

# RESPONSE TO THE PUBLIC CONSULTATION FOR THE EUROPEAN COMMISSION'S WHITE PAPER ON A EUROPEAN APPROACH TO ARTIFICIAL INTELLIGENCE

Nigel Cory | June 12, 2020

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## INTRODUCTION

The Information Technology and Innovation Foundation (ITIF) welcomes the opportunity to provide this submission to the European Commission (EC) in response to its white paper *On Artificial Intelligence: A European approach to excellence and trust* (referred to herein as ‘the white paper’).<sup>1</sup> ITIF continues to appreciate the opportunity to engage with the European Union (EU), the EC, European parliamentarians, and member states on how to support the EU’s digital economy, innovation, and international trade.

Our submission focuses on the whitepaper’s proposal for an ex ante conformity assessment framework to verify and ensure that certain mandatory requirements applicable to high-risk applications of artificial intelligence (AI) are met and how this would act as a barrier to trade. In addition, ITIF’s Center for Data Innovation is separately submitting a response that details issues with the impact that the white paper will have on innovation.

## OVERVIEW: DESPITE THE INTERDEPENDENCES OF AI, EUROPE DECIDES TO GO IT ALONE

The white paper’s introduction mentions the fierce global competition for AI advantage, one that it wants to be based on European values, yet it fails to recognize the likelihood that a new restrictive conformity assessment framework is likely to further undermine the EU’s position.<sup>2</sup> Europe is already struggling in this race. As the Center for Data Innovation’s report *Who Is Winning the AI Race: China, the EU or the United States?* shows, the United States leads the global race for AI, with China in second, and the EU lagging behind.<sup>3</sup> At the heart of this race is the ability of people and firms to engage in data-driven innovation. Yet, similar to the General Data Protection Regulation (GDPR), the proposed AI conformity assessment framework imposes a constraint on the use of new AI-based technologies that will be developed in significant part by non-Europeans, rather than focusing on supporting the actual development of data-driven innovation. In contrast to Europe, China has created a vast, protected domestic market and extensive government support mechanisms, including a concerted effort to help its tech firms and their products and standards go global.<sup>4</sup> China’s efforts to influence global standards builds on its firms’ ability to develop these new technologies, not the other way around. The same for the United States.

The whitepaper’s central problem is twofold. First, the EC is rushing to apply the precautionary principle—the idea that innovations must be proven safe before they are deployed—based on the widespread but incorrect beliefs that there is something inherently suspect about the technology, that organizations will have strong incentives to use the technology in ways that harm individuals, and that existing laws are insufficient to effectively oversee the use of this technology. Indeed, fears that algorithms could exhibit and exacerbate human bias, including facilitating discrimination and exploitation, have dominated discussions about how policymakers and regulators should treat algorithmic decision-making.<sup>5</sup> But the likelihood of these risks coming to fruition is often overstated, as advocates incorrectly assume market forces would not prevent early errors or flawed systems from reaching widespread deployment.

Moreover, it is early days, as policymakers, academics, and experts from around the world discuss the best approach to the governance of AI. Many proposed solutions are a poor fit, inadequate, and/or ineffective.<sup>6</sup> There may well be a role for some government-designed or approved process to test certain applications of AI in various sectors. Whether conformity assessments can work for AI in a way that relies on the same legal system and testing infrastructure that the EU applies to the product safety testing of physical goods, like toys, raises significant questions regarding practicality, viability, and technical application.<sup>7</sup> For all of these reasons, it's a mistake for the EC to rush ahead and enact a framework without much more research and extensive, proactive international cooperation.

Which raises the second major problem with the whitepaper: The EC does not seem inclined to recognize that AI creates interdependencies with other countries.<sup>8</sup> This should make cooperation with broadly like-minded partners a necessary prerequisite (not an afterthought or minor component) in terms of developing a regulatory framework that addresses shared policy goals, while supporting each country's firms' ability to innovate and trade as part of global production networks and value chains (both of which are increasingly services and digital intensive). The white paper states that the EU "will continue to cooperate with like-minded countries, but also with global players, on AI, based on an approach based on EU rules and values (e.g. supporting upward regulatory convergence, accessing key resources including data, and creating a level playing field)." Yet this is hardly reflected in either the whitepaper or in recent policies.

The whitepaper states that the EC "will closely monitor the policies of third countries that limit data flows and will address undue restrictions in bilateral trade negotiations and through action in the context of the World Trade Organization (WTO)."<sup>9</sup> Even if well-intentioned, an ex-ante conformity assessment framework would do just this.

The proposal, whose design is presumably founded on the EU's New Legislative Framework and its approach to standardization (outlined in Regulation No. 1025/2012), reinforces the EU's regional—and not global—approach to standards and conformity assessment in that it advantages its own intra-regional regulatory standards and a select, designated group of European standards bodies, with a secondary, more limited and onerous lane for firms and products that use a body or standard from outside Europe.<sup>10</sup> In addition, for those AI products that require a third-party test, the EU legal framework limits these to designated bodies ("notified bodies") located in the territory of an EU member state. With respect to localization requirements for testing bodies (i.e., non-recognition of testing reports from international conformity assessment bodies), this is precisely the kind of localization barrier to trade that the EC advocates against in forums like the WTO. Its application to new technology stands to exacerbate its negative impact on trade and interoperability.

Such Europe-specific conformity testing for data-driven applications represents a mechanism for localization and discrimination between local and foreign firms and their digital products. For example, in the context of foreign AI developed by firms in authoritarian countries (presumably China and Russia), Commissioner for the Internal Market Thierry Breton said manufacturers could be forced to "retrain algorithms locally in

Europe with European data,” adding that “We could be ready to do this if we believe it is appropriate for our needs and our security.”<sup>11</sup> This is a slippery slope to rush down. The EC should also be aware of the risk that in the future its own firms will likely be affected as other countries copy-and-paste and repurpose the EU’s own rushed approach in enacting their own opaque and arbitrary conformity assessment frameworks for AI. Ultimately, the spread of these frameworks will act as a barrier to the development of a more productive and innovative global digital economy given the central and growing role of AI.

The EC is obviously within its rights to determine what regulations it wants to enact in pursuing its legitimate policy goals, however, as with all domestic regulation and trade issues, this must be proportionate and nondiscriminatory so that it doesn’t act as a barrier to trade. The conformity testing framework will almost certainly reduce trade both in the extensive margin (the decision by exporters to enter a market) and the intensive margin (the quantitative decision of how much to export). Trade policy research shows how different and incompatible regulations across jurisdictions, however slight, can impede trade in goods and services. The time and money firms invest in abiding by differential testing processes can be significant, especially for small and medium-sized firms. Differential regulatory requirements have proven costly with traditional trade in physical goods. Expanding this to digital economic activity (where the distinction between goods, services, and even processes is unclear in the EU’s proposal) creates a whole other realm of potential trade disputes given it involves far more dynamic and complex technologies and assessments.

The proposed institutional framework for administrating this framework is equally problematic in how it outlines a new horizontal regulatory framework will lay on top of respective sectoral regulations and enforcement agencies at the EU level and in each member country. Creating or designating completely new agencies or offices, competencies, and coordination mechanisms is costly and complicated.<sup>12</sup> It also presumes the competency and appropriateness of notified bodies—many of which are private sector entities that have been formally designated by competent member state authorities and the EC—to carry out the assessment of high-risk applications of AI (however this is ultimately defined and applied that looks like).<sup>13</sup> This is exactly the issue that arose in the context of the Medical Devices Regulation/In-vitro Diagnostics Regulation (MDR/IVDR) Roadmap (explained in a case study below), where not only are there insufficient standards, but insufficient EU-based testing capacity. In this way, the whitepaper fails to learn some key lessons from the region’s recent experience in enacting similar new regulatory frameworks.

The EU’s Executive Vice-President Margrethe Vestager stated that an assessment will be made in the future as to whether this approach is effective or not.<sup>14</sup> The EC would be better served to fundamentally reconsider its conformity testing-based approach to regulating AI and instead work with like-minded partners on the best approach to address shared concerns about AI in high-risk sectors. If it does proceed with a conformity assessment framework, the EC should at least consider the international impact from the start, along with details about how it will build mechanisms for regulatory cooperation and interoperability (whether these are government-to-government or global, industry-driven, voluntary consensus standards).

Unfortunately, in this the whitepaper EU disregards careful policy development in rushing to seize what it thinks will provide it a first mover regulatory advantage on digital issues; all to the detriment of its local firms and economies and international trade and the global economy. But Europe shouldn't focus on being first with new digital rules, it should focus on creating and implementing rules that allow AI-driven businesses and innovations to flourish in Europe, and in other likeminded nations that embrace the principles of rules-governed, enterprise-led, market-based trade. European policies should be designed to enable and promote health and robust competition in digital industries, for doing so will have a powerful effect on promoting European productivity and economic growth.<sup>15</sup> The rush to regulation and implementation, without waiting on international discussions on AI and standards to evolve, indicates that the EU is willing to use AI regulation as a protectionist and expansionist strategy rather than building bridges between common approaches that each address shared public policy interests. Following on from previous regulations such as GDPR, the EU is determined to set a standard to define what "good" AI regulation is, but this strategy risks not achieving the actual objective, while impeding innovation, competitiveness, and trade for itself and its partners.

The submission analyzes a number of these issues in detail and then provides recommendations, as follows:

1. It explains how the regulation of AI does not fit well with ex-ante conformity assessment frameworks. It explains how using existing conformity assessment frameworks (for cybersecurity and marketing products) as a model for AI is neither desirable nor fair. To substantiate this, it includes a case study of how the EU's recent experience with implementing the MDR/IVDR roadmap provides many relevant lessons for the EU as it contemplates a conformity assessment framework for AI.
2. It looks at how ex-ante conformity tests for AI would become a new non-tariff barrier to digital trade.
3. It analyzes how limited access for conformity certification is a barrier to market entry, one which the EU and the United States have already had to deal with in other sectors.
4. It looks how conformity assessments raise the prospect of mandatory source code disclosure, which is another potential barrier to trade.
5. It provides three main sets of recommendations: one focuses on core issues to consider as part of its policy debate moving forward; a second on the steps to build a truly cooperative and internationally accessible approach to AI regulation; and a third that outlines the need for international cooperation on developing standards for new and emerging technology with trading partners that share its values.

## **1. AI DOESN'T FIT WELL WITH EX-ANTE CONFORMITY ASSESSMENT FRAMEWORKS**

The white paper requires "an objective, prior conformity assessment ... to verify and ensure that certain of the ... requirements applicable to high-risk applications ... are complied with." These ex ante reviews would be mandatory for all developers and deployers of high-risk AI systems, "regardless of their place of establishment." These assessments might need to be "repeated" in the case of AI systems that "evolve and

learn from experience.” If the AI system does not satisfy “the requirements relating to the data used to train it,” the remedy might be “re-training the system in the EU.” The whitepaper also calls for “competent authorities” to not only investigate individual cases, but also to assess the impact on society.

This section analyzes two key concerns:

- The challenge to develop a completely new criteria and standard (no comparable approach exists) for notified bodies to use to test AI—a dynamic technology, that may be a product, service, or process—in high-risk sectors (where a third-party certification is required). These criteria would need to be clear and detailed so that firms could build towards the final harmonized standard—no easy fit for AI; and
- The challenge to set up a sound institutional framework, especially regarding the needed mobilization of competencies and capabilities of member states’ oversight agencies and notifying bodies, and the process to designate and certify notifying bodies. The whitepaper seems doomed to repeat many mistakes the EC has already encountered when creating similar frameworks for other harmonized standards in the EU. It also doubles down on localism, by promoting the use of Europe-based testing bodies, which is inherently discriminatory to foreign firms and products.

The big question that looms over the EC’s strategy to use conformity testing for AI is how, or whether it’s possible, to come up with tests and criteria for dynamic technologies and risks and for notified bodies to administer these efficiently and effectively.<sup>16</sup> For example, conformity testing for a dynamic, learning AI system does not lend itself to the paper’s proposal that firms provide a static snapshot of information about the AI’s capabilities and limitations, the conditions under which they’re intended to function, and the expected level of accuracy. The criteria and benchmark that authorities will use in certifying AI as “safe” is a huge unknown. These would need to be made clear (in EU harmonized standards and for alternative pathway assessments) to firms so that they would have something to build and test toward. But this is extremely difficult. By what measure could AI be assessed as having a negative impact (for example, on demographic minorities) and how would firms determine that a dataset used to develop this AI is biased? Notified bodies will be tasked with making very technical assessments about AI applications as well as broad assessments aimed at determining whether an AI application does or does not have a negative impact on society. Who will be involved, and what criteria will they use, to make such a broad socio-political assessment?

The whitepaper also raises major questions about the capacity and technical competency of the conformity testing bodies (the notified bodies), oversight agencies, and national accreditation bodies to do the actual certification, designation of competent laboratories, and accreditation currently required under EU law, respectively. This involves complex reviews of both the algorithm and the datasets used to develop it. Local authorities, national accreditation bodies, and competent notified bodies would need to understand the programming and training methodologies, processes, and technologies to build, test, and validate AI systems.

It takes specific expertise in programming and statistics to evaluate the fairness and robustness of AI models and to try to suggest remedies should an issue be identified. And there can be tens of thousands of algorithms developed every year. How exactly are EU bodies supposed to keep up with this? What if there are regulatory backlogs (which are likely)? Does this mean developers would have to wait to come to market, ceding potential advantage to foreign competitors?

All these concerns will simultaneously play out in each EU member state, given each may be responsible for designating and overseeing notified bodies within their territories. The whitepaper states that: “Europe equips itself progressively with the capacity needed for testing and certification of AI-enabled products and services.” But the rush to establish a framework is in direct conflict with the need to ensure testing is done consistently and is based on clear guidelines

As the case study below on Europe’s updated medical devices regulations shows, building this type of capacity and competency represents a tremendous challenge. This challenge only gets harder given it would also require extensive coordination between conformity testing bodies and other domestic and regional agencies involved in certain issues where there is regulatory overlap. This highlights the risk of costly duplicative regulatory requirements given existing structures for finance, pharmaceuticals, aviation, medical devices, consumer protection, and data protection. There’s also the potential for different notified bodies and EU member states making differing conformity assessment determinations (as would inevitably be the case), which leads to a patchwork of regulations for AI across Europe.

Fortunately, the whitepaper recognizes that some of its requirements don’t fit well with conformity testing. This could signal a recognition that the EC is open to holding extended, detailed discussions with all stakeholders on these issues before proceeding. There may be a way to come up with a clear, objective criteria for notified bodies, under the purview of national accreditation bodies and notifying authorities, to test AI applications. But the EU needs to factor in a lot more time for discussion and research.

Moreover, the entire focus is based on a faulty premise: currently the EU does not regulate software (except as described below for security), it regulates the use of the software in certain applications. AI is no different. The regulatory focus should not be on AI algorithms, it should be on areas of EU society and economy that elected officials charge regulators with crafting regulations to protect the public interest. Whether the software is capable of learning or not should be irrelevant.

### **Existing Conformity Testing Frameworks for Cybersecurity, Marketing Products, and Medical Devices are Not a Good, Nor Fair, Model to Replicate**

The whitepaper implies that the framework would be based on existing arrangements, explicitly referring to two key models: Decision 768/2008/EC and the Regulation (EU) 2019/881 (Cybersecurity Act). The EC should not adapt or replicate existing conformity assessment frameworks (for testing, inspection, or certification) for any potential AI-focused system as these are inherently discriminatory in how they preference

local standards and testing centers. The EC should learn the lesson from the frameworks it references as models and avoid making the same mistakes in a new AI-focused system.

These existing models raise several issues:

- Can the EU and its members design and apply clear, objective, and harmonized standards to test dynamic technologies that involve dynamic outcomes, risks, and threats, such as with cybersecurity and AI?
- Existing frameworks are inherently discriminatory in preferencing local standards and testing centers.<sup>17</sup> This goes against the whitepaper’s stated goal that any system should be non-discriminatory.
- Creating an EU-wide certification framework is a hugely complicated process in creating country-level technical capacity and capabilities. An EU-wide framework may well end up becoming fragmented, or at least divergent, over time given it’ll depend in no small part on the capabilities of each EU member’s national cybersecurity agency and their competency in accrediting and auditing conformity assessment bodies.

Existing Conformity Assessment Mechanism are Onerous, Restrictive, and at their Core, Discriminatory for Foreign Firms, Products, and non-EU International Standards

If the EU follows its existing approach, a “presumption of conformity”—meaning that a firm can assume it has met the requirements of the corresponding directive by complying with the specifications in the standard(s) required by a particular directive—will be granted to a harmonized European standard for a given set of regulatory requirements (such as a particular application of AI in a high-risk sector).<sup>18</sup> Where third party conformity assessment is *required*, both EU and non-EU firms can avail themselves of the presumption of conformity accorded to the corresponding harmonized EU standard(s).

This is where the EU’s approach is inherently discriminatory. Firstly, if a firm decides to build, program, or develop to a standard(s) other than the harmonized EU standard(s) granted a presumption of conformity under an EU directive, it cannot benefit from the presumption of conformity and must demonstrate compliance directly with corresponding regulatory requirements by working with a notified body. The presumption of conformity is a major benefit as it means that, in principle, a firm need not interact with a notified body and that it’d only need to present compliance documentation (such as a supplier’s declaration of conformity) in the event that a government authority required it for market surveillance purposes. Where third-party testing is required and the firm must build to harmonized European standards, the notified body effectively faces no legal liability in establishing that the product is in line with EU law (i.e. the firm has a glide path to compliance).



The alternative pathway to demonstrating compliance—where a firm decides not to build to EU harmonized standards—is widely viewed as more onerous, restrictive, and uncertain. Even if a firm does not technically think its product requires testing under EU regulations, it may feel compelled to work with a notified body for the added assurance that its design is still in compliance with the essential requirements of relevant EU legislation. However, in comparison to the presumption of conformity pathway, the notified body has no real incentive (and/or capability) to make this alternative a comparable experience as it assumes additional legal risk in making an independent determination that the product conforms to EU essential requirements (which may be relatively general). Hence their reliance and preference for firms to use EU harmonized standards. This is a big part of the reason why many firms and policymakers characterize harmonized EU standards as de facto mandatory.

Second, the EU approach is restrictive: notified bodies have to be based in the EU, accredited by the corresponding EU-based national accreditation body, and designated by the relevant member state regulatory authority (Notifying Authority) as well as the EC. Absent a government-to-government mutual recognition agreement (MRA), these EU-based notified bodies are the only ones legally able to test to harmonized EU product requirements (where third party conformity assessment is required, as it presumably would be for high-risk applications of AI).<sup>19</sup>

The fear of this foundational discrimination is founded on existing EU policy as the whitepaper references Decision 768/2008/EC (on a common framework for the marketing of products), which creates these technical barriers to trade in the form of localized testing requirements. Article R17 on “requirements relating to notified bodies” states that a “a conformity assessment body shall be established under national law and have legal personality.”<sup>20</sup> This is commonly understood to mean that the assessment body has to be based in the EU and be approved by the EC. The EC recently reinforced its use of local testing bodies clear in recent negotiations with the United Kingdom, in pointing out how UK notified bodies will lose their status due to Brexit.<sup>21</sup>

### The EU’s Framework for Cybersecurity: A Work in Progress with Many Unresolved Issues

The white paper also identifies the Cybersecurity Act as a potential framework to replicate as it is also based of the EU’s existing conformity assessment framework and deals with a similarly new, digital issue. The EC should not replicate the Cybersecurity Act’s approach as it’s still very much a work in progress, and one which already exposes several issues that the EC should want to avoid in regulating AI. The Cybersecurity Act designates and strengthens a central European agency (the EU Agency for Cybersecurity, or ENISA) and establishes an EU-wide certification framework for specific ICT products, services, or processes.<sup>22</sup> It requires EU member states to designate one or more national cybersecurity certification authorities, who subsequently authorize assessment bodies to assess the conformity of certain products, services, and processes before being placed on the market.<sup>23</sup>

The EC has tasked ENISA to prepare draft certification schemes involving national accreditation bodies and conformity assessment bodies, which is a hugely complicated process involving one or more assurance levels (basic, substantial, or high), based on the level of risk associated with the product, service, or process. While the certification is in principle voluntary, it seeks to set a central standard for the framework to avoid divergent approaches among member states. However, the EC has indicated in some areas, such as 5G and cybersecurity, that testing requirements will be mandatory (which may depend on each member state's technical regulations, which again raises the prospects for differential regulations among members).<sup>24</sup>

This approach creates a new, significant, and complicated institutional challenge as it requires new country-level capacity and capabilities to review what would be a complicated process in a consistent way across Europe. The Annex to the Cybersecurity Act sets forth requirements for accreditation as a conformity assessment body, but ultimately, these depend on the country's respective national cybersecurity authorities, who are authorized to conduct audits of conformity assessment bodies and holders of EU cybersecurity certificates.

At best, the Cybersecurity Act is a premature model to replicate as it hasn't answered many of the same critical questions that need to be answered before creating another system for AI conformity assessments, namely: can governments design and apply some objective criteria to testing a dynamic technology and a dynamic threat and risk; and can EU member states set up the governance and build the capacity and competency to administer a highly complicated and unproven process?<sup>25</sup> This is why it's critical for the EC to support global, voluntary, and industry-led standardization discussions for AI, cybersecurity, and other digital issues given the critical role they play in addressing shared concerns, supporting innovation and trade, and bridging different regulatory regimes.

### Lessons to Learn From: The Case of the EU's Medical Device Regulation

Recent experience shows that the EC should avoid or at least be cautious when greatly considering expanding requirements for third-party conformity assessment, particularly in areas of new technology. Europe's MDR/IVDR roadmap (referred to as "the roadmap") was agreed on May 5, 2017. The MDR's implementation date was recently extended by a year from May 26, 2020 to May 26, 2021. IVDR has a five-year transitional period (until May 26, 2022). The roadmap applies to all medical devices for humans, including digital health. The roadmap aims to establish a modernized EU legislative framework to ensure better protection of public health and patient safety, by improving the quality, safety and reliability of medical devices, strengthening transparency of information for consumers, and improving market surveillance.<sup>26</sup>

The roadmap was updated and enacted to keep pace with technological innovation, and to address differential interpretations and application of the rules across EU member states, some of which were associated with high-profile incidents involving failed medical devices. Its scope is broad in that it covers hundreds of thousands of different medical devices and organizations that manufacture, import, and distribute them. It also extends to data in that it specifies requirements for the data collection of clinical investigations on

medical devices, which have been aligned with the requirements for clinical trials on medicinal products.<sup>27</sup> In a scenario that would inevitably arise with any new AI conformity test, beyond introducing new testing requirements, it also requires producers to get existing devices re-certified to abide by the roadmap.

A big difference between the MDR/IVDR roadmap and any potential framework for AI is that the former is about physical devices—AI is not a physical product. Yet, even with a physical product, this case shows just how complicated and challenging it is to develop new EU harmonized standards and to apply these as part of an updated conformity assessment framework.

Preparation for this huge and complicated process across every EU member state has been lagging. COVID-19 forced a delay in implementation that many stakeholders had already been calling for due to many issues with this new system. Indicative of this, a 2019 study found that just 27 percent of 230 medical device makers surveyed expect to be in full compliance.<sup>28</sup> Of those surveyed, 46 percent said they planned to use the MDR/IVDR roadmap’s transitional provisions to be able to sell their products in the EU until 2024, while working on their compliance programs. As of May 2019—when the survey closed, a year before it was initially due to come into effect—there were only five notified bodies in the entire EU designated to test the conformity of hundreds of thousands of medical devices.<sup>29</sup>

Following this, in January 2020—five months from MDR/IVDR roadmap’s initial implementation date—medical device trade association MedTech Europe outlined several major issues that could just as easily apply to a hastily developed AI conformity assessment framework:

- Most of the (current) 55 notified bodies were still awaiting their MDR designation, and thus were not yet able to certify devices to the new regulation. Furthermore, even with their designation, each notified body needs at least six months for each certification. As executive director of the Regulatory Affairs Professionals Society Paul Brooks stated: “If there are too few notifying bodies or their capacity to assess devices under EU MDR is inadequate to meet the demand, it will create bottlenecks that could result in product shortages, including for critically important and high-risk devices patients depend on.”<sup>30</sup>
- Notified bodies lacked the capacity to setup new arrangements for MDR and continue ongoing work, such as conducting surveillance of devices currently in the market.
- Notified bodies have not setup expert panels, meaning MDR is essentially inaccessible to various, high-tech devices, such as innovative implants and medicine-administering devices.
- Implementing laws and regulations (as called for under MDR) are still lacking, meaning that MDR certification is inaccessible for certain devices. Similarly, there is a lack of guidance from the EU on key obligations under MDR that notified bodies and manufacturers need to understand and apply for the first time for re-certification and new certifications.

- Given notified bodies are overworked and unable to accept applications from additional manufacturers (such as those whose notified bodies will not receive an MDR designation soon), a large number of devices will likely not be certified (leading to de facto orphaned devices).
- Given notified bodies are overworked, they do not have the capacity to assess applications for new and innovative products, which restricts innovation and negatively impact European patients.<sup>31</sup>

The time and complexity to develop and approve harmonized standards for use across the EU under the MDR/IVDR roadmap (that would be granted a presumption of conformity) is another lesson for EU policymakers in considering a similar system for AI. These harmonized standards are critical in that they are used to establish or claim conformity with the roadmap's requirements. Firms need these standards to show how they will establish conformity in their products, services, and processes.<sup>32</sup> The release of these harmonized standards for the roadmap was slow and inconsistent.<sup>33</sup> In March, 2020, MedTech Europe sounded the alarm in pointing out that many harmonized standards would be available by the (then) implementation date of May 2020. At this time (before the extension through 2021) MedTech Europe advised its members that they may need to use multiple standards (a potentially costly and complicated process) to demonstrate compliance given the absence of harmonized standards.<sup>34</sup> It is also worth mentioning that delays and issues with harmonized standards was also a problem with the EU's radio equipment directive in 2016.

In this instance, Europe should consider the innovative approach the U.S. Food and Drug Administration (FDA) has taken toward regulating medical devices that use AI. Not only has the agency created a Digital Health Unit, it's (pilot) pre-certification program would move from individual product review to a firm-based review for medical devices and the software they use, including AI. Further, a recent FDA whitepaper reimagines regulation of devices with AI/ML software, including allowing pre-market certifications anticipating change protocols permitting autonomous updates of medical devices using AI.<sup>35</sup> In general, the FDA seeks a flexible regulatory approach that can enable medical devices to dynamically learn and improve without having to be constantly reapproved. This allows firms to use data and AI to improve their products on a daily basis. Do EU regulators really want to recertify products every single day? It also recognizes that there are different tiers of medical devices, such that regulations should be tighter, for instance, on implantable cardiac devices, while being more flexible, for instance, with Fitbits or wearable monitoring devices. But in general, the FDA approach tries to empower medical device innovation using AI, while ensuring adequate safety standards.

## **2. EX-ANTE AI CONFORMITY TESTS WILL BE A NEW NON-TARIFF BARRIER TO DIGITAL TRADE**

There is a risk that if the EU goes forward with this, that discriminatory treatment against foreign firms and their AI-based digital products will become a new non-tariff barrier to trade. While created in an era of trade dominated by physical goods, the simple principle at the heart of the General Agreement on Tariffs and Trade (GATT) is just as important to modern services and digital-based trade in its goal of achieving both “the substantial reduction of tariffs and other barriers to trade” and the elimination of “discriminatory

treatment in international commerce.” These behind-the-border regulations are becoming more common and consequential as trade becomes more digital and services-based. The EC should consider the direct trade impact any of its regulatory proposals will have on its own firms and economies, but also the indirect impact on its firms if its (flawed) approach is subsequently copied in other countries (such as for cybersecurity in Brazil).

In the context of WTO agreements, especially the Agreement on Technical Barriers to Trade (the TBT Agreement), members have regulatory autonomy to choose the measures best suited to address their national policy concerns of public health and safety, environmental protection, and consumer information, amongst others, provided these measures are non-discriminatory, no more trade restrictive than necessary, and if firms can access of suppliers to assessments of conformity.<sup>36</sup> In essence, the TBT Agreement ensures regulations or standards do not become unnecessary or discriminatory trade barriers.<sup>37</sup>

As trade becomes more intangible, more countries are using standards as a cover for protectionism. While standards setting often reflects a genuine need to address a market failure of some kind or to achieve certain societal objectives, it can also be influenced by political economy forces, and, consequently, there is a risk the process is used as a tool for protectionism.<sup>38</sup> This “standards protectionism” is evident when countries or regions do not recognize testing results of safety tests performed in laboratories of exporters’ home countries and demanding duplicate tests at specially assigned assessment bodies.<sup>39</sup> National or regional standards, especially when rendered mandatory, act as barriers to trade, either deliberately or inadvertently, if they fail to provide fair access to foreign firms and their products, such as through equal recognition to comparable international standards.

The EU is no stranger to this voluntary, but in effect mandatory, situation. The EU’s approach to standardization (in EU Regulation No. 1025/2012), affirmed by recent rulings of the European Court of Justice, shows how harmonized European standards (i.e., those granted a presumption of conformity) hold legal significance under EU law and may therefore be considered as *de facto* mandatory.<sup>40</sup>

Trade policy is an important tool to help ensure standards are transparent, predictable, proportionate, and non-discriminatory. The WTO reports that duplication, delays or discrimination in conformity assessment procedures (CAPs) can significantly increase trade costs, and this risk is reflected in the growing importance of CAPs in WTO discussions and bilateral and regional free trade agreements.<sup>41</sup> A WTO review of the issue among members from 2010-2014 shows that CAPs raise proportionally more concern among WTO Members than technical regulations do and that testing and certification are the procedures that most frequently give rise to trade problems.<sup>42</sup> In response to this, recent trade agreements such as the United States-Mexico-Canada Agreement (USMCA) and Comprehensive and Progressive Agreement for Trans-Pacific Partnership emphasize regulatory disciplines and highlight the central role of institutional structures, which together, help to provide regulatory coherence for digital issues.

Limited and discriminatory conformity assessment procedures (like those in the whitepaper and used elsewhere in the EU) mean higher market entry costs for foreign firms, as they not only need to adapt their products to meet de facto mandatory local standards, but also have them tested in multiple different countries and regions. As noted, this affects both the extensive and intensive margins of trade.

The trade impacts of a discriminatory ex-ante conformity assessment framework for AI would depend on how different the regulations are in the importing and exporting country, and whether local firms would have a comparative advantage (over foreign, importing firms) in meeting stricter regulations. For example, large foreign firms with local subsidiaries will have an advantage, while foreign small and medium-sized firms will be most affected as they lack the resources and expertise to deal with multiple different foreign conformity assessments.

The impact will likely be prohibitive for firms from developing countries. Indeed, their governments and firms are typically characterized by a lack of access to information, technology, managerial capacity, and finance, which impedes their businesses' ability to adapt product development and delivery processes quickly and adequately enough. They are less likely to meet the EU's onerous requirements. Added to this is the cost and complexity of obtaining testing and certification services from only a select number of EU-based firms in order to demonstrate conformity.

The EC should carefully consider the impact that restrictive and discriminatory conformity assessment procedures will have on trade. While empirical evidence on the relationship between regulatory cooperation and trade is scarce, available studies suggest that regulatory divergence can generate substantial trade costs in some areas, and reduces trade. This suggests ex-ante conformity tests for AI would likely have a similar impact on modern services and digital trade. For example:

- Shepherd (2007) found that an increase in the number of standards in textiles and clothing, for instance, reduces a trading partner's export variety. When EU standards align to international standards (for example, International Organization for Standardization), the study found a small increase in the variety of imports from trading partners.<sup>43</sup>
- Reyes (2011, 2012) used a detailed database of U.S. firm-level data, trade data, and EU product standards to show that aligning EU products with international standards increases US exports to the EU through an increase in the number of US firms entering the EU market. While fixed entry costs did not have an immediate impact on prices and volumes, they acted as entry barriers for exporters, meaning that instead of merely making products more expensive, they reduce the likelihood of exporting.<sup>44</sup>
- Foletti and Shingal (2014) found that harmonization leads to greater trade at both the intensive and extensive margins. Regulatory heterogeneity is a greater impediment in the probability of exporting than in volumes.<sup>45</sup>

- Cadot and Gourdon (2015) used prices to measure the impact of non-tariff measures (NTMs), finding that regional trade agreements with provisions related to harmonization or mutual recognition agreements reduce the impact that NTMs generally have on price. Essentially, they found that such regulatory cooperation initiatives reduce compliance costs. They also note that mutual recognition agreements on conformity assessment have the most significant effect in reducing compliance costs and the impact on trade.<sup>46</sup>
- Fontagné et al. (2013) examines sanitary and phytosanitary (SPS) measures that are raised as specific trade concerns in the WTO SPS Committee, showing that these have a negative effect on both the extensive and intensive margins of trade as they involve compliance costs that increase unit values and prohibit market entry. Importantly, the study also found that harmonization of MRL regulation fosters decisions to export within the EU as well as agri-trade into the EU from developing countries.<sup>47</sup>

### **3. CONFORMITY ASSESSMENTS AND MANDATORY SOURCE CODE DISCLOSURE: A BARRIER TO TRADE THE EU (RIGHTLY) OPPOSES IN OTHER COUNTRIES**

While the way in which notified bodies would assess AI applications remains unclear, it may be fair to assume that firms would need to share proprietary data sets, algorithms, or source code as a means of demonstrating conformity with EU regulatory requirements. This is particularly problematic given the localization requirement for notified bodies. It also would appear to contravene the EU’s trade policy approach in third countries. The EU has agreed on provisions that prohibit mandatory source code disclosure in the EU-Japan Economic Partnership Agreement and proposed similar provisions at WTO ecommerce negotiations.<sup>48</sup>

Source code—the coded instructions at the heart of a computer program—enables computer technology to do the amazing things it does. For companies developing software, protecting source code is necessary to prevent other entities from stealing and free riding on the large R&D costs associated with software development. Indicative of the sensitivity around source code is the fact that when one purchases software or goods with software embedded, the software is generally compiled in “object code” form, and not with the actual source code, as this would make it much easier for thieves, hackers, and others to copy and misuse. In other cases, software firms use open-source licensing arrangements to disclose source code in order to allow others to modify and build on the source code, but such a decision is made by each individual or firm.

From a commercial perspective, not disclosing source code is standard practice, given intellectual property and security considerations. AI-based products often involve high-fixed costs for research and development to bring the first copy to market, but low marginal costs in subsequent copies. Hence why they represent an attractive target for foreign governments trying to collect and pass along the intellectual property to help local firms. Trade law provisions like the ones the EU and the United States support are important for trade and data-driven innovation as they reduce the risk of parties using concerns over “cybersecurity” or “algorithmic transparency” as an excuse to enact requirements that they hand over source code as a condition of market

entry market entry, which allows them to pass on this valuable intellectual property to domestic firms. China and other countries have proposed regulations that would require companies to transfer or allow access to source code as a condition of market entry—effectively acting as a barrier to trade.<sup>49</sup>

Similar to the EU, Australia, New Zealand, Singapore, the United States, and others have enacted new trade law provisions to protect source code. However, these provisions do not affect the scenarios where source code is disclosed as a matter of business (after entry), such as in commercial contracts, government procurement, patent applications, legal discovery, and for regulatory concerns (such as environmental). For these trade and innovation reasons, the EC should avoid including source code disclosure as part of pre-market conformity assessments.

#### **4. MUTUAL RECOGNITION AND ACCESS TO TESTING AS A MARKET ACCESS BARRIER**

The whitepaper states that: “Economic operators established in third countries wanting to enter the internal market could either make use of designated bodies established in the EU or, subject to mutual recognition agreements with third countries, have recourse to third-country bodies designated to carry out such assessment.”<sup>50</sup>

Unfortunately, the EU has reiterated their embrace of the precautionary principle’s current use of conformity assessment testing frameworks shows that these mutual recognition agreements are limited and definitely not prioritized by the EU. The EU has a limited number of mutual recognition agreements (MRAs) with Australia, Canada, Israel, Japan, New Zealand, Switzerland, and the United States.<sup>51</sup> However, overall, while these MRAs are highly valuable, they’re not widely used (as they are relatively difficult to achieve). Nor are MRAs an efficient or practicable means of facilitating the acceptance of reliable test results by bodies based outside of the EU.

For example, the United States and the EU have shown that (while challenging) they can find ways to build regulatory compatibility, thus reducing the negative impact of regulatory differences.<sup>52</sup> MRAs are one tool for this. For example, the European Medicines Agency has signed MRAs with seven other countries, including the United States.<sup>53</sup> The EU and United States have an MRA that covers marine equipment, medical devices, electromagnetic compatibility testing services, electrical equipment, and telecommunications.<sup>54</sup> Under the telecommunications annex, for instance, the U.S. National Institute of Standards and Technology (NIST) can effectively perform the role of an EU member state notifying authority, and designate a notified body under the EUC Radio Equipment Directive.<sup>55</sup> When the main package of MRAs was agreed to in six sectors in 1997, the U.S. government estimated that the package (covering \$47 billion in trade at that time) eliminated costs equivalent to two or three percentage points of tariffs.<sup>56</sup> The Peterson Institute for International Economics’ report *International Trade Meets Domestic Regulation: Negotiating the US-EU Mutual Recognition Agreements* provides a detailed background on these past efforts.<sup>57</sup> This past cooperation shows that cooperation is possible and significant for trade relations.



To their credit, the EU and the United States have tried to build on this earlier success, for instance in 2017, they negotiated an MRA on Pharmaceutical Good Manufacturing Practices (GMPs).<sup>58</sup> Most recently, in 2019, the EC published its proposal for agreement on conformity assessments with the United States (under one of the actions agreed under the EU-U.S. Joint Statement of July 25, 2018), in which it suggested provisions to ensure the EU and United States would accept the conformity assessment results of each other's assessment bodies, thus certifying products against the legal requirement of the other side.<sup>59</sup> The proposal covers all relevant industrial sectors where third-party conformity assessment is required by either side.<sup>60</sup> The proposal would not mean that U.S. standards would be made equivalent to the EU's, simply that U.S. bodies could inspect, test, and certify goods under EU technical regulations.

Essentially, it allows producers to test in the United States to EU standards and tests in the EU to U.S. standards, which would go some way to addressing the problem of there being limited accessibility to only EU-based testing bodies. At the heart of the EU's proposal was the recognition (even if implied) that its conformity system is non-reciprocal, so it (rightly) seeks to establish the ability for non-EU assessment bodies to help ease foreign market access to the EU market.<sup>61</sup> This is where the EU's approach falls short: non-EU certification and testing arrangements are far more limited and onerous for foreign firms and their products.

However, it is an imperfect solution that in an ideal world wouldn't be necessary, as it ultimately stems from the EU's pursuit of localized standards and restrictive conformity assessment testing. These MRAs essentially places demands on the U.S. government (and U.S. firms) to mirror the system of approvals and oversight that the EU uses in designating notified bodies in its market. Put differently, NIST, or another U.S. government authority, would have to assume a role comparable to that of a notifying authority in an EU Member State, rather than just having U.S.-based conformity assessment bodies apply directly to EU-based governmental authorities.

This elaborate mechanism wouldn't be necessary if the EU didn't have a localization requirement in the first place. That is not to say that all U.S. regulatory authorities accept international test results—it depends on the specific regulatory or statutory authority—but the United States does not have a blanket requirement for localization of conformity assessment bodies. Taking this a step further, absent an MRA or “conformity assessment protocol” (like the one in Comprehensive Economic and Trade Agreement (CETA) between Canada and the EU, which is reportedly having its own issues), there is currently no way in the EU system to leverage international accreditation schemes to allow for acceptance of international test results. This in spite of the fact that the EC lobbies foreign governments to accept test results from labs accredited by the International Laboratory Accreditation Cooperation and International Accreditation Forum (detailed below).

Given their trade and economic relationship, it's sensible that the EU works with the United States to expand testing options. But the EU's approach to AI highlights a broader, troubling goal of European regulatory imperialism in that it typically reflects an attempt to force developing countries, especially those with smaller markets, to conform to Brussels' standards. This is damaging to these economies, as their local government

may not have the capacity to establish standards at all, whether their own or those of others. In general, mutual recognition agreements should be easier when countries are at similar levels of development. But as the challenges between the United States and the EU show, this is by no means assured. This is indicative of the difficult (if not impossible) bar that the EU sets for developing countries in outlining the potential use of MRAs for AI.<sup>62</sup>

For this reason, among others, MRAs are not a great tool for achieving broad regulatory compatibility. A more innovation-friendly and better regulatory approach would be for the EC to leverage a broader range of global standards as a way of demonstrating compliance with regulatory requirements, accompanied by more resources for regulators. This would provide more flexibility for producers in weighing up the best options for viable, high-standard international test results. If nothing else, the EC should ensure that any AI conformity assessment framework consider how it will include expanded access to testing around the world to avoid limiting the use, development, deployment, and adoption of one of the key technologies of the 21<sup>st</sup> century.

## **5. RECOMMENDATIONS**

The EC should take the time to carefully reconsider the technical, governance, trade, and international cooperation and coordination aspects of its proposal for a conformity testing framework for AI, particularly one rooted in a legislative framework designed largely to facilitate intra-EU movement of industrial goods. More importantly the EU should reconsider whether it even needs such an expansive approach to AI regulation, in the absence of virtually any harms to date. Rather than jump ahead with a precautionary principle-based regime that will reduce AI innovation in the EU and distort trade, the EU should carefully monitor private sector action and only act if it appears that AI-specific regulation is truly necessary, which at this point in time it does not appear to be the case.

The recommendations below detail a few major parts for the EC's consideration as it moves forward.

### **5.1 Learn from Experience & Pursue a Lengthy, Thorough, Multi-Stakeholder Policy Development Process**

The EC should consider the core points below, many of which come from the OECD's work on how governments can ensure successful international regulatory cooperation:<sup>63</sup>

- The EC should wait. AI as a tool is too nascent for governments to jump headfirst into technology-specific regulation, at least in the vast majority of applications.
- The EC should allow time for a series of open discussions about all available policy proposals. The EC should not rush to enact a framework that will have long-lasting domestic and international implications on trade, innovation, its own competitiveness, and that of other economies.
- The EC should develop a common taxonomy on AI for use as part of discussions, given the proposal covers a broad range of economies, sectors, and technologies.

- The EC should do a comparative assessment of past and related regulatory frameworks and their development. As this submission details, these will likely hold valuable lessons for the EC as it considers a new region-wide framework.
- The EC should pursue a detailed cost-benefit analysis of policy proposals, including on the impact on competitiveness, economic growth, and trade.
- Any AI regulatory framework should incorporate mechanisms that provide flexibility for future adaptation given the impact that fast-changing technologies and business practices have on a given public policy objective. The EC should learn this lesson from GDPR's stringent rules, which provide little room or opportunity for future adaptation.

## **5.2 Build a Truly Cooperative and Internationally Accessible Approach**

The EC should ensure international regulatory cooperation (IRC) is a central part of any proposal to regulate AI.

Key recommendations:

- The EC should heed its own advice to other countries and discontinue its localization requirement for testing bodies and its built-in, de facto reliance on regional standards (some of which are fine, in that they are based on a limited subset of international standards). Firms in the EU simply won't be able to keep pace technologically if they apply their existing legislative framework for industrial products to emerging technology, and they risk hamstringing much of the rest of the world in the process given the critical role that trade and market scale plays in supporting innovation.
- The EC should build in (or least include the potential for) mechanisms to facilitate international regulatory cooperation and interoperability with major, like-minded trading partners. The EC should give greater priority to international interoperability in creating numerous clear, fair, and predictable testing options for foreign firms and their products.
- The EC should consider how its proposed framework will allow (or not) firms in developing countries to have their products certified to conform with EU rules. The EC should also consider how it can help developing countries build and strengthen their own capacity for regulatory quality and reform, including as it relates to any potential AI conformity framework.
- The EC should double down EU support for the work and processes of international standards development bodies including and beyond the Geneva-based intergovernmental standards development organizations, such as the International Standards Organization, the International Electrotechnical Commission, and International Telecommunications Union.

- The EC should support global, voluntary, and industry-led standardization discussions given the critical role they play in addressing shared concerns, supporting innovation and trade, and bridging different regulatory regimes. For example, it should build on the work of limited, past initiatives, like the European Multi-Stakeholder Platform for ICT Standardization to ensure that its regulatory authorities and industry have recourse to the broadest, most modern array of technology standards.<sup>64</sup>

The EC is not alone in debating how best to address the risks associated with the commercial use of AI. Brazil, the United States, Canada, and many others are developing national AI plans and weighing up how to maximize the benefits while mitigating the risks. Europe has much in common with many of these countries in terms of shared values and interests like trust, fairness, accountability, and effectiveness.<sup>65</sup> Given the negative impact of regulatory divergence on traditional trade, and the growing importance of AI and data to productivity and innovation, it's critical that the EU and its partners pro-actively work to avoid more such fragmentation among AI regulatory proposals. They all need to consider adopting common light-touch approaches that wait for potential problems to emerge, rather than buy into the fear that many in civil society have been promulgating that AI is something fundamentally new and dangerous absent a strong regulatory hand of government. Absent that, they should build bridges between different frameworks. The EU could take the lead in doing so as part of a broad, global policy debate, such as the Global Partnership on AI within the Group of Seven.<sup>66</sup>

IRC refers to the design of appropriate mechanisms, such as those on transparency, mutual recognition, and development and acceptance of global, industry-driven, voluntary consensus standards. At the heart of IRC is a shared interest in maximizing joint welfare, by ensuring a balance between the welfare costs related to regulatory changes and the benefits resulting from reducing regulation-related economic and trade costs. Reducing regulatory heterogeneity leads to lower prices for consumers, while an increase in the number of firms in a market should lead to greater competition and lower mark-ups. IRC mechanisms can be economy-wide or sector specific. Research from the Organization for Economic Co-operation and Development (OECD) and others shows that IRC mechanisms have a positive impact on trade and are driven by political considerations and path dependency.<sup>67</sup> The EC should consider these tools from the start so as to avoid putting the region on a path that will undermine its domestic economy and makes it much harder to work with its trade partners in the future.

The EU has considerable experience in tackling the complexities of regulatory differences with the United States and other trading partners. The EU should actively avoid adding more fragmentation by imposing specific rules for AI. It should apply lessons learnt from comparable policies and initiatives up front. The EC should either discontinue its proposal for localized testing requirements or at least build in (or include the potential for) bridging mechanisms, which may result from negotiations with its trade partners. A clear goal for the EC should be to allow and create numerous, clear, and predictable testing options for foreign firms and their products. Developing these options should be factored in from the start, and not left as an afterthought.

While differential and discriminatory regulations are challenging for U.S.-EU relations and between the EU and the select other group of developed countries with which they've signed MRAs, they represent a much bigger barrier to trade for firms in developing countries. The EC should consider up front how its framework will allow laboratories in developing countries to be certified to conform with EU rules so that foreign firms have a clearer path to conformity.

As part of this, the EC should consider how to factor in government-approved international accreditation schemes. A few of which exist, but these are generally underutilized. One example is the IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (CB Scheme), an international system for mutual acceptance of test reports and certificates dealing with the safety of electrical and electronic components, equipment and products.<sup>68</sup> Another example is the International Laboratory Accreditation Cooperation (ILAC), the international organization for accreditation bodies using various ISO/IEC standards to assess calibration, testing, and medical testing laboratories and inspection bodies.<sup>69</sup> Accreditation bodies are peer evaluated and have to sign regional and international mutual recognition arrangements to demonstrate their competence.<sup>70</sup> Similarly, the International Accreditation Forum (IAF) is the international organization for the accreditation of certification bodies.<sup>71</sup> Both organizations have formal and informal connections to a broad range of multilateral and regional organizations involved in standards and conformity assessments, such as the International Organization for Standardization (ISO) and International Telecommunications Union (ITU).<sup>72</sup> At the moment, being a signatory to ILAC or IAF is part of the criteria that non-EU-based accreditation bodies can present in order to be recognized under an EU conformity assessment protocol.

## **CONCLUSION**

Global trade involving a digital component—which covers a lot of modern trade—is increasingly fraught with compliance issues, whether it's data privacy (GDPR) or cybersecurity (the EU Cybersecurity Act). This is most definitely the case for EU-U.S. trade. These rules are constantly evolving, which also presents a learning curve that may be too steep and costly for many firms.<sup>73</sup> For firms in developing countries, it's even more significant. The whitepaper's proposed framework will have a major impact on those developing and deploying AI. The EC and EU member states should take the time to learn from past experience and carefully consider whether they even need to regulate a technology that is so critical to its economic competitiveness and the future of trade, and if they decide to regulate, do it as part of broader efforts with industry and likeminded partners.

*Nigel Cory is associate director for trade policy at the Information Technology and Innovation Foundation (ITIF).*

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