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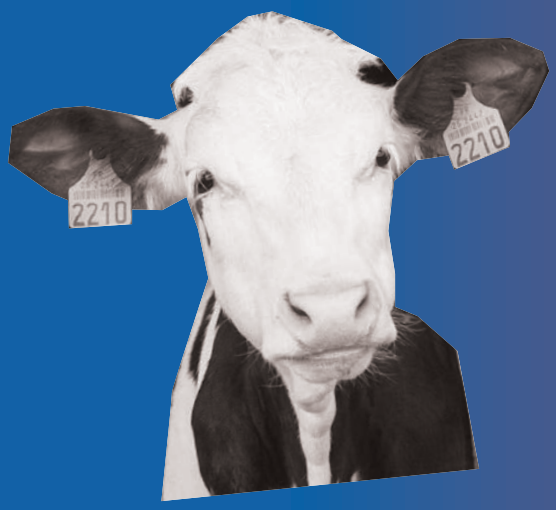
TRADING AWAY PROTECTION

Emerging threats from the EU-US trade talks on conformity assessment and regulatory cooperation



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US President Donald Trump's threats of hostile trade measures against EU imports have helped kick-start new trade negotiations. Worried over the prospect, the European Union will reconvene with the United States at the negotiating table to discuss a transatlantic trade agreement. This has led to concerns that such an agreement could lead to a lowering of standards, and criticism over a lack of transparency about what is being negotiated.

Similar public concerns helped derail the previous, comprehensive transatlantic trade agreement, the Transatlantic Trade and Investment Partnership (TTIP), which was put on the backburner in late 2016. Though the range of issues currently discussed by the two sides are not as broad as with TTIP, many of the same concerns raised previously by consumer groups, trade unions, and others still apply. Once again we see US negotiators and corporate lobbyists target key European precautionary measures in areas such as chemicals, pesticides, GMOs, and food safety, leading to fears of a lowering of standards.

On the EU side, the focus is mainly on something known as 'conformity assessment'. The EU would like to see more of its approved products enter the US market without further safety checks or investigation. While this may sound harmless, it could lead to less safe medical devices in the US, the introduction of hazardous electrical equipment, or to the marketing of toys that pose a risk to small children. Also, it would outrule the kind of safety checks made by US authorities that uncovered the fraud with emissions from cars, the scandal known as 'Dieselgate'.

Overall, both sides are asking the other to drop precautions over standards in different sectors, a situation which previously caused a crisis at the TTIP negotiations. But this time could be different. With the threat of a genuine trade war, the EU feels under tremendous pressure and could be tempted to make concessions to avoid US measures against, for instance, the European car industry.

Moreover, while the negotiations are currently being conducted over only a limited number of regulatory issues, there are signs that the EU negotiators in the Commission and the corporate lobby groups they coordinate with, are keen on inflating the negotiations to something much broader, a kind of TTIP-light. Unfortunately, a lack of transparency on the EU side prevents the public and politicians from monitoring developments and finding out what's on the negotiating table. For that reason, there is a need to demand transparency and for politicians to start questioning the substance of the negotiations.

Introduction

Trade negotiations between the EU and the US are up and running again. In 2016, negotiations on the Transatlantic Trade and Investment Partnership (TTIP) collapsed following public opposition on both sides of the Atlantic but now we see the two sides around the table again. And though it may appear as if ambitions are much lower today, centring on seemingly technical and harmless issues, we should make no mistake: some of the ghosts from TTIP are very much alive in the new round of talks. Once again we're seeing the two sides taking aim at laws adopted to protect public health, consumers, workers and the environment by so-called 'regulatory cooperation' provisions.

Regulatory cooperation is a model for collaboration that is intended to iron out differences in the long term that are difficult to handle in the short term. It includes work between official agencies, bilateral talks before new laws are adopted, involvement of business groups on both sides before regulatory measures are adopted, and formal complaint procedures. In the context of TTIP, regulatory cooperation was singled out by both sides as the answer to long-standing trade disputes in sensitive areas such as food, chemicals, and pesticides. In the end, regulatory cooperation became one of the most criticised elements of the talks. Critics believed it to be a subtle way of undermining protection in areas such as food, chemicals and pesticides regulation.

Despite this we are seeing regulatory cooperation emerge as a key part of the resumed negotiations. And though both parties are making an effort to underline, just as they did with TTIP, that social and environmental protection will not be affected, there are strong indications that the opposite is the case.

This paper sets out to examine the dangers by looking at the negotiating mandates on both sides and the respective political contexts which they are bringing to the negotiating table. What we see in the US is a rerun of attacks on EU safety standards, for example on chemicals and pesticides. And even though the EU mandate for the negotiations is – so far – restricted to so-called 'conformity assessments', there are serious risks to the American public built into the plan.

Conformity assessments are tests on whether products or a service live up to existing regulations and standards. At trade negotiations it can be a matter of whether tests conducted in one country should be recognised in another country without further testing, and of what kind of certification is mutually recognised. For instance, what kind of body, official or private, can be entrusted with the approval of a product before it is put on the market? As this is seemingly more about procedures than about the characteristics of a service or a product, it appears uncontroversial. In fact the choice of 'conformity assessment' can be crucial. Flaws in the approach of the EU, for instance, have proved risky for children, patients and workers.

The EU is eager to have its approach to conformity assessment acknowledged by the US at the negotiating table. And if the EU negotiators are to be successful, concessions to the US are the price. Both sides are on track to trade away protection to please the business community.

For that reason, citizens' groups need to be vigilant if we are to prevent the kinds of setbacks that many opposed during the TTIP negotiations.

1. Regulatory cooperation in response to looming trade war

In late 2016 the talks on the Transatlantic Trade and Investment Partnership (TTIP) were put on ice due to disagreements between the two sides. A public outcry against key proposals was followed by Donald Trump's election as US President, resulting in no immediate prospect of an agreement. Since then tensions have been the order of the day on the trade scene, starting with higher US tariffs on the EU's exports of steel and aluminium, followed by EU retaliatory measures against Harley Davidson motorbikes, Levi jeans and bourbon.

In May 2018, President Trump scaled up his effort by threatening to impose a 20 per cent levy on cars from the EU.[1,2] That pulled the EU to the negotiating table, and following a meeting between European Commission President Jean-Claude Juncker and Donald Trump in July 2018, the preparations began. In their statement of 25 July 2018, they vowed – among other things – to reduce barriers to trade in a number of sectors, including chemicals, pharmaceuticals and medical products, and to launch "a close dialogue on standards in order to ease trade, reduce bureaucratic obstacles, and slash costs".[3]

Though it was clear the new negotiations would be based on a more limited agenda than the previous TTIP negotiations, it was not be easy for the European Commission to garner support for initiating the talks. In March 2019, the European Parliament rejected a request for support for the new negotiations and ended up with no resolution at all.[4] At a European Council meeting in April, the proponents only just managed to garner support for the talks. This is despite the fact that the Commission was not seeking a broad mandate – with only tariffs and a limited version of regulatory cooperation in the proposal that was suggested and approved.

So, what is there to worry about? Actually, quite a lot. There is tremendous pressure on negotiators to deliver, from corporations as well as governments. Threats of new steps against European products from President Trump, even after the start of negotiations was agreed, has underlined the fact that the US wants tangible concessions. Since the European Commission has set out to avoid the escalation of trade disputes with the US in order to sidestep adverse effects on – among others – the German car industry, which is so crucial to the German economy, it will surely be seeking ways to please its partner at the negotiating table. And what is on that table is no small thing. Crucial principles protecting the public from harmful products and substances are up for grabs, with regulatory cooperation at the heart of the problem.

Regulatory cooperation – seemingly modest ambitions

Regulatory cooperation was one of the most-criticised elements of the TTIP negotiations. It was the preferred formula for resolving differences between EU and US approaches to regulation of standards in areas such as chemicals and food. A bureaucratic and opaque set of procedures intended to iron-out differences slowly over time, it was expected to largely take place behind closed doors, often with the direct or indirect presence of business lobbyists, and with a lesser role for elected politicians. As the negotiators on behalf of the European Union, Trade Commissioner Cecilia Malmström and her civil servants, failed to convince critics that consumer rights, environmental protections, and other public interests would be safeguarded, regulatory cooperation became a controversial and sensitive issue for the EU.

Yet, this is exactly the issue negotiators will pick up again, albeit seemingly with a narrower scope. According to EU plans, the negotiations on regulatory cooperation should be limited to 'conformity assessment'. Conformity assessment is a topic on what we might call the lowest shelf of regulatory cooperation. It is about procedures to certify whether a given product is aligned with existing rules. If both sides agree that products do not have to go through tests twice, businesses save time and money. This is not to say the EU will necessarily keep the negotiations narrow in the long term: a consultation opened by the Commission in April show the EU executive is preparing for a broader negotiation agenda in that it asked businesses for suggestions for 'regulatory cooperation' with the United States well beyond the mandated talks on conformity assessement.[5] But in the short term there will be no mandate to go any further than conformity assessments.

The position in the US is a different story altogether. Here, the objectives do not seem to be markedly different from the TTIP negotiations in the area of regulatory cooperation. The US is still keen on using regulatory cooperation as a means to attack key principles of precaution, which, in the eyes of the US Administration and US businesses, is little more than a shrewd protectionist measure. And regulatory cooperation is regarded by the US negotiators as an appropriate method to push for change.

On the scope of the negotiations, then, the two sides are not in sync. Though the US badly wanted to reach an agreement on agriculture, that was off the table for the Europeans. Aside from tariffs, regulatory cooperation would make up the working agenda. And while the US would like to see full-blown talks on law-making, and to generally pick up on the most thorny elements from regulatory cooperation under TTIP, the Europeans are going for a more limited approach.

Yet even with the most limited scenario focusing on conformity assessments, there are still serious risks. This becomes clear from a walkthrough of the negotiating objectives of the two sides and their respective political contexts.

Regulatory cooperation – a grim heritage

Regulatory cooperation is not a new invention. The first transatlantic projects on regulatory cooperation date back to the 90s, and there are plenty of experiences to consider. It is sometimes presented as merely close collaboration between corresponding regulatory agencies in attempts to remove unnecessary 'red tape', but it is more than that. Regulatory cooperation has broad implications for decision-making and can, for instance, see another country intervene at all stages of decision-making to ensure rules do not drift apart in a way that affects trade. It can de facto remove politicans from regulatory processes while giving business groups a bigger say.

When negotiating agreements on regulatory cooperation, negotiators often stress there will be no impact on social and environmental protections. Yet, there are plenty of examples where regulatory cooperation has led to flawed rules and serious market failures. The report *Dangerous Regulatory Duet*[6] gives some examples:

- When the US insurance giant AIG was close to collapsing in the wake of the financial crisis, its London office took centre stage. This was where the problems were actually located, but regulators had no idea. Under regulatory cooperation between the EU and the US it had been agreed to allow US supervisory agencies to monitor AIG in London, yet out of lack of interest that didn't happen.

- In 2000 a 'Safe Harbour Agreement' on data privacy was concluded in the framework of regulatory cooperation between the EU and the US. The US trade negotiators had complained over what they saw as a very strict EU law on data privacy which could be costly to US companies. The European Commission quickly found a way around it through a deal that would allow the US companies to evade monitoring by European authorities, a kind of 'conformity assessment' performed by the companies themselves. US companies – otherwise accustomed to a lax self-regulation model – were to abide by seven principles when handling information on EU citizens stemming from operations in the EU market. In 2013 it was clear to everybody this had not happened. A deal struck through regulatory cooperation had failed miserably. To appease the US, the EU had entrusted companies with the enforcement of the very EU rules that they had no interest in whatsoever. Eventually, the Safe Harbour Agreement was ruled to be in violation of EU law by the European Court of Justice, and abandoned.

Other examples include the delay for years of EU rules on animal testing and on ozone depleting substances, where US officials used the means available under regulatory cooperation, to question the proposed EU measures in order to postpone them. There is even an example considered by some to show that the US even managed to downplay if not sideline famous precautionary principle in a case about hazardous chemicals in electronic equipment, all thanks to the close cooperation with EU officials .

Broadly speaking, regulatory cooperation is about authorities working together, often in close collaboration with business groups, to remove perceived barriers to trade – with little or no involvement of politicians.

2. US objectives: a new attack on precaution

TTIP was set to become a milestone in the comprehensiveness of regulatory cooperation, and at the moment the US is trying to keep that ambition alive. This is clear from the US Trade Representative's *Summary of US-EU Negotiating Objectives* from January 2019.[7]

In the document, the US Trade Representative (USTR) proposes to allow 'stakeholders' in other countries (ie. lobbyists) to provide comments on draft rules and "require the authorities to address significant issues raised" and explain how the final measure achieves the stated objectives. The USTR also proposes to set up several bodies to discuss issues relating to 'sanitary and phytosanitary measures' (measures to protect humans, animals and plants) and 'technical barriers to trade', which would mean that regulatory agencies and trade negotiators would have more influence on how sensitive issues, such as food standards, are dealt with. The US model is to have strong enforcement measures on these barriers to trade, including through the establishment of a 'mechanism' to correct 'final administrative decisions'. It is left unclear what that means, but it seems that on the EU side, this would allow US authorities to object to precautionary measures in areas such as GMOs and food standards.

By any standard, this is a very intrusive proposal, especially in the context of the US attack on the EU's precautionary principle, according to which a given product or substance can be subjected to bans or limits to its use if scientific evidence as to its safety is not conclusive. This stands in contrast to the approach in the US, whereby a product or substance has to be proven hazardous before regulatory action is taken to limit its use.

Broadly speaking, the attack on the precautionary principle is the essence of the chapter on sanitary and phytosanitary (SPS) measures – in this connection mainly about food standards and agricultural production - in which it is stated there needs to be "enforceable and robust SPS obligations that build up WTO rights and obligations". This is a reference to long standing disputes in the WTO over, for example, hormone-injected beef, a case in which the EU has adopted more ambitious threshold levels than the WTO rules allow. As under the latest negotiations, US businesses are pushing hard for change along these lines. During a hearing organised by the USTR in December 2018, shortly before the publication of the negotiating objectives, both the National Foreign Trade Council and the National Cattlemen's Beef Association lashed out against the precautionary principle as a protectionist measure which the EU 'hides behind'.[8] They are seconded by the powerful US Chamber of Commerce, which prefers a more coded language. According to this organisation, the negotiations must lead to "science based approval systems for biotechnology and chemistry products", and they must address "non-science-based restrictions on agricultural trade in a transparent and timely fashion."[9] In the course of the hearing in December, this language was used 24 times to attack the precautionary principle as used by the EU.[10] And as so often before, the preferred targets were EU chemical regulation, GMOs, pesticides and food safety rules. So what, more specifically, is the US trying to achieve in the area of regulatory cooperation?

Chemicals: working around the precautionary principle

Chemicals has been a very contentious area for the two sides for more than a decade. EU legislation is far more cautious than the corresponding US rules, with the 'precautionary principle' ranking high among the conflictive questions. In cosmetics, for instance, the EU has banned more than 1.300 substances, whereas the US has banned only six.[11] During the TTIP negotiations, the US chemical industry and its European partner the European Chemical Industry Council (CEFIC), did their best to introduce what they called "science-based evaluations"[12]. Environmental research groups CIEL and ClientEarth commented that this this reflected "the continued reluctance on the part of industry and, regrettably, many U.S. political leaders to embrace the precautionary principle, which recognizes that the lack of full scientific certainty must not be used as an excuse to avoid cost-effective measures to protect the environment and human health when there are threats of serious or irreversible damage." [13]

With TTIP gone for now, and considering that the fight over the precautionary principle was a factor in its demise, the question is if the chemical industry and the US government have learnt their lesson. It seems not, though the gist of its proposal is well hidden.

One of recommendations of the US chemicals lobby group, the American Chemicals Council (ACC), to the USTR is to "create a distinct track for regulatory cooperation for the chemicals sector and build on the outcomes of the USMCA". So what exactly is the outcome of the USMCA (the new trade agreement between the US, Mexico and Canada which replaced NAFTA) specifically on chemicals?

From a European perspective, the USMCA annex on chemical substances includes relevant rules on assessments of chemicals. Besides a reference to the need to protect citizens, in the text the 'parties' "recognize the importance of developing and implementing measures in a manner that achieves their respective level of protection without creating unnecessary economic barriers or impediments to technological innovation."[14]

In other words, considerations for human health and the environment should be tempered by economic concerns, including those related to innovation. According to the Institute of Agriculture and Trade, one of the US critics of the USMCA, "the overall impact will be to make it harder to adopt precautionary policies that protect the most at-risk populations."[15]

This fits hand in glove with an ongoing attack against the precautionary principle in the European Union, staged by a so-called think tank, the European Risk Forum, acting on behalf of the chemical industry and the fossil fuel industry, among others.

Since 2013 they have worked to have the EU institutions adopt an 'innovation principle' according to which: "whenever policy or regulatory decisions are under consideration the impact on innovation should be assessed and addressed." In that it evades any definition of 'innovation', it is often characterised more as a "lobby product, formulated by a think tank and promoted mainly by the companies that finance the think tank", as one lawyer put it.[16]

One of the main players in the European Risk Forum and in the campaign for an 'innovation principle' is the European chemicals lobby group CEFIC. On their behalf, the European Risk Forum is waging an attack on the EU's REACH regulations (Registration, Evaluation, Authorisation and Restriction of Chemicals). At a meeting with the Commission, they said "some legislation eg REACH, deliberately 'stigmatises' certain product groups. This kind of legislation should trigger the Innovation Principle since it can be a major barrier to innovation".[17]

Looking at what we know about the US mandate, it appears to accommodate this agenda. So, what we have here is a US government which appears willing to lend a helping hand to the chemicals industry on both sides at the trade negotiations with the EU. It comes in the form of yet another attack on the precautionary principle, this time in the form of the promotion of an 'innovation principle'.

It could be argued that due to European skepticism, these issues will hardly make it to the negotiating table. However, in a report to a committee in the European Parliament, the EU negotiators in the Commission have already showed openness and said that "the EU is ready to consider stakeholder inputs on potential areas for voluntary regulatory cooperation."[18]

Pesticides and GMOs – the US on the warpath

Precaution in the EU is targeted by the US in other ways as well – some of which are becoming classics in a decade long trade stand-off between the two sides. The US is a major exporter of pesticides and as one in ten pesticides produced in the US contain substances that have not been approved in the EU, there is a lot to be gained for the US at the negotiations.[19]

Perhaps the most aggressive rhetoric comes from US Secretary of Agriculture, Sonny Perdue, a man with a past in the fertilizer business whose nomination was hailed by agribusiness groups.[20] In April 2019 Perdue spoke to a committee in the US House of Representatives[21] where he stated that the European Union "will pay the price" if the restrictions on the use of pesticides which contain the potentially carcinogenic[22] and endocrine-disrupting ingredient glyphosate are maintained, or if its more strict rules on GMOs are upheld and enforced.

The EU rules on GMOs have been a major nuisance for the USTR for a very long time, but there is no sign of the US backing down on any account. According to the summary of its mandate, the US is going for "specific commitments for trade in products developed through agricultural biotechnologies"[23], as well as measures to prevent 'unjustified labelling' – a reference to a disagreement between the two sides on labelling of GMO products. The USTR is going for a new approach in the EU towards GMOs in that it wants "new and enforceable rules" to eliminate "unjustified trade restrictions … that effect new technologies" and to ensure that "science-based SPS measures are developed … in a non-discriminatory manner".

On a more fundamental note, the European Union has been discussing a new variation of GMO products, so-called New Plant Breeding Techniques, and according to a judgment from July 2018, they are to be regarded as GMOs and hence regulated by the GMO directive, with some relatively strict procedures in place. At the time, the Secretary Perdue swiftly deplored the decision: "Government policies should encourage scientific innovation without creating unnecessary barriers or unjustifiably stigmatizing new technologies. Unfortunately, this week's ECJ ruling is a setback in this regard," he said.[24]

The question of new GMOs is still up in the air in the European Union. It will be up to the new EU Commissioners, which take their seats later this year, whether special rules should apply to new GMOs or not. If the US Administration gets its way at the negotiations and an ambitious approach to regulatory cooperation is agreed, Perdue will be there to push the Commission not to regulate at all. To him, there is no need to regulate "where there is no risk present".[25] As for the biotechnological industry, ambitions for the negotiations are high. The response of the Biotechnological Innovation Organization to the consultation of the USTR sets the target: "EU regulations often delay or deny U.S. producers of new technology and hinder market access for U.S. agricultural products, contributing to an ever-growing trade deficit. A trade agreement with the EU must address the continued departure from science-based decision making that is unnecessarily denying farmer access to new technologies in the United States and around the world."[26]

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> **The US won't be able to guarantee European consumers that imported food products meet EU standards. In fact, the food safety system overseen by the US government can't even assure US consumers that our food is safe. The US has a broken system that's rapidly deteriorating under the Trump administration.**
>
> Sharon Anglin Treat, Institute for Agricultural and Trade Policy (IATP)

Photo by Annie Spratt on Unsplash

Food inspections with less inspection

While the attack on EU rules on GMOs, chemicals and pesticides are all well within what is covered by the term 'regulatory cooperation', it is not clear how far the EU negotiators can make this fit with its mandate to negotiate on 'conformity assessments'. But chemicals, pharmaceuticals and soybeans were singled out at an early stage as areas where steps should be taken to facilitate trade, which would include certification and inspections, at the least.[27]

One implication for trade in food seems to be clear, though. Here 'conformity assessments' are chiefly about tests and inspections. If the two sides can agree to mutually recognise their food inspection systems, trade will become easier. US exports, for instance, would not have to pass by the EU's external veterinary border controls.

Why would that be a concern to Europeans? For example, is the US system not able to prevent infected meat from being sold on the US market or from being exported? There is a worrying development on that front. At the moment, the US Administration is scaling back on food safety and its policy strikes in the middle of the issues to be discussed with its EU counterparts.

Over the past few years, experiments have been conducted to allow slaughterhouses to conduct a large part of inspections themselves. Now, the experimental phase is over and the model will be expanded from 5 plants to 40, covering 90 per cent of the pork consumed in the United States.[28] The plan is to reduce the number of federal inspectors by 40 per cent – from 365 to 218. Instead, plant workers are expected to pick out bad meat, but they will not have an easy job: the cap on slaughter line speed is also being cancelled, allowing plant owners to set the speed they want.

Sharon Anglin Treat of the Institute for Agricultural and Trade Policy (IATP) said:

"The plan proposed by both US and EU trade negotiators is to rely on each other's systems for inspecting products and certifying compliance. How then will the US system—which relies heavily on chemical treatments to kill contaminants and end-product inspections—guarantee that US products meet the tougher food safety standards of the EU, where farm-to-fork tracking protects against contamination throughout production, slaughter and processing? Bottom line: The US won't be able to guarantee European consumers that imported food products meet EU standards. In fact, the food safety system overseen by the US government can't even assure US consumers that our food is safe. The US has a broken system that's rapidly deteriorating under the Trump administration."[29]

3. The EU: exporting risky products

In contrast to the US, whose summary of its positions is informative, the published EU position is not rich in detail. While the EU cannot be said to have been transparent during the TTIP negotiations, the new talks represent a major step back. In the public domain there is little more on the intentions of the EU negotiators than a remarkably short negotiating directive and a few reports so committees in the Council and the Parliament. According to the negotiating directive, the EU is to negotiate an agreement on 'conformity assessment' that will apply across sectors (horizontally). It should allow 'an importing party' to accept conformity assessment results by a body in the territory of 'the other party', and 'an institutional structure' should be set up "to ensure the implementation of the Agreement".[30]

This is hardly the full story of the plans of the EU negotiatiors in the Commission. At a 'stakeholder's meeting' in Brussels in July 2019, the EU negotiators convey an obfuscatory message. According to Commissioner Malmström, "we are also engaged with the US in other areas where we already have authority from the Council or do not need a formal mandate". As Max Bank from LobbyControl said, such statements make it unclear whether the EU is negotiating solely within its mandate or not.[31] Shortly after, the Commission announced the completion of a new agreement with the US on pharmaceutical products with links to a more than 20 year old agreement on 'mutual recognition' with the US.[32] It seems the Commission is exploring ways to expand the negotiation agenda without having to go through the burdensome process of asking for a mandate and debating with elected politicians. On top of this, the formal impact assessment process in the EU – the obligation to explain the implications of an initiative in a thorough report – has been waived "due to the political imperative to move ahead quickly in order to lower trade tensions", and because "it is expected that the new agreement will not have significant economic, social or environmental impacts beyond those benefits arising from simplification of conformity assessment for specific product sectors."[33]

Once again, it could be argued, we are being served the idea of a trade-related agreement without any downside and of a purely technical and rational nature. But there is strong evidence to suggest this is not the case. With the emphasis on 'conformity assessment', the European Union is preparing an agenda that suits its interests, and the potential negative impact on public health and consumer rights is considerable.

Conformity assessments – not so straightforward after all

Conformity assessments are about the tests and procedures used to ensure that a product lives up to standards and technical regulations. And if the starting point is broadly similar rules, it shouldn't be a big deal to recognise the methods and procedures of the other side. In that way, a product will only have to be checked once, and trade will be facilitated.

However, specialists in the area strongly disagree. As two academics put it: "The process for verifying that products meet established standards is as important as the standards themselves, and it can have significant economic and safety impacts".[34] The question here is if there are areas where there is a risk that an agreement could lead to such negative impacts if the two sides agree to recognize one another's procedures.

For while some of the standard attacks on EU protections are well known, it is perhaps not common knowledge that when it comes to product standards, the US approach is in some ways more intrusive and sometimes more protective to the public than the corresponding European system. In the EU, there is no requirement for independent certification for most products. Manufacturers are allowed to self-declare conformity of their products to legislation and put a mark on it – the CE mark – where appropriate. As the European consumer groups the European Consumer Organisation (BEUC) and the European Association for the Coordination of Consumer Representation in Standardisation (ANEC) say in their recommendations to the EU negotiators: "CE marking is no more than a claim from the manufacturer that the product meets European legislation and is meant for market surveillance authorities, not consumers. In other words, the manufacturer does not have to provide an independent confirmation of the claim in most cases. Consumer organisations in Europe have long expressed concerns about CE marking and still advocate strongly to not show it on the products or their product packaging."[35]

The remarks from the consumer groups are about a model of conformity assessment used widely by the European Union for decades: the Supplier's Declaration of Conformity (SDOC). Generally speaking, independent testing is not required. What a manufacturer needs is for a 'notifying body', appointed by a member state, to accept its claim that its product lives up to the technical regulations and standards. This does not necessarily imply a test by the body in question, nor an unannounced visit to the production site. At the negotiating table, then, the EU is working towards having its SDOC model accepted by the US to save European companies from having to have their products investigated in the US. This is a simple quest for market access, not because the EU has something on offer to improve product safety. A survey produced by the International Federation of Inspection Agencies and the International Confederation of Inspection and Certification Organisations showed that "17% of the self-declared products showed dangerous faults" compared to less than 1% dangerous faults for products that were third-party certified, ie. by an independent body.[36] Strikingly, the European Commission's own assessment does not appear to be more favourable. According to its own investigations "as many as 32% of toys, 58% of electronics, 47% of construction products or 40% of personal protective equipment inspected do not meet the requirements for safety or consumer information foreseen in EU legislation."[37] Yet this does not make the Commission show restraint when it comes to asking the US to give its seal of approval to EU conformity assessments.

To explore what the potential consequences may be if the US makes concessions to the EU in this area, it is worth asking what sectors the EU is looking at in particular. For while the EU is trying to obtain a 'horizontal agreement', ie. one that applies across sectors, naming sectors would give an indication of the gist of what the EU wants. Such a list has not been made public by the EU negotiators, but in connection with a consultation of stakeholders in March and April 2019, we were told the Commission was looking for a horizontal agreement to facilitate the acceptance of certificates in "a number of selected sectors such as electric and electronic equipment, machinery, medical devices, toys, recreational crafts, pressure equipment, construction products, measuring instruments, etc."[38]

Of these, three sectors in particular can help illustrate the pitfalls: medical devices, electric and electronic equipment, and toys.

Dieselgate: Why removing duplicate investigations is not an end in itself

Car production is a highly sensitive area at the talks, not because of safety regulations or differing approaches to standards or technical regulations, but because of Trump's threat of tariff hikes or import quotas.

In the former area there seems to be a more relaxed atmosphere between the two sides and a will to work towards getting rid of duplicative conformity assessments. Yet only a few years ago it was a 'duplicative conformity assessment' performed by the Environmental Protection Agency in the US that discovered fraud in Volkswagen's emissions reporting.

In the EU, it was left up to carmakers to perform the crucial test, and in the case of VW that proved too tempting. The company had fraudulent software installed to show a better fuel efficiency performance and hence lower CO_2 emissions than what was actually coming out of the exhaust pipe.[39]

Dangerous implants certified by the private sector

There are many recent examples of the flaws of the main EU approach, some of which are highly relevant to the negotiations. One of the areas singled out as a low hanging fruit is medical devices.[40] Here, the Commission believes there is "scope to work on reducing duplication of regulatory costs".[41] This is despite tangible differences in the approach of the two sides, some of which are quite fundamental. In fact, the EU's approach has shown shortcomings so serious that in 2011 scientists attacked EU rules for allowing Europeans to become guinea pigs for industry – a place to test products in the flesh before entering more regulated markets.[42]

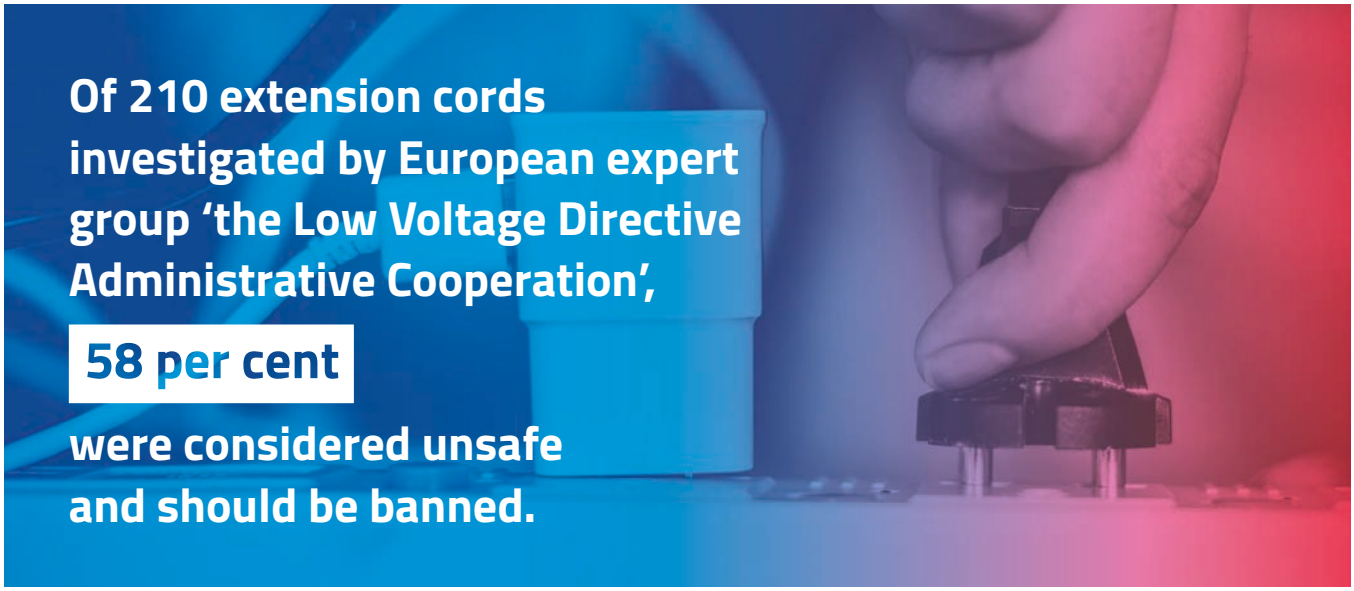
The category of medical devices covers a broad range of products used for diagnostic or therapeutic purposes, including prostheses, artificial limbs, walking sticks, pacemakers and other devices. Unsurprisingly, this is generally regarded as a high-risk area, but that does not mean the EU takes a cautious approach. Conformity assessment of medical devices are covered by rules that put private standard-setting companies at the heart of the approval process.

The flaws in this approach came to the fore with the PIP scandal. PIP is the French company behind approximately 30,000 breast implants which turned out to contain industrial silicone of the kind used in mattresses, and which could cause infection and possibly even cancer.[43] Presumably the implants lived up to the standards certified by TÜV Rheinland, a German 'notified body' which was trusted to develop and monitor standards of this type.

During a court case, involving 1,500 victims, it emerged that TÜV Rheinland had neither conducted any tests, nor paid an unannounced visit to PIP. TÜV Rheinland's response was that the relevant EU directive did not require it to do either of those things. In fact it was under an obligation to give advance notice to PIP before a visit, had it decided to do an inspection.

The outcome of the scandal was a change in the European rules, which came into force in May 2017. But they were hardly a turnaround: the Commission had the wording tweaked so that visits are now 'recommended'.[44] As experts in the area remark in a technical document: "conformity assessment procedures remain essentially the same."[45]

What would happen, then, if such a system is approved as equivalent in the context of an EU-US agreement? On the other side of the Atlantic rules are fundamentally different. In the US, a breast implant would have to be approved by the US Food and Drug Administration before it is put on the market.[46] Cutting that cost out of the equation would give European companies a more competitive edge in the US market, for sure. And the main industry association in the sector is clear in its submission to a consultation on the negotiations that it wants to see the elimination of "duplication of approvals or regulatory activities where possible" and ultimately to see "mutual recognition" of conformity assessments. In other words, if a product is approved in the EU through self-declaration, it should automatically be approved in the US.[47] The price to patients could be high.



Electrical equipment – workers in peril

The Commission has worked for years to convince US agencies that the 'trial-and-error' approach to product standards inherent in the EU's 'Supplier's Declaration of Conformity model', is as safe as the way the US often goes about it , namely through an assessment done by a private but independent laboratory or a government agency'. One such incident was when the Commission tried to convince the Occupational Safety and Health Agency (OSHA) that the EU-style approval of electrical equipment secured a high protection level. The issue was whether EU procedures were safe enough for the products to be used in US workplaces.

According to the Commission, there really is no difference between tests done in an official laboratory and one done by manufacturers themselves. "Manufacturers that intend to comply with the legislation will only market products that have passed such tests", the Commission wrote to the OSHA. The Commission also stated that "market [48]
In response, the OSHA remarked that as a general rule "the manufacturer may be unqualified to perform testing, lacks independence, and has financial incentives that could override the need to identify defects".

Faced with the suggestion that the US should simply let European products pass without having to go through a US laboratory, the OSHA set out to investigate whether electrical equipment used in workspaces was equally safe in the EU as in the US. As the Commission had not provided any evidence to back up its claims of safety, the OSHA was left to its own devices and had to go through the cumbersome work of analysing workplace injury statistics related to electrical equipment. In the end, the conclusion was telling: EU workers are exposed to twice the risk as their US counterparts when working with electrical equipment.[49]

In the exchange between the two sides, the OSHA never received data from the EU to explain, for instance, hundreds of fatal accidents with electrical equipment (from 2003 to 2005). So to find more specific indications, the OSHA looked at two products: portable lamps and extension cords, both investigated by a European expert group run by national market surveillance authorities called the Low Voltage Directive Administrative Cooperation. The group had found that of 226 portable lamps tested, no less than 72 per cent, failed one or more of the technical requirements, and nearly half contained serious technical hazards. Of 210 extension cords investigated, 58 per cent were considered unsafe and should be banned.

In conclusion, referring to risks to US workers, the OSHA rejected the proposal to introduce a similar system in the US and hence allow EU products to enter the US market without passing by a laboratory test first. But with the new negotiations, the EU may get a second chance, and European industry seems to be pushing for just that. When a product is certified by one body, it should open the door to the market on the other side, is the message from ORGALIME, an industry association that includes manufacturers of electrical equipment, to the Commission's consultation.[50]

Toying with self regulation

Both medical devices and electrical equipment are priority sectors for the European Commission at the negotiations, and so are toys. The discrepancy between the approach in the EU and the US are not about the protection levels or standards themselves. Toys are covered by international standards, supposedly strict standards that touch on – among other things – the use of lead in paint for children, and the risk of young children choking on small parts in toys. Rules in the US and the EU are basically the same. But the way they are enforced are not. As consumer groups BEUC and ANEC point out in their recommendations to the negotiations, "there are sometimes differences in regulators' assessment of what a high and a low risk product is, and which the adequate level of protection should be. For example, independent third-party testing is mandatory in the US for toys for children under twelve years whereas this is not the case in the EU."[51]

For the EU, having to have products tested in the US after a toy company has declared them safe based on European standards is a trade barrier. To work around this and similar issues, the model that came out of the trade negotiations with Canada, the Comprehensive Economic and Trade Agreement (CETA), is the preferred outcome, according to a leaked document.[52] That model simply takes away the requirement for testing and approval on the other side, and this is good news for toy manufacturers. The Commission stated in a press release: "CETA will help cut costs for EU firms, especially the smaller ones. This will happen thanks to the mutual recognition of so-called 'conformity assessment certificates' for a wide range of products, from electrical goods to toys. For example, if an EU firm wants to export toys it will only need to get its product tested once, in Europe, to obtain a certificate valid for Canada, thus saving time and money."

A CETA-style agreement that covers toys would certainly change a lot for EU toy exporters. In the US, toys will have to go through a 'third party assessment', ie a laboratory not run by the toy company in question will have to make sure the product lives up to standards. In the EU, on the other hand, producers or suppliers can issue a guarantee, a so-called Supplier's Declaration of Conformity (SDOC), in which it is promised the standards are respected. Apparently – perhaps unsurprisingly – such a promise may not deserve warm appreciation.

The ground zero of toy scandals is the year 2007. That year, more than 19 million toys were recalled for not being aligned with adopted standards. This led to new rules in both the EU and the US that were comparable in terms of protection levels, but different in terms of enforcement. The EU opted for SDOC, whereas the US went for Third Party Assessment (or 3PA).

The difference in recalls is staggering: when weighted for the size of the two markets, recalls in the EU are 10 to 20 times higher than in the US. The root source of this disparity is that more unsafe products reach children in the EU than in the US.[53] Should the two sides make an agreement on conformity assessment on toys, this could be bad news for US children and their parents.

The academics behind the investigation highlight their results as an example of a broad trend: There is ample literature that contends that while the US was once the more cautious regulator, Europe has since eclipsed it as more risk averse and willing to shift the burden of proof to first proving a product is safe rather than waiting for evidence that it is not. Product specific analyses, such as this one, show best how Europe is more cautious in some areas, such as toxic substances, while the US is more cautious in other areas, such as product safety testing through conformity assessment."[54]

Conclusion: a real risk of a risky deal

Even though the negotiations between the US and the EU operate at a level of ambition lower than the TTIP negotiations, with a much narrower range of topics, some of the most contentious issues have re-emerged, including the EU rules on chemicals, GMOs and food safety. New issues or a new emphasis reflecting the economic interest of European corporations are also bringing new concerns to the table. Through the talks, the EU is looking for concessions on one of its main methods of 'conformity assessments', the SDOC approach, even though this has turned out to be highly risky.

At the outset it may seem the two sides do not even agree what the talks should be about. While the US would like to see a broad negotiation agenda, the EU governments have only approved negotiations on a limited issue that suits the interests of EU based companies. But on the European side preparations are being made to expand the negotiations to a broader set of issues.

In a worst case scenario the two sides will come to an agreement where flaws in the regulatory systems on both sides are introduced to the other side – all in the name of global trade. Considering the fate of the TTIP negotiations, such a development may seem unrealistic to many bystanders, but something is different this time around: credible threats of trade sanctions, if not an outright trade war, have been made by the US president, sending the jitters through governments in Europe. The powerful German government, the favourite target of Donald Trump, believes its car exports could be in peril.

With this in mind, a truly toxic agreement cannot be ruled out. There are many unknowns at the moment, not least because the European Commission has decided to scale down transparency. This should not be allowed to pass. Politicians must start questioning the Commission and demand a full account of the intentions behind the short mandate. Its refusal so far to do an impact assessment is also unacceptable. This lack of transparency prevents a meaningful public debate.

But more importantly, the substance of the talks must be drawn into question. It may be that corporations can save a little time and money and that trade can be snappier if conformity assessments are to be mutually recognised, and it may be that it is easier for US meat exporters to skip the EU's veterinary border control. But the examples above show that we are not dealing with inconsequential technicalities, but measures that could have a real negative impact on citizens.

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Trading away protection

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