregate to 6 digits level, also tariff levels can be very high in a few cases.

However, this broad tariff picture is further softened considerably – be it in a discriminatory fashion – by FTAs and customs unions, as well as by GSP, and for the EU GSP-plus and EBA¹³. Nowadays, FTAs apply in all parts of global trade. For ASEAN FTAs have grown in importance with the ratification of RCEP, gradually realising zero-tariffs inside the group, the partial membership of CPTPP (4 ASEAN countries so far) and selected other FTAs. As is well-known, the EU has a string of FTAs and is keen on adding other ones to this stock. The implication is that even the applied WTO tariffs are not levied in a range of bilateral trading relationships. GSP and related programmes further reduce the relevance of tariffs. A pretty extreme illustration is found in EU tariffs: traders from less than a dozen countries actually pay full EU tariffs!

For risk regulation, the situation is quite different. In regulation, there is no distinction between 'bound' and 'applied', simply because societal risks are at stake. Unless economic integration treaties are very deep indeed, risk regulation simply differs between countries, also between FTA partners. Some FTAs have (more) ambitious forms of regulatory cooperation (see further) but whether it actually leads to improved market access is far from clear. There is also no such thing as a GSP in risk regulation, let alone an EBA or GSP-plus. In other words, unlike with tariffs, the trade costs of regulatory heterogeneity are given and – so far – not easy to be addressed effectively.

3. Risk regulation - an unwelcome guest in the world of trade?

The large bulk of EU regulation is 'risk regulation'. This is also true for other OECD countries and becomes increasingly the case for developing countries as their income per capita rises over time. Risk regulation addresses well-known market failures such as a lack of safety (of goods and services, and/or of their production – hence, for workers - and distribution), health risks, environment and climate issues, and consumer protection (insofar as not caught under the other failures). For short: SHEC¹⁴. Risk regulation amounts to a significant increase in socio-economic welfare, if properly done.

The (welfare) benefit amounts to the risk reduction due to such regulation. Ideally, risks are reduced to a level that society is prepared and capable to live with, hence the relation with the level of development. Calculations of benefits hinge on the risk differential between existing (if any) and newly proposed laws, expressed in terms of (fewer) lives-lost or (fewer) cases of illness or injuries ¹⁵. The benefits of lower risks also create trust, a form of social capital which is likely to raise productivity, other things equal.

Such regulation has two types of costs: (a) the resource costs of imposing SHEC regulation, addressed in regulatory impact analysis (RIA, largely based on benefit-cost analysis¹⁶), (b) the additional costs of trading goods and services across borders due to differences in regulation between export and import countries, such as substantive compliance costs with the rules in the country of destination and the costs of verification (e.g. certification, testing, MRAs, pre-shipping inspection, etc.). Nowadays many countries in the world apply RIAs ¹⁷ and this has undoubtedly helped to pre-empt the worst cases of regulatory failure. Beyond that, it is much less clear because RIAs are merely a help for decision-makers – be it in full transparency – and their presence does not exclude political agenda's to prevail at times.

¹³ GSP-plus currently applies to 9 trading partners of the EU, with several more applicants. The programme provides still better market-access (as far as tariffs are concerned) once some 32 [mostly UN] conventions or treaties have been ratified. EBA refers to everything-but-arms for the 48 poorest countries (i.e. tariff-free).

¹⁴ Note that, in financial services and capital markets, saver's and investment protection (here, via strict transparency e.g. in the case of IPO's) are not discussed here, but they matter too of course.

¹⁵ Or, possibly, other forms of damage not falling under private law (e.g. unlike liability which does fall under it).

¹⁶ See for instance <u>www.oecd.org/gov/regulatory-policy/ria-tool-for-policy-coherence.htm</u>

¹⁷ The OECD (2022) considers the EU as a trendsetter. See <u>www.oecd.org/gov.regulatory-policy/BRP-brochure-2022-web.pdf</u> for the highlights and the links to all 27 EU country reports.

RIAs have the effect of making analytical market information available to everyone, of incorporating all objections from stakeholders, verifying a range of regulatory options, not just one, and the estimated effects, qualitative and/or quantitative. In other words, RIAs make specific one-sided lobbying much more difficult. Moreover, in the EU at least, RIAs have to pass a semi-autonomous "Scrutiny Board" before being published together with the Commission's regulatory proposal. Given the widespread use of RIAs in the world, risk regulation would seem to be significantly welfare increasing for society – it is clearly greatly appreciated in many countries as a basic entitlement for a decent living. An interesting laboratory experiment, showing exactly that, was provided by BREXIT: the repeated soundings of radical Brexiteers to drastically lower regulatory requirements originating from EU risk regulation were ill-received by a large majority of UK consumers and workers.

Nevertheless, when analyzing intra-EU *trade* or trade with or between other countries, risk regulation is far too often discussed in the public debate with an emphasis on '*costs*', that is, "regulatory trade costs". The welfare *gains* from risk regulation remain disconnected from partial equilibrium customs union theory or simple general equilibrium trade theory with indifference curves or algebraic versions of all this. Such analyses are invariably about tariffs and changes in them. In the rich recent empirical literature about (regulatory) trade costs, most articles merely mention – usually in passing – that such (risk) regulation is 'legitimate'. The implicit reason is presumably that it addresses market failures. But that addressing market failures is, on the whole, a welfare-increasing activity is nowhere explicit. Instead, a typical term employed is that there are "frictions' caused by problems of regulatory compliance when trading ¹⁸. Moreover, whereas the 'welfare' benefits of (say) lower tariffs or a not-so-protectionist common external tariff of a new customs union are 'triangles', the benefits of reducing regulatory heterogeneity between countries, whilst maintaining the pursuit of risk regulation objectives, are comparatively larger. This must be so because risk regulation cost differences – referring to the entire volume of trade - consist of rectangles (and *without* possibly offsetting 'welfare' losses due to the loss of tariff revenue¹⁹).

When SHEC regulation is first imposed or upgraded, society must make sure that the resource cost incurred, because of the new rules, is minimised whilst respecting the risk regulation objectives (the benefits). Still, the more important question is how to maximise the benefits of the new rules for consumers and workers, possiby also of firms in some respects. After all, (EU) regulation finds its justification in the (net) benefits. Here, political practice flies in the face of sound regulatory policy making: in "Brussels" debates, the 'costs' often prevail, sometimes to the point of irrationality (admittedly, the relatively uncontroversial proposals neither generate much noise nor severely one-sided lobbying, hence there is likely to be a bias). For example, the two most important proposals since RIAs are used in 'Brussels' – namely on REACH, the chemical regulation enacted late 2006, and the services directive, also enacted late 2006 – were unbelievably controversial, so much so that in both cases there has never been a serious estimate, let alone a solid discussion, on the welfare benefits of these major proposals²⁰. Outside the EU, there are numerous examples of the one-sided emphasis on costs, with little, let alone decisive, emphasis on benefits.

¹⁸ Two examples: in Pelkmans & Winters (1988, p. 27; p. 37; etc.); Baldwin & Wyplosz (2019, pp. 112/3; pp. 131-133 calling them 'frictional barriers', also 'beyond-tariff barriers' (p. 134).

¹⁹ This point was already made in Pelkmans & Winters, 1988, pp. 18-19. Daniel Gros insisted that this clarification about the welfare benefit be made explicitly.

²⁰ In the case of REACH, the RIA was of very dubious quality (no Scrutiny Board was around yet): moreover, with some 30 pages of analysis mostly on costs, and just half an assertive page on benefits (based on a single WP of the World Bank on SVOLs and QA-LYs!), and no other options, it was essentially useless. This was, however, not exposed in TTIP because of the overly complicated and essentially 'soft' chemical regulation in the US, rendering it impossible for the EU to negotiate a possible chemical deal (Elliot & Pelkmans, 2015). For the services directive, the RIA was weak – in particular because the most powerful elements (scrapping 7 bad practices from Member States in services and another 8 in FDI for services, including the highly anti-competitive 'economic needs condition') had not received any even rough estimate - but, moreover, the proposal was drastically changed by the EP (dropping the origin article, f.i.) and no EU institutions dared to re-do the RIA given the inflammatory climate about this ['Frankenstein'] directive. Meanwhile, lessons have been learned and the Scrutiny Board has built up a tough reputation.

For goods or services *trade inside the EU*, the powerful free movements (goods, services, labour, capital), the building of the ever deeper EU single market [setting a precedent; there are regular EP-IMCO reports²¹ querying what are the cases of goods and services *not yet* falling under the single market regime, and what can be done about it], the rulings of the CJEU putting the bar high for exceptions to free movements or allowing forms of mutual recognition, and, finally a steady stream of proposals from the Commission on integrating specific 'left over' sectors or activities, or, suggesting a common strategy of harmonisation (often together with business) all add up to a sustained pressure to remove intra-EU barriers given a common understanding about the regulatory objectives and about some critical instrumental implications. The typical cases 'left over' are difficult because of diverse regulatory strategies in the past – sometimes with 'lock-in' problems and incompatibilities, such as in the construction materials sector – or due to extreme sensitivities in some exceptional instances (as in fertilizers, now resolved after many years). Economists are often quick to suggest that such difficulties reflect protectionism – possibly so, but it should not be forgotten that one simply cannot always assume – even in the EU – that regulatory objectives of countries are the same or equivalent or the same in each and every detail²².

In international trade outside the EU, none of these four permanent and strongly facilitating factors can be assumed to play a role. But countries have learned over time and the OECD – occasionally joined by APEC – has been most active in analyzing and promoting regulatory cooperation (IRC) in many ways ²³, to be discussed below. Also various FTAs have been experimenting with forms and intensities of IRC between their members. Disdier, Stone & van Tongeren (2019) found empirical evidence that bringing in IRC (on matters falling under TBTs and SPS) in FTAs has a significant and positive effect on trade flows, especially because of legal enforceability of IRC mechanisms.

One might wonder whether that conclusion would also follow for ASEAN, having moved a considerable distance towards what it calls the AEC (ASEAN Economic Community)²⁴ including a 'single market'. Precisely on NTMs such as TBTs and differences in national SPS measures, however, ASEAN has largely remained at the talking stage. ASEAN has enacted ATIGA, an agreement liberalising intra-ASEAN goods trade, but the addressing of NTMs or credibly striving for (greater) convergence of the underlying national regulations have barely moved ahead. There are certainly pressures to act more firmly together. Just observe that ASEAN has witnessed a major increase of NTMs inside the grouping from 1634 measures in 2000 to no less than 5975 in 2015²⁵, the year that - at least, formally - the AEC was inaugurated. On the one hand, this tripling in only 15 years should be a reason for appreciation because rising per capita income has prompted ASEAN countries to enact SHEC regulation, implying significant (but admittedly unknown) positive welfare effects. From a pure (intra-ASEAN) trade perspective, however, such NTMs are likely to hinder trade and/or make it more costly. It thus signifies a setback on the way to deepen the AEC; it could even partly nullify or reduce the gains from AFTA. Moreover, the legal enforceability of AEC accomplishments goes against deeply entrenched ASEAN traditions²⁶. Direct ASEAN enforcement remains a taboo in the region and other mechanisms are soft (e.g. Member States checking their own enforcement) and slow and less transparent (complaint procedures at ASEAN level).

²¹ The most recent overall report is Dahlberg, Marcus, Kubovicova, Pelkmans et al. (2020). More specialised reports include Enschelmaier (2019) on goods, Marcus et al (2019) on digital and Pelkmans (2019a) on services falling under the very broad services directive.

²² For example, with phosphate fertilizers, the core problem – long having remained unsolved – was how much cadmium in such fertilizers could be tolerated. Such sensitivities not only depend on a general risk of what problems cadmium might cause for public health, but also hinge on the (many) types of soil, the probability of leaking into water, the kind of agriculture practiced, the costs of low-cadmium fertilizers, etc.

²³ See OECD (2004), OECD (2013) and OECD (2017).

²⁴ For detail, see Pelkmans (2016) and (2019b).

²⁵ See Ing, Anandhika, Cadot & Urata (2019), p. 91.

²⁶ Of 'mushiwara' and the "ASEAN way".

Altogether, whilst the benefits of risk regulation (disciplined by RIAs) have significantly improved overall socio-economic welfare in OECD countries and increasingly in middle-income countries, and are unlikely to be fundamentally questioned in these societies, the consequences for trade tend to be costly. These costs are likely to increase over time the lower the initial level of development, in view of the rising importance of risk regulation with the rise of per capita income. In OECD countries there are signs that the amount of risk regulation has plateaued, sometimes even forced by means of one-in-one-out approaches. However, addressing the costs of differences in risk regulation between trading partners has turned out to be an uphill struggle. Even when ignoring hiccups inside federal countries, the EU example shows how much it takes – beyond the basics of the TBT and SPS agreements – before the costs of regulatory differences in national risk regulation disappear or become exceptional.

The question is how to address effectively and to significantly reduce such regulatory trade costs. In section 4 the query is what trade negotiators can do, at multilateral level, regional level and with the help of MRAs. In section 5 IRC approaches with different ambitions are studied, with the help of the IRC ladder. Section 6 analyses global technical standardisation and the unique EU leadership in pushing it, with great accomplished benefits as well as huge potential benefits.

4. Trade negotiators reducing regulatory trade costs

Trade negotiators dispose of three sets of tools which can be used to lower regulatory trade costs: via WTO agreements and with regional and/or bilateral agreements, as well as mutual recognition agreements (MRAs).

4.1 The WTO level

The WTO basis consists of the TBT and SPS WTO agreements since 1995. Although there are regulatory elements in other NTMs, TBTs and SPS measures together are dominant ²⁷; they are also the two principal consequences of risk regulation. However, Box 1 briefly calls attention to regulatory barriers in the area of environmental regulation and of labour market regulation. At the WTO level it is mainly the regular work of the TBT and SPS committees (including discussions on 'specific trade concerns', STCs) which should help to 'manage' regulatory trade barriers. Specific trade concerns tend to refer to rather obvious cases where complaining trading partners (and possibly other ones) suffer from national measures not in line with the WTO agreements. As shown by Espitia, Pardo, Piermartini & Rocha (2022, p. 345), STCs have increased in number over the years, with an annual average of around 75 from 2008 to 2017, compared to an annual average of less than 30 in the period 1997-2007. Still, they are a tiny fraction of all TBTs notified (recently, some 3000 a year), implying that STCs cannot be used as even a proxy measure of regulatory trade costs. Moreover, because the WTO TBT committee is active in discussing STCs, they are quite often removed or reduced. Cernat & Boucher (2021) concluded, on the basis of a careful matching exercise (at 6 digits level), that the EU's pursuit of STCs in the TBT committee resulted in € 83 bn of facilitated EU exports in the decade up to 2020²⁸.

Nevertheless, the much broader picture of these costs – beyond STCs - are a derivative of *all* SPS and TBT measures ²⁹. The very large bulk of regulatory trade costs result from TBT and SPS measures which are perfectly in line with these WTO agreements. This does not mean that these two agreements have not been useful to world trade. On the contrary, by and large both agreements have trickled down to national regimes and processes how to enact and enforce the relevant laws and decrees. This has happened due to 'transparency', i.e. obligatory notifications (which can be discussed in the committees) and the STCs which trigger detailed dialogue.

²⁷ Also Espitia, Pardo, Piermartini & Rocha (2022, pp. 345/6) for empirical evidence supporting this view.

²⁸ Of course, also other WTO partners are likely to benefit from the removal or reduction of STCs.

²⁹ However, in some instances, such measures might actually *facilitate* market access.

Moreover, quite apart from STCs, the permanent work of the TBT and SPS committees has almost certainly been most useful for a 'better (risk) regulation culture' as a discipline, a mould in which national initiatives have to fit, inducing a positive effect on trade (see also OECD & WTO, 2019). This is perhaps even more difficult in SPS because health and food safety concerns are so prominent. As Crivelli & Groeschl (2016) have shown, SPS measures have a significant impact on trade, be it that timing and form matter a great deal for the outcome.

BOX 1 – On environmental and labour provisions in regional agreements

Similar to TBT, regional or bilateral agreements including environmental provisions were very few before 1991. Since then an annual average of almost 10 new ones is observed for 2 ½ decades (Monteiro & Trachtman, 2022). A stark contrast can be found between agreements with or between developing countries and those between developed countries ; environmental quality is much less well guaranteed in the former. It should be noted that, in some respects, environmental regulation about products appears to be like a TBT. A crucial provision is the adherence to MEAs as this 'multilateralises' the regional provisions. Monteiro & Trachtman, op. cit. find fairly low shares for 'MEA compliance'. Does this refer to full implementation of MEA's provisions or to mere ratification, with all the reservations or (temporary) exemptions available for developing countries? For example, China has ratified no less than 12 MEAs (much more than the EU demands in FTAs), including 11 amendments, 3 extra Protocols and 4 extra conventions, although some do not fully apply yet (Hu & Pelkmans, 2022, pp. 81-83), even *without* having concluded many FTAs. Impressive is the [near 100 %] score in regional agreements for the balance between environment and trade goals, a preventive clause that reduces protectionist fears especially in developing countries. Overall, diversity is rather high.

On labour regulation (Raess & Sari, 2022 for a survey), the preliminary query is whether this concerns risk regulation or rules about values and (minimum) income distribution, not to speak of social protection, or a blend of all these. What is certain is that occupational health and safety firmly belongs to risk regulation but few concerns have been dealt with multilaterally, or, even in regional agreements. In part, this is due to the very cautious attitude of negotiators about specifications of production methods (rather than merely 'like' products). Emerging pressures to set minimum levels have, so far, been addressed by e.g. the OECD, the ILO and ad-hoc voluntary consortia of companies in selected sectors.

Trade liberalisation under GATS has been underwhelming and barriers to trade in services remain substantial (e.g. Borchert et al., 2020). New work exploiting panel data for 48 (mostly developed) countries and 5 sectors (Benz & Jaax, 2022) shows ad valorem equivalents of regulatory trade costs of 16 % for communication services, 20 % for business services, 23 % for transport services, 190 % for insurance services and 211 % for financial services. Only recent newly negotiated FTAs comprise some non-trivial efforts to open up more in services. However, with the GATS Reference Paper and the agreed 'additional' commitments (by the 70 economies covering some 90 % of world services trade), accomplishments at world level have changed as well. Trade costs in services are much higher than those in goods (Jafari & Tarr, 2017) and their gradual recent reduction is also lower than the reduction in goods. The new commitments are not about regulatory substance and GATS partners remain free to apply market access and national treatment limitations. Instead, the new commitments are about disciplines not unlike some of the provisions in the TBT and SPS agreements, more precisely about transparency (suspected to be more problematic still than in goods), legal certainty and predictability, as well as about regulatory quality and facilitation. Such disciplines have been shown to have a positive impact on trade in services as well as on the participation in Global Value Chains (WTO, 2019; Hoekman, 2020).

4.2 How regional agreements lower regulatory trade costs

Regional and/or bilateral agreements have a great potential to lower regulatory trade costs. The survey by Stone & Casalini (2022) shows how important regional or bilateral trade agreements can be for the lowering of the costs of SPS measures for partners (see also Cadot & Gourdon, 2016). First, by (further) streamlining SPS requirements as this tends to lower compliance costs. Second, by providing reliable information about foreign products as this reduces the home bias and might, in this fashion, also have the effect of lowering the price impact of SPS measures. Third, regional or even bilateral agreements tend to put a natural brake on protectionist-motivated measures, including SPS. Fourth, and more generally, by organizing joint structures which facilitate trade-liberalising agendas, via technical cooperation, sharing with a view of developing standards or regulations, or indeed developing standards together. In the case of SPS, mutual recognition of conformity assessment procedures (in regional agreements) significantly lowers SPS-induced trade costs (Disdier, Stone & van Tongeren, 2019). As far as TBT provisions in regional agreements are concerned, a true revolution has taken place since 1991: whereas between 1958 and 1990 very few regional agreements included TBT provisions, since then an annual average of around 10 new ones can be observed for 2 ½ decades (Espitia et al, op. cit., p. 348). Stronger, the increasing importance of TBTs acts as a strong incentive for countries to enter into regional agreements. It is also good to observe that TBT-related commitments in regional or bilateral agreements have become progressively 'deeper' (idem, pp. 356/7). Integrating conformity assessment measures is quite common in regional agreements, in contrast to standards and technical regulation. The authors do not specify what 'integration' of conformity assessment really means - probably 'mutual recognition' and 'equivalence' – but the effective functioning of MRAs is notoriously difficult to accomplish³⁰ and equivalence remains dependent on the importing country (whether in TBTs or SPS)³¹. For standards, 'harmonisation' is the preferred approach, but again what is actually referred to remains unclear, hence the actual impact on trade as well. It is most unlikely that many regional agreements would harmonise towards standards in the sense that 'regional standards' would be written. Neither does there seem to be hard evidence for this position. Presumably, partners might wish to 'harmonise' by adopting *international* standards, usually the best solution globally and quite practical regionally. However, standards are not legal instruments and are not decided by governments. Rarely, if ever, is there an agreed schedule to adopt harmonised standards between the regional partners, or more than a general encouragement for their standards bodies.

4.3 Mutual recognition agreements

Addressing regulatory differences with a view to trade costs has remained a fundamental characteristic of the EU and the EEA, because the radical principle of free movement (of goods and services) forces Member States to regulate in common. Outside the EU the unique Trans-Tasman Arrangement³² has also remained a stand-alone case. Since the late 1990s, an amazing agenda of MRAs between the US and the EU has inspired other countries as well, making MRAs potentially interesting as one route to lower regulatory trade costs ³³. Examples include MRAs between the EU and several other countries and a few APEC initiatives e.g. in electrical goods and telecoms equipment. However, the benefits of MRAs are quite limited. It is good to comprehend why. The mutual recognition implied in MRAs solely refers to the recognition by the relevant authorities in country A that (accredited) conformity assessment bodies [CAB] in country B can test goods against the technical standards or technical specification in a law of country A. The consequence is that producers or sellers in B can have their goods, meant to be exported to A, tested in their own country, thereby avoiding some (regulatory) trade costs, namely, bringing samples to A first which can be costly and tends to take more time.

³⁰ See Pelkmans & Correia de Brito (2015); the steps from an agreed text to a working MRA are considerable.

³¹ For SPS, consider the US/EU Veterinary Equivalency Agreement, see Josling & Tangermann (2015, pp. 283/4).

³² An explanation is given in Annex 2 of Correia de Brito, Kauffman & Pelkmans (2016). The TTA is unique because New Zealand has accepted far-reaching arrangements even inside Australia as well as a common food safety agency.

³³ For an extensive survey see Correia de Brito, Kauffman & Pelkmans (2016).

It might also be helpful that producers are familiar with their national CABs. For some specific goods (e.g. machinery) such MRAs are likely to save quite some resources; in other cases, the difference is slight. It is crucial to appreciate that the principal costs of TBTs are not found in testing and certification – whether abroad or at home - but in compliance costs, more often than not a multiple of testing expenditures. And all a MRA can ensure is that the costs of testing and certification at home (by a CAB which has been accredited under the MRA) is – presumably – somewhat lower than when sending the sample to the trading partner; a MRA is not about avoiding such costs – its advantage is merely about the cost differential.

The principal reason why MRAs, despite their modest accomplishments, have proven to be problematic before functioning or before implementation, has to do with the reticence of regulators. The context in which regulators typically work is not so conducive for tackling the concerns of trade. Their prime concern – indeed, their duty - is to ensure the level of risk regulation objectives in their home country. Typically, trade negotiators seek to make deals by framing packages of a country's rules and practices which could be subjected to common disciplines, to mandatory reference to (say) international standards, to mutual recognition and/or to forms of harmonisation of procedures or even of the substance of risk regulation. If that does not already make regulators to accept degrees of adaptation as an ordinary part of trade negotiators. Such policy scenarios risk to be a recipe for failure, as regulators are not trade negotiators, and they should not be. Risk regulation is not a matter of 'give and take'. Beyond the principles in the SPS and TBT agreements which essentially ensure to discipline national regulators (and thereby largely avoid such rules to be protectionist), regulators from two or more trading partners find it difficult to be dragged into negotiations about adaptation, let alone, regulatory alignment.

In Pelkmans & Correia de Brito (2015), a detailed scrutiny of US/EU MRAs in six sectors is conducted. Some 16 years after the MRAs were concluded – in 2015 - the MRAs for electrical safety of goods, medical devices and pharmaceuticals GMP³⁴ were still not operational. Only in 2020 the pharmaceuticals one became operational on the basis of a new agreement, emerging from TTIP and facilitated by an informal global gathering of medicine regulators (ICH). The conclusion is that MRAs, which generate only small cost-cutting benefits except for a few cases, and which solely deal with recognition of specific conformity assessment capabilities – hence not changing anything in the prevailing regulatory regime in country A - nonetheless remain very difficult to conclude or implement. Moreover, once a partner decides on regulatory reform – as the EU did on medical devices (making it more strict, closer to the US model) and for recreational boats (here, adding environmental aspects) – the prospective MRA is in jeopardy as well. Also APEC has fostered MRAs but found that only selectively member countries took it up and only in specific telecoms equipment and some cases of electrical safety.

³⁴ GMP= good manufacturing practices.

5. International regulatory cooperation for lowering costs

International regulatory cooperation [IRC] can slowly and unconspicuously contribute to the lowering of regulatory trade costs. But IRC is not well monitored, very imperfectly reported and rarely considered as a genuine tool by mostly skeptical academics ³⁵. The OECD (1994, 2013, 2017) has been a tireless champion of IRC. In order to structure the open-ended notion of IRC, consider Figure 2. The IRC ladder (adapted by Chase & Pelkmans (2015) from OECD (2013) in Figure 2 has 12 steps. These steps become more ambitious when moving upwards. The lower six steps gradually become more involving, without however going as far as hard legal commitments. Nevertheless, much highly useful work is almost permanently conducted whether on technical classification of chemical substances, detailed analysis of taxation (without any obligation) or 'better regulation' analyses. When IRC becomes quasi-permanent (step 6) in some domains, mutual understanding and a-political approaches may well form a stepping stone for agreements or conventions. With step 7 (here, MRAs) modest obligations enter the arena. At stage 10 (mutual recognition, as applied in the EU), one enters the field of economic integration. Indeed, mutual recognition does not work without unquestioned and well-enforced free movement ³⁶. But even here the EU was eventually forced to enact two successive regulations ³⁷ in order to improve the actual functioning of mutual recognition for companies operating in the single market. Common regulation which does away with regulatory trade costs is covered only in steps 11 and 12. In other words, for world trade, steps 10 - 12 simply do not apply.

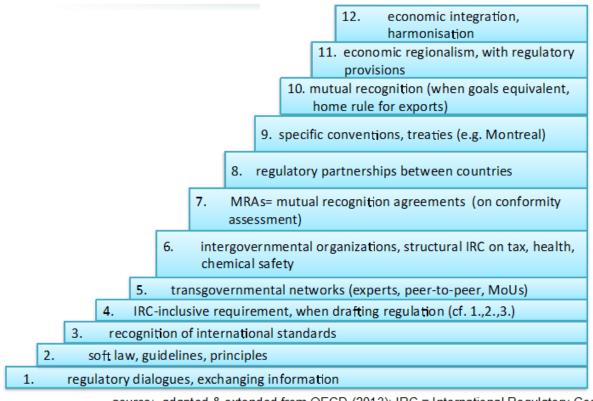


Figure 2: The ladder of international regulatory cooperation

source: adapted & extended from OECD (2013); IRC = International Regulatory Coop.

³⁵ Thus, as an example, massive and sustained cooperation, including IRC, in sustainable development (both 'green' and 'social') between the EU and China for over 20 years has been studied by Hu & Pelkmans (2022). We demonstrate that this extensive and intensive cooperation has exerted a positive, and at times stimulating, influence on bridging gaps in the two broad areas, leading eventually to greater convergence, also of regulation, between the EU and China.

³⁶ For detailed analysis see Pelkmans (2012).

³⁷ The latest one being Reg. 2019/515.

MRAs constitute step 7 in the (adapted) ladder of regulatory cooperation. All lower steps are voluntary in nature, though useful. The question is: how useful for lowering trade costs? If Disdier et al. (2019) are correct about legal enforceability of IRC initiatives as a condition to be effective – whilst noting that such IRC in their sample takes place in FTAs, thereby assuming a higher degree of trust – the lower 6 stages of IRC will not bring down regulatory trade costs more than marginally or very slowly. Step 7 on MRAs may help but the benefits tend to be highly goods specific and modest, if indeed they can be made to work. Step 9 (specific conventions) may be useful. This is in particular the case for MEAs although their meaning for trade differs enormously³⁸.

How do regional agreements fare nowadays with respect to IRC and the hoped-for lowering of regulatory trade costs? New initiatives in East Asian economic regionalism have recently been launched with CPTPP and RCEP. The latter is 'light' on anything that can be expected to lower regulatory trading costs. CPTPP is 'deeper' in several respects but unfortunately hardly in chapters on TBTs, SPS, 'regulatory coherence' and environment. International standards are encouraged. On SPS the agreement adds detail on cooperation, consultation and transparency, improves information flows with primary contact points and a duty to notify, emphasizes science and to discuss scope and findings of audits (customary in this type of regulation). These provisions are uncontroversial but add relatively little. The TBT chapter seeks to reduce 'unnecessary' NTBs without hard obligations - and improve access to information on technical requirements. Most of the firmer measures are in a series of Annexes but even these do not go far. The chapters on 'regulatory coherence' and on environment are also not very 'deep', be it that the environment chapter is subject to dispute settlement. In short, CPTPP is - as far as these four chapters are concerned - mainly about agreed IRC steps lower than step 7 (MRAs), with few hard obligations³⁹. The case of the US - nowadays outside East Asian arrangements and without more than a few tiny left-overs of TTIP - would seem to be even less promising nowadays, following Bull (2022), arguing that only an incremental approach to IRC might work. The author ends up advocating just four of the six steps below MRAs.

In contrast, the EU-27 and the EEA-3 operate on step 12 ('economic integration and common goods risk regulation, including verification'). In actual practice, also the UK is still applying this regime ⁴⁰ and the British Standards Institute has been allowed to remain a member of CEN/CENELEC. Moreover, the EU's strategy to conclude 'deep and comprehensive' FTAs entails the incorporation of selective MRAs (an ambitious example is CETA) and a range of lower IRC steps. These may include commitments (rather than encouragements) to use international standards in goods regulation where appropriate or specified. All these FTAs are a bit different but, on the whole, relatively ambitious with respect to IRC's steps. The following countries have concluded such FTAs with the EU: Ukraine, Moldova, Georgia, and candidate countries having an association agreement⁴¹, Canada, Korea, Singapore, Vietnam, Colombia, Peru, Chili, the Mercosur countries and New Zealand⁴². In 2018 the EU/Mexico FTA was upgraded "in principle", with a range of provisions to align standards and deepen bilateral regulatory cooperation. FTA negotiations are ongoing with Indonesia⁴³ and Australia.

³⁸ Thus, the relevance for trade is high for e.g. CITES (endangered species), the London convention (marine dumping of waste), the Montreal ozone protocol (with specific products), the Basel Convention on hazardous waste, the Paris agreement on climate change, the Stockholm convention on POPs and the Rotterdam convention on prior consent for trade in hazardous waste.

³⁹ Of course, there are other regulatory chapters that may well reduce regulatory trade costs, such as several services chapters and a special chapter on textiles and apparel.

⁴⁰ As a result of the UK-EU27 debate on the Level-Playing-Field, see e.g. Baldock, Lydgate, Pelkmans, Zuleeg et al., 2019.

⁴¹ The EU-Turkey customs union (although not a FTA) included. Its annexes incorporate a huge number of EU directives with specifics of EU risk regulation which Turkey has enacted at home. Although little noticed, this alignment has greatly promoted Turkey-EU goods trade and induced significant FDI in Turkey. Turkey has also adapted its regime of technical standards: its standard body is a member of CEN/CENELEC since nearly 15 years.

⁴² The FTA between the EU and New Zealand was concluded on 30 June 2022 and still has to be ratified by both partners. The negotiations with MERCOSUR were also technically finished in 2022 but it is widely expected that the ratification process will be difficult at best and likely to lead to further reforms.

⁴³ The EU/Indonesia talks are now dragging on for almost 10 years, despite the detailed technical preparation of a High Level Group coming out with an *unanimous* report in May 2011. [The present author served as co-chair of the HLG, together with Indonesian colleague Djisman Simandjuntak].

Some other negotiations with similar intent are stuck: Malaysia, Thailand, the Philippines, which is curious because the EU-27 and ASEAN have agreed in 2021 to strive for an EU-ASEAN FTA in the near future. The EU/India trade talks have been pursued as a stop-and-go process for more than one and a half decade, but in June 2022 EU/India FTA negotiations have been relaunched (despite some skepticism in Brussels, not least because India backed out of RCEP at the last moment). Although the EU clearly attempts to pursue a worldwide FTA strategy – with 'deep and comprehensive' agreements which would presumably help to reduce regulatory heterogeneity and its costs for trade – many countries are not yet covered, the two most important ones undoubtedly being China and the US. Even without a FTA with the US, a number of bilateral MRAs and other accomplishments ought to be noted, including an US/EU Veterinary Equivalency Agreement (1999). Josling and Tangermann (2015) caution that the practical effects of this agreement have been modest, for two reasons: (i) there is a ranking of equivalence per product and only the highest ranked products (a small list) benefit from this recognition (i.e. the exporter's measures suffice for the importing country); (ii) few products have been added later to those with the highest ranking.

The EU and China have concluded a few agreements (e.g. air services; GI products; customs facilitation) but a FTA (once proposed by president Xi when in Bruges in 2014) is not considered given the EU's prior conditions⁴⁴. All there is is a bilateral trade committee to address trade irritants on a regular basis. However, the EU and China have engaged in very wide and intense economic and technical cooperation for over two decades, stimulated by the summit, in trade issues, as well as in 'green' and 'social' aspects of sustainability. On the trade side there is no systematic or annual reporting⁴⁵; on sustainability and trade, Hu & Pelkmans (2022) have scrutinised the amazing and largely successful work. On regulatory heterogeneity and its trade costs, no systematic information would seem to be available and - as far as the author knows – not many new cooperation efforts are being undertaken other than environmental and climate related. With one exception: the EU and China have intensified cooperation on technical standards, with dedicated presence of CEN/CENELEC in Beijing, funded by the Commission. However, this bilateral cooperation hardly penetrates, so far, the standardisation work on the wide area of ICT technology as practiced routinely in ETSI⁴⁶ – in ETSI standardisation is typically driven by hi-tech companies and consortia of companies (see also section 6).

It follows that regulatory trade costs *ar* addressed in many ways throughout the world economy, both by trade negotiators and by national regulatory authorities, but almost without exception the efforts are not all that convincing. The approaches typically move barely beyond the lower steps of IRC and retain all the discretion that domestic regulators prefer. To what extent these efforts actually reduce regulatory trade costs is not known but great optimism seems not to be warranted. Moreover, as noted in ASEAN with a more-than-three-fold *increase* in NTMs in 15 years⁴⁷, for middle-income countries (and soon for low-income developing countries) the trend is that NTMs are bound to increase secularly for several decades as their income per capita rises. Such income growth causes the demand for risk regulation to increase secularly. This trend underscores the crucial importance of modest IRC complementing the TBT and SPS agreements at this stage in order to pre-empt countries to move in an adverse direction as far as non-tariff trade barriers are concerned. Nonetheless, these IRC modes do not really foster regulatory convergence in earnest, so such costs may well stay high. In transforming itself into the AEC – ASEAN Economic Community – ASEAN has now begun, hesitantly, to promote regulatory initiatives much higher up the IRC ladder as explained in Box 2.

⁴⁴ For detail, see Pelkmans, Hu, Francois et al (2018), providing an extensive analysis of all the main chapters of such a FTA. The conditions of the EU for such a FTA are spelled out on pp. 34/5.

⁴⁵ One might check the regular report on G20 measures, e.g. the one of 7 July 2022, see www.wto.org/english/news_e/news22_e/ report trdev_jul22_e.pdf as well as the EU market access portal: www.trade.ec.europa.eu/access-to-markets/en/home

⁴⁶ ETSI = European Telecommunications Standardisation Institute, established in 1988.

⁴⁷ See Ing, Anandhika, Cadot & Urata (2019), p. 91

BOX 2 – ASEAN's regulatory approaches to address TBTs

ASEAN has concluded the ATIGA Agreement for the 'free flow' of goods. ASEAN may conclude 'agreements', but it has also introduced 'directives' (a clear EU influence) although these are best interpreted as agreements as well. Enforcement is essentially up to the Member States themselves, with some soft (and not always public) peer pressure.

ASEAN avails of a few MRAs and some harmonised regulatory regimes. In 2019 there were MRAs for selected electrical/electronic equipment, for GMP⁴⁸ for medicinal products, one on bio-equivalence (forthcoming) and one on the inspection system for food hygiene for prepared foodstuffs (forthcoming). Two more MRAs were under preparation: one on type approval for automotive products (not cars as such) and one on building and construction materials. As to harmonisation, the early cosmetics directive, the electrical / electronic equipment regulatory regime and the medical device directive have been enacted. Under preparation were two agreements on harmonised technical requirements, one on technical medicines and one on health supplements. In some of these instances it would seem that GVCs incorporating ASEAN production sites but which have a wider scope over East Asia have been critical factors. Source of harmonisation: Doan, Rosenow & Buban (2019, pp. 21/2); see also Pelkmans, 2016.

Another example of gradualism based on IRC, drifting gradually to world technical regulations, is the UN-ECE WP 29 about vehicles and parts based on three UN Agreements. In the IRC ladder (Figure 2), it is found at step 9. The basis is the 1958 Agreement (which regulates car type approval and the mutual recognition of such national approvals), the 1997 Agreement on uniform conditions for technical inspections and the 1998 Agreement which allows a system of self-certification⁴⁹. Although this UN-ECE WP-29 began as a European venture, since 2000 it has turned into a genuine worldwide 'forum' as it calls itself. The EU has been a major stimulant to widen the effective membership, mostly via FTAs (e.g. Korea, Canada, Japan) and technical cooperation (e.g. India, China, US). Although it can hardly be surprising that worldwide car and parts standardisation (but in laws) would be beneficial for economic welfare, there is only one solid study, by Freund & Oliver (2015) estimating the economic benefits (for US/EU trade only). Their proposal is to accept that type approvals and the US self-certification (subject to checks by the regulator) ought to be mutually recognised for the simple reason that the level of safety is equivalent. Between the US and the EU, mutual recognition would bring efficiency, variety and innovation as well as a 20 % increase in bilateral trade. The authors suggest that this significant regulatory improvement would bring larger welfare gains than tariff removal!

A novel though select approach is IRC directly amongst the national regulators. There are two prominent examples: medicines and medical devices. In medical devices, a large and diversified sector subject to rapid technological change, there are two semi-global fora: the GHWP (Global Harmonisation Working Party) with 32 members especially from developing countries (and e.g. not the EU) and the IMDRF (International Medical Device Regulators Forum)⁵⁰, established in 2012 which explicitly aims to 'strategically accelerate' the processes of regulatory harmonisation and convergence of the GHTF, now renamed GHWP. The IMDRF focusses on global standards (such as ISO 13485), pursues a truly worldwide UDI⁵¹ (which by 2022 has largely been realised), a harmonised format for product registration submission and harmonise the regulatory requirements for medical devices intended for a particular individual. These regulators' fora - and especially the IMDRF –

⁴⁸ Good Manufacturing Practices.

⁴⁹ Essentially, because the US could not adopt type approvals, this being a very costly transformation; however, the US still does not adhere in detail to the practical implementation of the 1998 Agreement.

⁵⁰ Members are Australia, Brazil, Canada, China, EU, Japan, Russia, Singapore, South Korea, UK and US.

⁵¹ The Unique Device Identifier, for traceability in value-chains and e.g. for repairs and updates.

and their technical documents⁵² may directly facilitate world trade in medical devices and/or help to underpin the legal clauses and recognition in MRAs about these devices, without problems with regulators on both sides. Given the huge technological challenges in medical devices (such as AI applications, personalised implants, cybersecurity, interoperability and data integrity), the pressure on IMDRF will continue to generate deliverables of direct value to national regulators, patients and suppliers.

With respect to medicines, the initiatives have been spearheaded by OECD countries in the ICH, the International Council for Harmonisation of technical requirements for pharmaceuticals for human use⁵³. The ICH has four classes of Guidelines: quality, safety, efficacy and multidisciplinary. Thus, in the case of safety, 20 Guidelines have been agreed divided over 12 categories. Altogether, towards the end of 2022, a total of 137 Guidelines have been agreed over the four categories, up from around 50 in 2014. This agreed but voluntary setting controlled by regulators appears effective in reducing regulatory diversity. One specific accomplishment in saving (unnecessary) costs is the CTD (the Common Technical Document), a product of the multi-disciplinary Guidelines. With the CTD only one single file for the (heavy) approval process is required with all required data, ensuring acceptance in the US, the EU and Japan. This might be regarded as a partial substitute of the US/EU MRA. The FDA and EMA and/or the Commission and EU Member States have also developed a series of other instances of regulatory cooperation, such as inspection in 'active pharmaceutical ingredients' manufacturing, in change requests, paediatric medicines and alert systems and common formats in pharmacovigilance.

Noting the dynamism in these two heavily regulated sectors, it might be worthwhile reflecting about other sectors generating severe regulatory barriers and entice regulators to gear into action, without necessarily giving primacy to trade considerations.

It follows that regulatory trade costs *ar* addressed by means of IRC throughout the world economy, both by trade negotiators and by national regulatory authorities, but very often with the handbrake firmly on. The approaches move typically barely beyond the lower steps of IRC and retain all the discretion that domestic regulators prefer. To what extent these efforts actually reduce regulatory trade costs is not known but great optimism seems not to be warranted. Moreover, as noted with the example of ASEAN, for middle-income countries (and soon for low-income developing countries) the trend is that NTMs are bound to increase secularly for several decades as their income per capita rises. This trend underscores the crucial importance of modest IRC at this stage in order to pre-empt countries to move in an adverse direction as far as non-tariff trade barriers are concerned. Nonetheless, these IRC modes do not really foster regulatory convergence in earnest. The one shining exception is found in medicines and in medical devices where the regulators have taken things in hand, leading to convergence and facilitation (less red tape costs).

⁵² Guidance documents for the GHWP

⁵³ Initiated in 1990. See https://www.ich.org

6. Cost reduction via global technical standardisation

Regulatory instruments addressing risks in agriculture and industry frequently rely on standards. Standards are by definition voluntary, even though colloquial wording in some parts of the world often confuses standards and regulation⁵⁴. Regulation can comprise references to specific standards, as compulsory or as one of several options to comply. In case of a standard being used as a single compulsory option for compliance, the standard has been transformed into legislation and loses its defining character. But in the EU's New Approach⁵⁵ there are essentially two options: reliance on a 'European Harmonised Standard' (EHS) - which gives a right⁵⁶ to free movement – or a claim to fulfil the requirements of the relevant directive but in that case this must be explicitly confirmed by so-called Notified Bodies (EU-recognised conformity assessment bodies, regularly checked via EU accreditation). In the latter case – quite rare, in fact – the Notified Body will test and conform directly on the text of the relevant directive but likely also check the company's use of the European Harmonised Standard, which might be partly modified due to e.g. technical progress. However, because EHS cannot be prescriptive but are confined to setting safety or health thresholds (or minimum values or e.g. tolerances of materials), including for problematic materials, whilst leaving producers free to design the product as they deem fit, such EHS can accommodate many product specifications. Every five years these standards are checked for the need to incorporate technical progress.

However, standard setting is not the same everywhere in the world. This increases the likelyhood for numerous products that regulatory barriers emerge and remain, due to the standards they rely on. It is therefore of the greatest importance that countries can rely on *world* standards for SHEC regulation. The more world standards exist, and the more frequently countries refer to them in their risk regulation, the fewer regulatory barriers in goods market would exist. Dependent on the kind of standards, frequently the reliance on a world standard would also imply the test methods involved i.o.w. it would directly help (more) convergence in conformity assessment, too, as well as their possible mutual recognition. International standards are developed by ISO, IEC, ITU, the Codex Alimentarius, the OIE and the IPPC⁵⁷. These bodies have developed many standards and their accomplishments augment by the year. Very often their standards guide national laws or become minimum conditions of health (of humans, animals and plants) or safety. For ICT and electrotechnical products, their standards (may) combine safety and interoperability.

There are two central questions to be answered when assessing the importance and limitations of international standards.

6.1 Towards the primacy of international standard setting

One is how to reduce and eventually pre-empt national standard setting which is not based on or identical with international standards. In the past, many national standard bodies have developed technical standards without regard to international standards or, purposefully made them distinct for protectionist reasons. China is often mentioned which is correct, but many other countries were doing this in the past (e.g. Korea, Japan, Mexico). In the framework of (deep) FTAs, these discrepancies can be addressed. Of course, this may well augment the exposure of local business to external competitive pressure, and hence the speed of adaptation might be low. On the other hand, in a number of cases, participation in GVCs or solid export positioning or FDI abroad might be compelling

⁵⁴ The Annex to the WTO TBT Agreement clearly defines standards as voluntary (e.g. for business) and regulation as a legal instrument, with the normal enforcement.

⁵⁵ Nowadays called the NLF (New Legislative Framework) since 2008, adding greater sophistication to the system, especially conformity assessment and accreditation.

⁵⁶ Formally, a "presumption"

⁵⁷ ISO= International Standardisation Organisation; IEC = International Electrotechnical Committee; ITU = International Telecommunications Union; Codex Alimentarius (of the FAO) writes standards (often, max. residue limits for public health, also tolerances) in soil, water, the human body, etc. of chemical substances; see also FAO & WTO (2017), Trade and Food Standards, see www.fao.org/3/i7407e/i7407e.pdf; OIE = World Organisation for Animal Health; IPPC = International Plant Protection Convention and its secretariat.

reasons for change. In China's case standard setting long was a matter of the government; indeed, government control long seemed imperative and – in more subtle ways – probably still is⁵⁸. Following China's 2017 reform the technical influence of companies has increased considerably, but there is still no such thing as in the rest of the world: standardisation as independent technical work conducted by private non-profit organisations. The US has an excellent level of expertise but most of its leading standard bodies are based on a business model, rather than a non-profit institution, with considerable drawbacks. The most famous one is ASTM⁵⁹. Amongst the major standard setting countries the US is the only one allowing standards (on a specific issue) to be written by several bodies. In ANSI (the US organisation for standardisation) there is a powerful tradition – perhaps the better term is 'ideology'- of fostering a 'market' for standards. The strong conviction of practically all other countries that standards have a 'public good' nature (cf. Kindleberger, 1983) and that standards' issues and technical solutions ought to be resolved in the cooperative setting of the relevant body has still not fully swayed US standardisers. Also the commercial interest in maintaining its system throws up a natural impediment to readily accept world standards, the more so once the world system begins to grow in importance. To make it even more confusing, the leading US standardisers have begun positioning themselves as 'international' (as they do sell their more sophisticated technical standards to many manufacturing plants all over the world, mostly due to GVCs), although such standards have - in most cases - not passed the ISO /IEC procedures with inputs and votes from all over the world⁶⁰.

What is not often realised is that standard bodies promulgate numerous standards that are *not* connected in any way with risk regulation, yet they are, or can be, highly relevant for trade. For example, in the EU some 80 % of CEN (non-electric) standards are not EHS and need not be⁶¹. The share in CENELEC is lower because compatibility issues, and even interoperability at times, appear more often in CENELEC work, or, the core safety issue of electricity is similar for many goods, causing relevant EU directives (e.g. the famous Low Voltage directive) to refer to far more standards. Many standards are often used by international business and *distinct* standards for the same issue is seen as inefficient and unnecessary, even when risk regulation is not at issue! In GVCs such costly diversity may be resolved by a lead firm but for components which are sold outside the GVC as well it might still be problematic.

6.2 Organising for and promoting world standards

The other question to be answered is how best world standards can be promoted. The status of the six world standards bodies (see before) recognised in the Annex of the TBT Agreement (and in the main text of the SPS Agreement) has become entrenched in each and every relevant WTO meeting, in many FTAs, in recommendations of the OECD and e.g. APEC and in declarations of the International Chamber of Commerce. This constitutes a significant improvement compared to the pre-WTO period (before 1995). But the Annex to the TBT Agreement is long on principles, yet very short on programming or action plans. Fortunately this 'action gap' has been filled up to a large extent by Europe, in very close cooperation with ISO and IEC, as well as by ETSI for ICT, be it in a somewhat different context and technological environment.

⁵⁸ See Ruehlig (2020). It should be noted, however, that the pre-2017 standardisation system in China was overly complex, with 5 types of standards, with (too) many ministries involved, with (at times) conflicting standards at the provincial or local level and undue interference by not-so-knowledgeable bureaucrats.

⁵⁹ The technical reputation of ASTM (International) is beyond any doubt. For the EU the core problem is the incompatibility of the two standards systems. Recently, the OECD has published a positive report on ASTM – see OECD (2021), <u>www.oecd.org/gov/regulato-ry-policy/irc-astm-case-study.pdf</u>.

⁶⁰ But, for example, ASTM insists that it carefully follows all procedures giving stakeholders a voice, as is customary in world standardisation. See OECD (2021, op. cit.)

⁶¹ A simple example: two decades ago European steel companies and their wholesale buyers agreed that there were far too many types of steel bars, for historical reasons. This generated inefficiency in numerous building contracts. The CEN work resulted in 55 agreed steel bar standards, down from several hundreds.

The European strategy to promote international standards is indeed unique. In order to appreciate why the Europeans have initiated this 'internationalisation procedure', one has to remember that CEN and CENELEC were founded as European regional bodies of ISO and IEC in the early 1960s. It was only in 1985 when the New Approach was enacted – strongly based on EHS – that CEN and CENELEC began to promulgate European standards, both EHS and European standards not linked to risk regulation. However, the conviction that a strong link with internationalisation should be maintained never disappeared. In 1991 the first version of the Vienna Agreement was concluded (followed by newer versions later) between CEN and ISO, as well as the Lugano Agreement (followed by the Dresden and the Frankfurt Agreements) between CENELEC and the IEC. These Agreements pursue joint standardisation between Europe and the world level. The underlying motto is "One standard, one test – accepted everywhere". Both the Vienna and Frankfurt Agreements give practical effect to the basic guidance in the Annex to the TBT Agreement that international standards have primacy over regional and national standardization⁶². Normally, the ISO resp. IEC lead the entire process once the European standards bodies have formally expressed interest. Once the ISO or IEC and CEN and CENELEC resp. vote in favour (the ordinary scenario), the world standard will also become a European standard⁶³. In other words, standardizers from many non-EU countries participate and the chair may come from another continent, but this is - as a rule - considered irrelevant: what matters is the above motto (which drives out much inefficiency and uncertainty). ISO and IEC also claim that usually world standards are the best guarantee for quality, given the widest possible input.

For ISO the Vienna agreement has been very stimulating: when Vienna began in 1991, no more than 178 documents had been jointly developed between the ISO and CEN in order to avoid unnecessary duplication (and diversity); in October 2021 this had increased to some 5500! Overall ISO had developed (late 2021) nearly 24000 standards, hence some 23 % of these are identical to CEN ones. Seen from the EU end, some 34 % of CEN standards are identical to ISO standards. In IEC, given electricity safety, connection and compatibility requirements, the incentive to go for world standards is greater: no less than 4865 CENELEC standards are identical to IEC standards at the end of 2021, that is, some 74 % of all CENELEC standards, and another 6 % (411) standards are based on IEC, together no less than 80 %. For IEC this amounts to some 53 % of the stock of IEC standards in 2022, an impressive share. Here the EU truly leads by example and that example ought to be followed by all other members of ISO and IEC. It would further augment the stock of world standards and, for this reason alone, greatly contribute to lowering the costs of regulatory divergence, or, indeed, lowering the divergence directly. Informally, European standardizers have repeatedly suggested to China, for example, to conclude a 'Beijing' and a 'Shanghai' agreement (similar to the Vienna and Frankfurt agreements which work so well) with respectively ISO and IEC, which would signal a major improvement for world trade, and possibly stimulate other partners to join as well.

In telecoms and closely related ICT, ETSI plays a major role as well as a special role. First, one has to appreciate that the world level in these fields is formally represented by the ITU (International Telecommunications Union). However, unlike ISO and IEC, the ITU is an agency of the UN and hence made up by representatives of the countries. Although the ITU has become much less lethargic than a few decades ago – in response to the rapid technological progress in ICT – it is still mostly reactive, whilst acting as a formal global standardiser when relevant for regulation. ITU often sets prerequisites of new standards in a new technology or consortia, and/or some general conditions but the operational technical standards , based on the specifics of a given ICT technology, are usually generated by specialised consortia and, in turn, submitted to ETSI's relevant technical committee(s) for public inquiry and formal approval. Note that ETSI and the ITU have a tradition of MoUs which are deepened and widened every 4 or 5 years.

⁶² See <u>www.boss.cen.eu/media/CEN/ref/va_faq.pdf</u> and <u>www.iso.org/va</u> for Vienna; and <u>https://boss.cenelec.eu/fadel/pages</u> for Frankfurt.

⁶³ Note that this must imply that any (other or diverging) national standard in the 34 CEN-CENELEC member countries must be withdrawn.

ETSI, however, started in 1988 as an EU stand-alone organisation, split off from the then still prevailing state-owned telecoms system called CEPT⁶⁴. ETSI is not based on national standardsetting organisations, as are CEN and CENELEC, although some of these are members. ETSI members also include many companies, big and small and irrespective of origin, so indeed from no less than 65 countries of all five continents. In fact, individual membership is allowed as well. Thus, in actual practice, ETSI is strongly business -driven and global, although as a European standards body it applies all the openness and public inquiry required for EU-related standard bodies, insofar as EHS are concerned. However, in telecoms and closely related ICT EHS play a less prominent role than in electrical and non-electrical standardisation. All ETSI standards are publicly available and free-of-charge. Indeed, unlike in non-telecoms standardisation, this is customary in all telecoms and closely related ICT/internet standard bodies in the world. Nonetheless, EU societal stakeholders from consumers and workers find ETSI unbalanced when it comes to voting. Non-business voting is guite marginal for the large majority, namely, regular ETSI standards which de facto are world standards. The national standardisation bodies from Europe are involved either directly as ETSI members and/or via what are called 'national delegations'; this is also expected to be the channel of influence for consumers and labour unions as well as 'green' forces. Only for EHS - some 7 % of annual ETSI standards production - their influence is greater as voting is restricted to European delegations. All this is the result of the membership of many companies (often paying non-trivial fees linked to their turnover) from all over the world. Until recently, this was a problem the EU could live with. ETSI standards are anyway not so sensitive in terms of health, safety, environmental considerations or consumer policy (with only few exceptions). Only since a little over half a decade ago, aspects of security and privacy have become more preponderant, creating sensitivities for EU societal stakeholders and eventually even for EU political decision-makers.

However, from a world economic view, ETSI plays a highly valuable role because it is competent, forward-looking, often leading, open and truly global. In fact ETSI has come to fill a gap in this fastmoving telecoms/internet area (in a very wide sense) because it provides global leadership and initiative, often prompted by technological frontrunners in consortia, working with or inside ETSI. This is possible because ETSI work is typically bottom-up, guided by general traditions in standardisation. It has this characteristic in common with traditions in internet standardisation. Nevertheless, its organisation is considerably stricter than original internet standardisers as explained in Box 3. Now that significant convergence has taken place between telecoms and internet applications, the accommodation of "open" standard setting processes, which can easily be used wordwide, was and is crucial for ETSI too. Even though ETSI is far more organised and stricter, Box 3 should help to appreciate the more informal and open standardisation approaches about internet-related issues of three leading networks or organisations with a de facto global reach.

⁶⁴ In fact, CEPT had a much wider European membership than the EU-12 in 1988.

BOX 3 – Global and open standards generated by ICT networks

When ETSI broke loose from the rigid, national state-run telecoms traditions based on fixed telephony in 1988, the first internet standard called RFC1083 was agreed by the IETF (the Internet Engineering Task Force, born in 1986) as well. These two environments were completely different. The IETF never had members until today and all its participants are volunteers. A standard is created after a Request For Comments [RFC], and called 'internet standard'. The process is largely spontaneous: 'a specification undergoes a period of development and several iterations for review by the Internet community and revision based upon experience' (see <u>www.ietf.org.standards/</u>). This process of iterations is led by the rapporteur, also acting as arbiter. The IETF is still prominent today: it is best known from the internet protocol TCP/IP. In ETSI, there are 'national delegations' as members, plus many companies, big and small, from all over the world, plus a few societal stakeholders. The public inquiry follows the traditions of European standardisation bodies and the process is legalised, including voting. ETSI (like CEN and CENELEC) enjoys a conditional exemption from EU competition policy, and follows an EU-inspired policy on the use of IPR in the standardisation process, in particular with respect to SEPs (standard-essential patents). The numerous issues with SEPs cannot be discussed here but because - often - considerable money flows are involved, and because telecoms standards typically involve many SEPs, both collusion in patent pools and endless fights in courts create complications. As an illustration, in a recent empirical study by Bekkers et al. (2020), the starting point was a stock of 25072 patents, which was growing rapidly. The contrast between IETF and ETSI could hardly be greater. Initially, this was irrelevant. But once the convergence was setting in, it did matter. ETSI work began to rely more often on these highly informal open, free and global standards from IETF and others.

The World Wide Web Consortium [W3C], founded in 1994, is about web standards, protocols and design, including a range of programming languages. Its foundation was set up by MIT, the European Commission and the European organisation for Nuclear Research. It is now a global organisation. HTML is a well-known standard from W3C. Standards are mainly proposed by 'Chartered Groups' consisting of members and invited experts. The standards are freely accessible. Although there are members, the process remains rather informal.

Yet another influential organisation is the IEEE, a huge professional organisation of electrical/ onic engineers, first US based, today with more than 50 % non-US membership (some 423.000 from 160 countries). The IEEE deals with many other specialisations than telecoms – in 39 socalled 'societies' focused on a single area - and standard-setting is only one of many activities (e.g. it also publishes some 200 peer-review journals). The IEEE standards association has generated 2100 standards (including projects), with a spread over 175 countries (<u>https:// standards.ieee.org</u>). For activities covered by ETSI, the IEEE is best known for the Wi-Fi standard (as IEEE 802.11) which is regularly updated.

Given that ETSI covers many technological areas with still more technical committees, dealing with rapid technological progress in a 'converged' environment, standard-setting has predominantly become a bottom-up process. This tendency has been strengthened by the strong internationalisation of its membership and the innovative power of many consortia present. ETSI is also quite different from CEN and CENELEC in that ETSI writes fewer EHS (7% versus some 20 % in CEN/CENELEC) and that CEN/CENELEC standards are globalising but not in the extreme fashion as ETSI. ETSI has gradually developed an important position in telecoms and closely related ICT standardisation. An illustration is found in a comparison with the IEEE: the IEEE has a stock of 2100 standards, but these are not nearly all telecoms/ ICT-related, whereas the *annual* standard output of ETSI is around 2000, and *all* are telecoms/ ICT-related.

ETSI's very existence and gradually accomplished prominence may well have the effect of preempting the emergence of competing regional or national standards. Thus, ETSI is de facto no longer 'European' and basically accommodating many initiatives from anywhere in this fast-moving ICT world⁶⁵. Teubner, Henkel & Bekkers (2021) present an in-depth analysis of 100 ICT-related consortia, the large majority of which works closely with ETSI, as a group or via its leading companies. Many of these consortia are active as standardisers, but often bring in 'their' standards in ETSI for global recognition. Such consortia have members from all over the globe and these members may, in turn, be also a member of a range of other consortia, for reasons of (a new or specialised) technology, spreading risks with respect to frontier innovations, experience in writing standards, etc.

In telecoms and internet, global reach is critical given required interoperability of products, services and components. The European origin of ETSI is, strictly spoken, only important for the 7 % of its output of standards, which are EHS. Nowadays, the strategic position of ETSI is crucial however. Amongst the many activities, a well-known 'Partnership' is '3GPP' on future mobile telecoms systems such as 4G and 5G, shifting to 6G. 3GPP consists of 7 standard setting organisations including ETSI, and is organisationally embedded in ETSI. China (with CCSA) and the US (ATIS) are represented too, so are Japan (ARIB and TTC) and India (TSDSI). In other words, ETSI has been successful in actively promoting de-facto world standards in highly dynamic areas of telecoms technology and related ICT products, to the tune of more than 2000 standards a year. ETSI has proven to be highly adapable, given rapid technological change. It has proven capable of accommodating or incorporating many hi-tech consortia having sprung up about new technologies or special services⁶⁶. These vibrant consortia get a lot of leeway in ETSI - the bottom-up philosophy is real. And the final result is, more often than not, a stream of truly global standards. Regrettably, the European Commission has recently begun to criticise ETSI for its minimal regard of its societal stakeholders (a suggestion contradicted by ETSI) and for failing to base standardisation in, for instance, AI and surveillance technology on key 'values' such as privacy and security. Behind this friction is the perception of the too powerful position of Huawei in some ETSI technical committees (see also further). In 'Brussels', it is also felt that the long drawn-out misconduct of Apple in not respecting numerous patents from competitors and hence not paying or not paying fully the FRAND-based royalties, resulting from a conscious, aggressive strategy dating back to 2009/10, ought to be corrected in ETSI by a much tougher set of SEP obligations⁶⁷.

Finally, a word on the *control* of standardisation. Recently, it is frequently suggested – often in US business circles but recently even more vigorously in China - that 'who sets the standard, has the market'. Originally, this slogan referred to companies, not countries⁶⁸. If this slogan were applied to international standardisation by national standardisation bodies, especially by the bigger countries, it would spell disaster. China's recent standardisation strategy might suggest that the leadership expects international standardisation to be a 'winner' for them. However, standardisation has a long tradition of openness, open inquiry of drafts and merit-based decisions. Attempts of domination instead of cooperation are unlikely to succeed. Moreover, a standard is voluntary and imperial tendencies would be answered by non-adoption in markets. Nevertheless, it is held by some that China would be out to increase influence and control of international standardisation, based on this slogan. Some of the tactics employed by Chinese participants in world standardisation are indeed resisted, or, generate irritation, hence at times even harm Chinese companies ⁶⁹.

⁶⁵ See www.etsi.org for committees, technologies, standards, etc.

⁶⁶ See Teubner, L. et al. (2021) for detail on 100 such consortia.

⁶⁷ See f.i. Cohen (2020), Mueller (2022) and Apple's submission to a consultation by the Commission's DG Enterprise on 14 Febr 2015 see <u>www.apple.com/legal/intellectual-property/frand/Apple-inc-Submission-to-EC--Public-Consultation-on-Patents-and-Standards.</u> <u>pdf</u>. Note that Apple's interpretation of ETSI IPR policy (in Art. 6.1) in the OPTIS vs. Apple case was dismissed by the Court of Appeal in Oct. 2022. In fact, Apple submitted 1751 late SEP declarations to ETSI.

⁶⁸ It is often suggested that the founder of Siemens asserted this over a century ago.

⁶⁹ See Bruer & Brake (2021) for examples of blockvoting (by Chinese companies), thereby defying the choice on the merits. Other tactics include e.g. 'patent stuffing', i.e. salvo's of patent proposals which are often not novel or not more than very marginal, presumably more a result of the domestic pressures in China to show active attempts to pursue the line of the leadership.

At the moment China invests far more in world standardisation than before but that would seem like catching up rather than an attempt to control. One has to recognise, moreover, that China is home to some 18 % of the world's population, with a share of world industry which is still higher. Therefore, it would seem to be a natural development⁷⁰.

Nonetheless, as noted, it would seem that the European Commission is resisting the increasingly dominant role Huawei plays in ETSI committees on mobile technology. Often Huawei can do this as a result of its deep investsments in mobile technologies (esp. infrastructure) and standardisation. Of course, Huawei is not alone in mastering expertise in 5G. Both Ericsson and Nokia are leading players too. But unlike in the case of the two Scandinavian companies, the Commission fears have to do with security issues in Huawei's technology and with privacy protection, especially with respect to AI. It insists that ETSI ought to incorporate or impose strong safeguards in this respect. For ETSI, this creates a severe dilemma: either such safeguards are proposed for ETSI work, but this might be pre-empted or overruled, or, such safeguards are incorporated in EHS about mobile technology (e.g. 6G) but in that event, the European harmonised standard is no longer global and a parallel semi-global standard might emerge somehow. The latter is not only costly – although one might take the view that that is worth it – but it might tend to encourage China (and possibly others) to seek alternatives for ETSI which might be much more costly in the longer run. Moreover, it might also slow down standardisation.

There is nonetheless one category of standards where cooperation is not always practiced. For 'network compatibility standards', compatibility if not interoperability is essential. This agglomeration of subsectors and of advanced services largely overlaps with the domain of ETSI. If such standards are pushed by individual companies (so-called 'non-cooperative standard setting') in an innovative setting and succeed in attracting a strong customer base, there will be special cases where 'winner takes all' (see e.g. Padilla, Davies and Boutin, 2018, for an authoritative survey). It should also be taken into account that these are typically the advanced sectors where royalties or other patent payments have become very important. The conduct by Apple might well be explained by its former tradition of non-cooperative standardisation in computing, whereas interoperability in modern telecoms renders such a strategy impossible – Apple might simply have decided to hold out as long as possible, having observed the weaknesses in the SEP regimes.

China has publicly spoken out in favour of 'autonomy' in order to avoid paying many billions of dollars yearly for using 'standard-essential patents' [SEPs] in subsectors of wireless and some other ones. Only recently, with China catching up, such costs tend to reduce with cross-licensing, FRAND-based or not. Moreover, some cases in Chinese courts have disrespected SEP stacks, thereby lowering their value dramatically. Given the way China seeks to further industrialise based on Manufacturing China 2025 with selected heavily subsidized advanced sectors, and given that it happens to dispose of a large home market (which can be protected or distorted in favour of Chinese winners), then the standard might sometimes 'have the market' [or, perhaps more precisely, be handed over the market]. If that were to happen, one query is how open the standardisation process will be, and in addition whether and how all this would lead to regulatory trade costs for world trade? Would that standard also be pushed in global standardisation consortia or the technical committees of ETSI? What if global standardisation gets fragmented in such cases? However, in an area where all this plays a role – telecoms and digital - China (via CCSA) has not yet acted this way: its companies have joined and are active in 3GPP, together with ETSI and 5 others ones. It is also active in other consortia. Because ETSI also comprises leading hi-tech companies, it remains to be seen whether and how China's strategies would eventually opt for fragmentation and how that would play out. However, in 2023 the more probable risk is that the EU, thus far the unguestioned promotor of global ICT standards, might force 'value-based' safeguards, related to privacy and security, unless some set of compromises can be found.

⁷⁰ Although Bruer & Brake (2021) do discuss attempts to manipulate standards processes, the authors also find many measures of greater Chinese influence either not worrisome or indeed a natural development.

7. Conclusions

The benefits of risk regulation have significantly improved socio-economic welfare in OECD countries, increasingly so in middle income countries, too, and will gradually do so in developing countries in tune with rising incomes per capita. At the same time, the consequences for international trade tend to be costly. Given recent empirical research on these regulatory trade costs, there is no doubt about the urgency to effectively address these costs in world trade.

The present survey of what is actually done to effectively lower regulatory trade costs in the world economy demonstrates that there is a desire to work together, but usually without more than relative light commitments whilst retaining almost all discretion for regulators. One may usefully distinguish trade in economic integration groupings which routinely pass joint risk regulation measures and ensure enforcement in common, from groupings which recognise the problem but find it difficult to move beyond non-commital forms of IRC. The former consists only of the EU27, the EEA3 and probably the UK (for goods). More selective but still quite ambitious regulatory alignment is found in (EU) association countries and a few FTAs with the EU27, because these countries are all eager to have the best access to the EU single market. The OECD advocates IRC to its member countries and publishes regularly policy studies showing the potential of IRC to lower regulatory trade costs. However, in many important (other) bilateral and regional trade relations, regulatory trade costs are rarely addressed, let alone effectively. Only ASEAN's AEC has recently begun to pay attention, but still only very selectively.

In world standardisation, a field too often neglected, a silent evolution is taking place. The standardisers all over the world have gradually come to de-emphasize national standardisation and shifted to international or regional (but often based on international) standards. Most conspicuous is the EU's strategy to give primacy to the writing of world standards. The results are stunning: by now some 34 % of CEN standards are identical to world standards of ISO, whereas some 80 % of CENELEC standards are identical to or based on world (IEC) standards. Even more impressive is the work conducted in ICT, broadly defined. The large majority of ETSI standards (writing as many standards annually as CEN and CENELEC together) are de facto acting as world standards in ICT. Although ETSI has a clear EU origin, it has gradually developed into a highly flexible global ICT network with leading companies in its committees (from 65 countries in 5 continents). In a very different field, where regulations instead of standards are relevant, namely cars and parts, the EU has made great efforts to convince other countries to adhere to the UN-ECE WP29 agreed regulations, and this has had some results, be it that the US still has to implement the 1998 Agreement and China is still adapting to it. In some specific cases of risk regulation (e.g. medicines and medical devices), regulators in the world have formed informal conferences able to agree on common specifications, procedures and 'guidances' which often find their way into laws and decrees, or other relevant applications, ensuring the lowering of regulatory trade costs step-by-step.

All-in all, the overall conclusion is mixed: there is an incredible amount of talk in many trade committees and bilateral and other trade policy meetings tend to be full of elegant wording without commitments. But there are also elements of progress, between regulators, here and there between trade negotiators and amongst standardisers at world level, especially in ICT but increasingly also in electrical and non-electrical standardisation. Greater urgency is badly needed and actors should be more ambitious than just 'hastening slowly'.

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Annex. Some explanations of Figure 1

In Table Ann.1 one can find current tariff levels -WTO-bound and applied - of 14 selected WTO trading partners, all populous countries (except perhaps Canada) and/or important traders. For OECD countries, the applied tariffs for 'all goods' is always low, here ranging from a simple average of 3.4 % to 7.5 % for Mexico, and South Korea with 13.6 % as an outlier. For medium-income countries such as China (7.5 %).

WTO Members	Simple averages, all goods		Simple averages, agricultural goods	
	bound	applied MFN	bound	applied MFN
Brazil	31.4	13.3	35.5	10.1
Canada	6.7	4.0	16.1	15.9
China	10.0	7.5	15.7	13.8
European Union	5.3	5.2	12.6	11.7
India	50.8	18.3	113.1	39.2
Indonesia	37.5	8.1	47.5	8.7
Japan	4.6	4.2	18.4	14.9
Korea (S.)	18.3	13.6	64.9	56.8
Mexico	36.5	7.5	46.4	13.5
Pakistan	96.6	60.8	96.2	13.4
Philippines	25.9	6.1	35.4	9.9
South Africa	19.0	7.8	39.0	8.8
United Kingdom	5.3	3.9	12.5	10.0
United States	3.3	3.4	4.5	5.2

Table A1: 2021 tariff levels (6 digits), selected countries

Source: 2022 WTO Tariff Profiles; columns 2 and 3 give the share of HS subheadings (in %) for all goods; columns 4 and 5 give the share of HS subheadings for agricultural goods only

South Africa (7.8 %) and Brazil (13.3 %) simple averages are somewhat higher, whereas for developing countries averages may well be higher still (e.g. India with 18.3 %) but not always (Indonesia 8.1 %; Philippines 6.1 %). Only Pakistan's simple average is very high: 60.8 %. Table 1 also includes simple averages for agricultural goods. These are higher than for 'all goods', except in the cases of Pakistan (a striking 13.4 %) and Brazil (10.1). Assuming that bound tariffs have basically become negatiation tariffs, it is reasonable to focus on applied WTO tariffs. For all goods, these tariffs range between 3.4 % and 8.1 %, for 11 of the 14 trading partners, with Brazil, India and South Korea being in the 13.3 % to 18.3 % range. For agricultural goods, the tariff levels are quite different: only four countries have averages below 10 %, and three of those four are developing countries! The other countries range between 10 % and 15.9 %, plus two outliers: India (39.2 %) and South Korea (56.8 %).

An imperfect but nonetheless helpful underpinning of the proposition that regulatory trade costs are high can be provided with the help of tariff-equivalents of the costs of regulatory barriers. This will be done with two examples: one is between the US and the EU when preparing for the TTIP negotiations, and the other is drawn from recent work about ASEAN countries.

Berden & Francois (2015) carefully compare four empirical studies, one with two distinct approaches, of the AVEs⁷¹ of the US and the EU-28 just before 2013. AVEs are like fictitious tariffs, reflecting the regulatory costs of market access when exporting from country A to B. The studies use different methodologies and have dissimilar sector coverages. As a result, the estimated AVEs differ significantly between the studies. First, the total averages for EU/US: 49.6 /49.5; 17.7/17.5; 41/42.2; 17/18.7; 16.4/18.1. These averages are much higher than average applied MFN tariffs in Table 1, even for the lower AVEs⁷². For agriculture they range between 15.8 % and 51.3 %⁷³, but subsectors such as bovine meat and fruits and vegetables reach up to 80 %. The totals for manufacturing are between 32.3 % and 42.8 %. Interestingly, for machinery, a sector where conformity assessment has led to frictions between the US and the EU, the highest AVE is 6.2 %, whereas pharmaceuticals reach as high as 29 % and processed foods even 73.3 %! In services the range goes all the way up to 47.3 %, but starting from 8.5 %. Of course, in services there are no tariffs in the first place.

ASEAN has long hesitated to begin addressing regulatory trade costs⁷⁴ but has meanwhile built up a database with the help of international economic organisations. Literature is expanding quickly but – for present purposes of illustration of the importance of regulatory trade costs – two results are mentioned here. First, ASEAN countries differ but are mostly medium or low-medium income countries (except for Singapore and Brunei). For this category of countries, the demand for risk regulation of goods and services can be expected to rise during a few decades, which in turn is likely to push up regulatory trade costs rapidly. Data confirms this in a striking manner. Between 2000 and 2015, NTMs have increased from 1634 to no less than 5975, by some three-and-a-half times. Nearly 70 % of these NTMs consists of risk regulation by means of TBTs and SPS (Ing, Anandhika, Cadot & Urata [2019], pp. 91-93). It is also likely that - for some instances of risk regulation – the costs per regulatory measure increases over time, as the stringency of requirements and/or enforcement goes up as well. In other words, ASEAN's steady reduction of tariffs to zero for other ASEAN countries notwithstanding, there is a serious risk that intra-ASEAN market access has become more costly, not less, despite tariff decline. Suc an upward trend may well occur for another one or two decades. In other words, regulatory trade costs matter a great deal for ASEAN.

How rapid such trends may increase further is illustrated by Doan, Rosenow & Buban (2019) studying the further trend from 2015 to 2018 in ASEAN: in this short period another 218 SPS measures and 519 TBTs were notified. Second, authors (e.g. Ing & Cadot, 2019) struggle with the estimation procedure to identify AVEs and operate on a two-digit product basis (indeed, much like in the survey of Berden & Francois, op, cit.). Such a high level of aggregation tends to lower the aggregate AVEs; instead, risk regulation is often highly targeted at the 6 or even 8 digits level and might, selectively, well have higher costs. For SPS measures AVEs in ASEAN vary between 3.7 % and 16.6 %, in many instances higher than applied tariffs. At the sectoral level, for animal products, AVEs range up to 21.2 % (Thailand) and for fats and oils up to 38.8 % (Vietnam). For most TBTs AVEs in ASEAN are much lower, from 2.8 % (Cambodia) to 5.7 % (Indonesia). For automobiles and parts and for the textiles sector, however, AVEs range up to 12.9 %75. All of this has to be read against today's intra-ASEAN tariffs of (next-to) zero and vis a vis non-ASEAN trading partners – ASEAN countries' applied MFN tariffs for all goods ranging from zero (Singapore) to 11.5 % (Thailand), and for agricultural goods from zero to 12.6 % (Cambodia), plus two outliers (17.1 % for Vietnam and 31.4 % for Thailand). Thus, only selectively, external agricultural tariffs do matter still. For the rest, AVEs of regulatory trade costs will often dominate. Moreover, the RCEP and - for 4 ASEAN countries - CPTPP as well as a few FTAs have eroded the applicability of ASEAN of ASEAN countries' external tariffs.

⁷¹ AVEs refer to 'ad valorem equivalent' of the costs of accessing the market via trade due to regulatory differences. Sometimes the term TCE (trade cost equivalent) is employed.

⁷² For the lower AVEs, India has the same level and Pakistan is an outlier.

⁷³ In Table Ann.1, in column 5, 11 of 14 economies show simple average applied MFN tariffs for agricultural goods *lower* than the lowest AVE; Canada is equal, and India (39.2 %) and South Korea (56.8 %) are outliers.

⁷⁴ Dating back to 1987. For background, see Pelkmans (1987).

⁷⁵ All results from Ing & Cadot, op. cit.

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