

BE-US Chamber paper on a “Regulatory cooperation component to an EU-US economic agreement”

(TRADE internal assessment of relevance for EU-US trade negotiations)

The US Chamber - BE non-paper submitted in response to the joint EU-US solicitation on regulatory coherence is meant to launch some ideas on the "regulatory component" in a future EU-US FTA. The paper contains a number of useful elements covering two of the three regulatory pillars in the HLWG's interim report, namely:

- *"Horizontal disciplines on regulatory coherence and transparency for goods and services¹, including early consultations on significant regulations, impact assessment, upstream regulatory cooperation, and good regulatory practices".*
- *"Provisions or annexes containing additional commitments or steps aimed at promoting regulatory compatibility over time in specific, mutually agreed sectors".*

As regards "horizontal disciplines" (see mainly sections on "Regulatory Principles" and "Transatlantic Regulatory Tools") general rules furthering convergence (see Common Understanding on Regulatory Principles of 2011) would be completed by a mechanism strengthening upstream cooperation, i.e. regarding draft legislation and regulation, both as regards Impact Assessments and as regards consultation of stakeholders. The ideas are interesting but rather vague as to how this should be achieved in practice, within the confines of our respective administrative frameworks and regulatory cultures. There is also some confusion as to the assessment of trade impacts and the actual stakeholder consultations. The two sections raise a number of issues as to methodology and feasibility.

As regards sectors, (see mainly section on "Regulatory Outcomes") the paper recommends to establish a "proactive" requirement directing and empowering regulators to seek mutual recognition, as well as a process by which regulators would be "required to respond to stakeholder-identified opportunities" to examine equivalence. However, at this stage, lot will depend on the joint submissions from EU and US businesses (sectors targeted: most importantly automotive, chemicals, pharma; possibly also medical appliances, insurance, machinery). Only general comments can be made.

Initial discussions took place with the business associations, ENTR and SEC GEN. As a next step, we will be assessing how the pursued objectives could translate into binding provisions in a possible future FTA.

¹ In principle covering also legislation by US states.

*Business Europe –US Chamber of Commerce:
“Regulatory cooperation component to an EU-US economic agreement”*

Preliminary assessment

The Business Europe and the US Chamber submission contains both suggestions for **horizontal provisions** (focussing on new legislation - good practices, principles and new consultation mechanisms) and **sectoral provisions** (focus on existing legislation). These are assessed below as to their content (What is the concrete proposal); validity and feasibility (Is the principal idea valid and feasible?); and methods as to incorporate them in a possible FTA (i.e. is there a precedent on either side, etc.), always on the basis of reciprocal steps on the US side. NB: At this stage we consider premature to discuss the "Institutional Provisions" of the paper.

Preamble

"Although FTAs generally avoid chapeaux to individual chapters, it is, however, important that a US-EU agreement break from this mode in regard to how it approaches regulation. A US-EU agreement charting a course for regulatory cooperation for regulators in both markets must be guided by a unified vision in order to sustain a continuous high-level commitment. It would also signal to **third countries** the importance the US and the EU place on high quality, least trade restrictive approaches to regulation. The unique level of ambition in a US-EU agreement requires a clear statement of **how deep EU-US regulatory cooperation benefits consumers, investors and the environment** by allowing regulators to devote scarce resources to enforcement against higher-risk jurisdictions, without diminishing their ability to regulate or achieve their regulatory mandate. This will give U.S. and European citizens greater confidence in traded products and services even as it helps regulators ensure optimal allocation of their scarce resources. It would also ensure businesses have better predictability, and that small and medium sized businesses in particular are better able to engage in transatlantic trade."

Comment:

Proposal: Paper suggests including arguments **why** regulatory cooperation benefits all stakeholders – predictability, more efficient enforcement of rules protecting consumers, etc.

Is it valid and feasible? The principal idea is valid-first, providing a signal to third countries that this agreement is *special (gold standard)* as regards reg coherence and second, a signal of a "culture" change in our transatlantic cooperation. NB: *General Q* how this could best be achieved will also arise for other areas in the FTA, notably rules.

How could it be incorporated? BE wants to place these considerations as a "preamble" to the "regulatory coherence" chapter. Although not usually done for single chapters similar text could be placed under "objectives" or "principles" of the regulatory coherence chapter (see Korea FTA, CETA Article X.2 lit. 4.) Specific paragraphs can also be negotiated as part of in individual chapters and (wholly or partly) moved to the general preamble.

<p>Regulatory Principles</p> <p>Here the text of an agreement is relatively straightforward. It essentially would draw from the various core regulatory best practices that are embodied in US and/or EU administrative law. It would also reaffirm and formalize work already done in the June 2011 <i>Common Understanding on Regulatory Principles and Best Practices</i> and April 2002 <i>Guidelines on Regulatory Cooperation and Transparency</i>, developed bilaterally between the US and the EU.</p> <p>Much of this has arguably already been negotiated between the two parties, therefore, its inclusion would be easy and it would serve:</p> <ul style="list-style-type: none"> • To make the regulatory component of the overall agreement comprehensive. • As a model for other trade negotiations for how regulatory best practices have linkages to the same market liberalization goals that serve as the impetus for trade negotiations. • Demonstrate a commitment from both the US and EU to go beyond any level of regulatory coherence or cooperation in current or in-process trade agreements. 	<p><u>Comment:</u></p> <p><u>Proposal:</u> To negotiate a chapter on regulatory cooperation/coherence and use as a starting point our respective administrative laws and the Common Understanding 2011² (while also capturing the main principles of the 202 Guidelines to the extent not superseded by the 2011 document).</p> <p><u>Is it valid and feasible?</u> YES. Agreed in principle with US to have a "regulatory coherence chapter" as the interim report points to "horizontal disciplines on reg coherence for goods <u>and</u> services". There are precedents as to the inclusion of a chapter on reg coherence; i.e. in CETA and TPP. But we would aim to go beyond previous FTAs.</p> <p><u>NB:</u> <i>The Common Understanding consists of three basic levels: 1) 'Principles' (reflecting our respective administrative laws) and 2) 'Practices' (how we should apply these laws) on 3) practical actual cooperation mechanisms (both present and future). The first two parts refer to our common understanding on "how to regulate", the third basically to transparency and consultation of stakeholders (improve present and develop new cooperation tools). The Common Understanding falls short of the ambition in the interim report in that it does <u>not</u> aim for 'compatibility' and 'coherence', nor for the objective of avoiding red tape (like the joint solicitation).</i></p> <p><u>How could it be incorporated?</u> Language contained in the Common Understanding and 2002 Guidelines even if non-binding ("should", "endeavour") can be incorporated in the FTA and made binding. DS would apply (no waiver) not to undermine the significance of the disciplines while knowing that we will not launch a case for breach of cooperation (lack suitable remedy in terms of "nullification" and "impairment" to get compliance).</p>
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² http://trade.ec.europa.eu/doclib/docs/2011/december/tradoc_148392.pdf

Regulatory Outcomes

The US-EU agreement should create a clear goal that **encourages regulators to evaluate the body of regulation** and corresponding conformity assessments governing **various sectors** to determine to what degree each regulatory framework delivers **equivalent** regulatory outcomes. Once this is determined, regulators can implement a “sliding scale” of regulatory cooperation enhancements to maximize the desired level of coherence, which can include full equivalence.

The creation of the **mandate** in the agreement and corresponding **implementing legislation** should help ensure any **statutory barriers** to cooperation are removed. Where such equivalence in regulatory outcome is acknowledged, regulators would grant regulatory equivalence to products and services **found to be in compliance** with either regulatory regime. These decisions would need to be evidence based – unlike traditional trade negotiations, decisions should not be based on tradeoffs.

This process should be oriented to **allow stakeholders as well as regulators to identify entire sectors and regulations within sectors that are potentially ripe for an equivalence evaluation**. Such a regulatory cooperation component will add a proactive requirement **directing and empowering regulators to seek mutual recognition**, as well as a process by which **regulators would be required to respond to stakeholder-identified opportunities** to examine equivalence – neither of which currently exist in the EU or the US. Further, embarking on the exercise of examining equivalence can yield benefits even if the regulators are unable to arrive at recognition of full equivalence. For example, regulators can increase efficiency by enhancing mutual reliance through **information and resource sharing or removal of duplicative testing and reporting requirements**. Examining equivalence can identify barriers or other issues preventing progress and lead to the development of the pathways and progress needed to arrive at full equivalence in the future.

Comment:

Proposal: Regulators will be encouraged/mandated/bound to engage in evaluating equivalence upon a specific substantiated request from stakeholders with a view to seeking MR. If regulators cannot agree on MR, they should strive to increase efficiency and thus engage in other types of regulatory coop, including information sharing; resource sharing, removal of duplicative testing and reporting requirements.

Is it valid? Yes. Functional equivalence and MR are important instruments to consider in individual sectors, first and foremost in automotive sector (ACEA assessing equivalence between FMVSS and UNECE regulations and agreed GTRs). MR also relevant for chemicals (API, finished drug products, pesticides). 'Duplicative testing' relevant for pharma, information sharing relevant for all sectors.

Feasibility? Yes, if a targeted and joint request comes from industry. Chamber approach to consider equivalent all regulations with similar overall objective not feasible.

How could it be incorporated? We would need to set up a structure in the agreement (institutions/process) through which new MRAs can be adopted/concluded. Article 218.9 TFEU (decisions by a body set up by an agreement) may be an option that would not require EP consent but only Council decision (but political consultations of EP might be warranted depending on the subject matter).

NB: In US equivalence agreements cannot be incorporated into the FTA itself but, under their current authority, agencies would have to go through formal rulemaking in order to make an equivalence determination. While the FTA itself could include a section which would commit regulatory agencies to make equivalence assessments, it could not anticipate the outcome of such rulemaking.

This process will also support **regulatory reform** in both the US and the EU, which is increasingly putting a premium on conducting **ex-post assessments** or look-backs of existing regulation; the best approach to these assessments is still very much in its infancy. However, an agreement that directs regulators to explore whether regulatory frameworks in the US and the EU achieve equivalent outcomes ties together and enhances the **current ex-post assessment trend** and would aid in the development of a greater capacity and ability to assess how regulation is working in what is often a globalized market.

Once regulators implement their **new mandate** and begin examining compatibility towards **reaching equivalence, when appropriate and desired, or enhancing regulatory cooperation**, special factors would come into play to ensure that the arrangement remains ‘evergreen,’ including flagging all new regulations in a sector undergoing such an examination. The agreement should recognize that full equivalence isn’t the only outcome – we can build incrementally through mutual reliance, removal of duplicative tests, resource sharing, and streamlining regulatory processes, such as enforcement and testing.

NB: It is not clear what the "regulatory" reform refers to (could be reference to the two US Presidential decrees of January and May 2012, on ex post evaluation and international regulatory cooperation; On the EU side, COM/SEC GEN will likely to revise its IA guidelines, which were last reviewed in 2007). Also, there is no general "trend" to ex-post assessment, as this is a very complex and time –consuming exercise and has not been applied often by either side. But SEC GEN is interested in stronger ex-post assessment and the topic is also a standing item on the Forum.

Transatlantic Regulatory Tools

Working within the existing EU and US regulatory promulgation process, an agreement would adopt new procedures that create a **formal consultative role between the US and the EU for select regulations** consideration by either Party to be “significant.” These “significant” regulations can be defined to cover issues of key importance to conducting business on either side of the Atlantic or to understanding how a regulatory mandate (e.g. health or safety) is being met when the regulated good or service will be traded across the Atlantic.

Possible factors that might **trigger** the formal consultative role are:

1. Where regulation will impact goods or services where the **volume** of such bilateral trade or investment is **significant**.
2. **Any new regulation** or change relevant to a sector where an **existing regulatory cooperation arrangement** between the EU and the US **will be impacted**.
3. Regulation is being considered in an **emerging policy area** or developing sector that has great potential for growth.

Comment:

Proposal: BE/Chamber have been asked to provide information as to where exactly the present consultation system fails and to show, taking a practical example, how the "formal consultative role" would work in practice and how it would interact with present procedures (minimum criteria for consultation, IA, etc.).

Is it valid? Yes, in particular when trade with US, our largest partner and most advanced economy, is at stake. Addressing divergences at the root is preferred option. Paper needs to explain why the "present system" is not sufficient and needs to be improved.

Feasibility? Yes, but will depend on exact level of ambition and scope. "Triggers" proposed by EB/Chamber are very broad and could be understood to cover virtually all regulation. As compared to regular "transparency" chapters a much more targeted mechanism is envisaged, which (at least in the case of the sectors covered in the FTA) would put burden on administrations to consult, even when the exporting party does not care. This system may also imply a system of bilateral notifications of all initiatives (which so far we have always resisted).

How could it be incorporated? International agreements can in principle foresee specific consultations. Binding bilateral consultation mechanism could be incorporated as part of sectoral annexes and/or as part of the "Regulatory Cooperation/Convergence" chapter. In addition, since the COM (SEC GEN) will be carrying out a review of its consultation mechanisms (minimum standards or 2002) this could be used to introduce some improvements (provided US does the same).

Regulatory Compatibility Analysis (RCA)

An important element of this process relates to the **right of each side to be consulted early in the domestic regulatory process**. This is particularly relevant given the apparent structural differences in the US and EU legislative and regulatory systems. These different structures will require some innovative thinking on how stakeholders, and regulators, on both sides can provide meaningful input into the process, where justified.

Such an approach is highly possible, in fact, in the 1980's the Administrative Conference of the United States (ACUS) made two recommendations endorsing a process call "**regulatory negotiation**" which put stakeholders at the table with regulators to essentially co-write regulation. Similarly, the EU has a longstanding policy to promote regulatory cooperation, and where possible convergence, with its major trading partners. This discussion paper posits a modified hybrid international version of the existing ACUS recommendations and the realization of the EU's regulatory cooperation ambitions.

Comment:

Proposal: Basic request is to agree on a formalised process which would allow "each side" (i.e. both EU and US businesses) to come in earlier as is the case now on draft legislation – where "justified" (scope of application tbd: across the board or certain sectors only?).

As to the concrete mechanism, one concrete option put forward is a "hybrid" of the "Regulatory Negotiation."³ In strict terms, this is not about "consultation" but rather the very basics of how text of legislation" is produced. Suggestion is to have everybody at the table (stakeholders, regulators) to agree the main elements of a piece of regulation with the help of a "neutral facilitator", before the competent agency proposes it in its final form, adopts and implements it.

NB: Regulatory Negotiation or "Reg Neg" is a process in US administrative law, through which an agency develops a proposed rule by using a neutral facilitator and a balanced negotiating committee composed of representatives of all interests that the rule will affect, including the rulemaking agency (or agencies). Reg Neg is not mandatory for US agencies, just an option. The Negotiated Rulemaking Act of 1990 (Reg Neg Act) encourages agencies to use negotiated rulemaking when it enhances the informal rulemaking process.

Is it valid? Improving consultation with stakeholders is certainly relevant to avoid unnecessary divergent outcomes. However, we will need additional explanations why the existing systems do not suffice. COM has recently carried out a revision of its Consultation Policy, which concludes that "the COM consultation policy and tools remain valid and respond to international best standards".

³ 'Reg Neg ' was also flagged by OIRA as a suitable tool to improve transatlantic regulatory coherence (starting with pilot projects in particular sectors).

Further, while, arguably, **some consultation already occurs**, an agreement would serve to add a well-articulated and developed methodology to elevate and **formalize those efforts**. The formalization will create a cohesive system between regulators and also assure continuous progress.

In particular, the agreement would develop a process and methodology for consultation called a **Regulatory Compatibility Analysis (RCA)**. An RCA would be conducted by OIRA or Sec Gen level, and for financial services in the newly created Financial Stability Oversight Committee (FSOC) in the US and the Sec Gen or other appropriate venue for the EU.

Feasibility? As for the basic request, see previous section. As to the second part, the "Reg Neg" option, this goes far beyond early "consultation" and would require a change in the COM's basic approach to rulemaking, both as to the exclusive right of the COM as to proposing and drafting of legislation and regarding the COM approach to consultations. On the EU side, stakeholder consultations usually occur in the middle of the process (after initial reflections in green paper and before the COM draft is adopted by College), while US consults at the very beginning and the very end (i.e. on the basis of an almost final or quasi final draft, without responding to individual third parties' comments). *NB: These divergences have also prevented EU and US from agreeing in the HLRCF on a common approach on how to improve transparency of our notifications to the TBT Committee⁴.*

Precedents? There are next to no precedents on the use of "Reg neg". It was recommended in the 80ties by ACUS and strongly pushed by the Clinton Administration but was hardly ever (successfully) applied in the US save for one case, i.e. parking permits for the disabled, which involved the DoT, the 50 US States transportation departments, as well as the Canadian Transport Ministry. Through negotiated rulemaking, the US and Canada agreed on a model agreement, which was then implemented separately in the US (at federal and state level) and in Canada through their separate processes.

How could it be incorporated? As to the basic request, see previous section. As to the second request, the "Reg Neg" proper, our administrative laws would presumably need to be changed. Another alternative would be to strengthen the "trade impact" element of the COM's IA – and the same on the US side (by the regulators). In addition, a more informal process, building on the Common Understanding on regulatory principles and best practices, could be considered, i.e. strengthening existing or explore new mechanisms. Public solicitations on important legislation addressing specifically the regulatory aspects, improved early warning tools, meetings with senior level officials, stakeholders, etc.

⁴ US insisted in notifying WTO Members of requests for information and advanced notices of proposed rulemaking. EC side refused as such consultation takes usually place when there is not yet any draft available and therefore a TBT notification at that stage would not comply with the recommendation of the TBT Committee that notifications should be made when a complete text of the proposed measure is available.

RCA Methodology

The agreement should also spell out a **RCA methodology** to use as a baseline for avoiding unnecessary divergence of new regulations. The RCA is meant to inform regulators' final decision and is not meant to be determinative. Much consultation with regulators and stakeholders will need to be done to **properly calibrate this methodology**. But as a rough starting point, some questions to be considered as part of the methodology include, but are not limited to:

1. What are the costs/savings to the private sector (if any) of complying with a single set of regulations compared to the costs of complying with two or more sets of divergent regulations?
2. What are the budgetary savings to the two regulatory authorities of developing, inspecting, and enforcing two sets of regulations compared to one?
3. How much is transatlantic trade likely to increase as a result of the lower transaction costs from the elimination of the divergent rules?
4. How much would estimated benefits increase if regulatory spillover benefits to the transatlantic partner are included in the benefit estimates?
5. Would there be a change in the regulatory alternative recommended if the net-benefits are increased relative to the baseline of divergent regulations?
6. What are the quantitative and qualitative benefits of a transatlantic regulatory alternative compared to the domestic-oriented regulation?
7. Whether existing measures have become unnecessary or outdated by reason of changed circumstances, such as fundamental changes in technology and if the requirement can be removed or redeveloped more effectively through a cooperation activity.

Comment:

Proposal: The objective is straightforward: inform regulators' choice with a view to avoiding unnecessary divergences. But the concrete mechanism remains rather blurred. It is not sure at what moment in the legislative process these Q should be asked (by OIRA? SEC GEN?) .

Is it valid and feasible? In principle yes but not in the proposed form. The 7 questions asked can easily be mistaken for a (provocative) “de-regulation” agenda. The tone of the Q remains doubtful as in many cases there will not be two similar pieces of future legislation to be compared. Other Q seem superfluous: it is clear that for businesses complying with one set of rules is usually less costly. By contrast, for agencies, cost savings could be achieved even while applying different sets of regulations, i.e. by way of mutual recognition of inspections or certifications, tests, etc. Q 6 would seem problematic, as most regulators will be mandated to achieve certain objectives in view of their domestic market and its citizens.

How could it be incorporated? To have an influence on the final decision by COM and US regulators, these questions be asked before the draft rule is being submitted for adoption. The type of questions asked could be imagined as part of a dedicated stakeholder consultation (sectors) and also as part of the IA as such. However, it is unlikely that impacts on trade with one single country and its stakeholders could be singled out in the IA Guidelines (also problematic in respect to our obligations under the TBT agreement).

*One could consider strengthening the trade impact criteria (erga omnes) in our respective IAs when the Guidelines will be reviewed (2013) but this has to be in synch with US commitments (taking into account the pace of the negotiations). This could include an assessment of whether equivalence and MRAs should be considered when we legislate in an important area. **NB:** On US side any “reciprocal” commitment is likely to be limited to regulation coming from regulators at federal level (not Congress and not states).*

Information Sharing

For many industries there is an enormous amount of **data required by regulators as part of conformity assessment** or product approval processes. However, this information is often **business sensitive**.

The agreement should contemplate ways to **incentivize and structure**, perhaps on an **industry by industry** basis, **information sharing** arrangements that give both regulator's and stakeholder's confidence in data sharing, while addressing **any other hindrances** to open communication and information sharing. Further, the agreement should include harsh penalties for the release of **confidential business** information outside of a regulator-to-regulator context. Such assurances would be helpful to encourage industry to sign confidentiality waivers.

Comment:

Proposal: "Incentivise" and "structure" information sharing arrangements per sector. BE/Chamber propose bilateral arrangements" between EU and US sector regulators, which would facilitate sharing of certain data, which is "business sensitive" (could be business secrets or simply any non-public commercially relevant data to be provided by both EU and US companies under certain legislation).

Is it valid? Yes because lack of coordination as to respective administrative procedures create delays in product introduction and commercialisation and duplicative processes generate red tape. Better information sharing both between agencies and private businesses is of high relevance in many sectors, in particular the pharmaceutical and the chemical industry. Business associations like CEFIC-ACC and EFPIA mentioned this as an important element of negotiations, leading to more coherent outcomes of regulatory assessment and increased efficiency.

Is it feasible? Yes but worth exploring different routes. The solution suggested may expose agencies (incl. to litigation) in case of information they disclose, i.e. IPR and data protection/privacy violations, and the like.

How could it be incorporated? To avoid the pitfalls mentioned above, one could consider allowing recycling of the information (companies can submit to EU what you have submitted to US) rather than having US send the same info to EU regulator and vice-versa. Further "alignment" and standardisation" of data requested from companies would be useful. NB: US regulators would need a mandate for sharing data (Congress needs to legislate) in certain circumstances. *NB: Problems have recently arisen with the conclusion of the EU-US product safety agreement: In 2011 negotiations on an almost completely finalised agreement had to be suspended given that US legislation does not allow for an exchange of confidential business information as does the EC legislation. Vice-versa, the alternative soft forms proposed by the US (unilateral declarations) are not allowed under the EC Data Protection Directive.*

Transparency

Provisions should also be drafted to:

1. Provide for a **central registry** of all **regulatory cooperation agreements** between both the US and EU, as well as between either the US or the EU and a respective trading partner.
2. **Create transparency and stakeholder engagement** guidelines to govern any US-EU bilateral dialogue. (e.g. US-EU Investment Dialogue, Financial Markets Regulatory Dialogue, Energy Dialogue, IPR Dialogue).

Comment:

Proposal: Two parts: First, central registry of all agreements between EU and US and with third countries. Second, principles guaranteeing sufficient stakeholder involvement in any bilateral dialogues (both sectoral and horizontal).

Is it valid? Yes; registry would be useful in view of the multitude of different agreements and would help stakeholders but also administration (facilitates also comparison of agreements, in view of coherence). Solid stakeholder involvement is also important since the situation in certain dialogues is clearly not satisfactory (most complaints by stakeholders concern the FMRD and the Energy Dialogue).

How could it be incorporated? The registry could be a web-page where all agreements are referenced and briefly described. Alternative would be a more formal approach requiring both parties to "notify" to the other side new agreements with third countries (probably superfluous). As to the stakeholder engagement we could aim for specific provisions on how to involve stakeholders in the sector annexes (difficult to envisage "separate" general stakeholder process, for all legislation, for the US only). TEC and Forum can provide a model regarding structure and frequency of stakeholder contacts (beyond the consultation throughout a particular legislative process).

Preserve regulator decision-making authority

This agreement can't undermine the sovereign right to regulate or force the hand of regulators in determining the final form a regulation takes. In order to recognize this the agreement must preserve a regulators right to regulate even after new tools like a regulatory compatibility assessment has been employed, but also:

1. Reserve the right for regulators to reject an individual product/service (at any time, if available by sector) from the scope of coverage afforded by a regulatory cooperation/equivalence arrangement (a "veto" authority). When this is done regulators should be required to notify their counterpart and provide rationale.
2. Provide for the unconditional immediate suspension and, after consultation, termination within a short period of time (say 90 days) of any regulatory cooperation/equivalence arrangement.

Comment:

Proposal: First: Provision in the FTA to preserve the right (in general) of regulators to regulate as they see fit. Second: Rights for regulators to discontinue application of any given MR or equivalence arrangement in relation to individual products (while providing reasons). Third: Right for regulators to unilaterally suspend and terminate any MR or equivalence arrangement as a whole.

Is it valid and feasible? Yes, although number one may be stating the obvious - the formulation chosen, however, is unfortunate and again reminds of an anti-regulation agenda, i.e. "Agreement must preserve a right to regulate EVEN after new tools like RCA have been employed. Number two and three seem quite far-reaching and may create not only frictions for trade but also a crisis in the mutual trust between authorities. *NB: See recent case of the Energy Star Label Agreement, where EPA suddenly terminated an existing MR agreement accepting SDOC in the EU as sufficient and reintroduced third party certification, quoting a single case where a product had been found to be not in compliance with the required specifications.*

How could it be incorporated? With regard part 1 we would put some general language to balance the "soft" obligations or general principles. This could be envisaged in a general statement in the (preamble of the) Regulatory Coherence /Cooperation chapter. See example of the CETA where it is stated in Article X.2 (Principles): "*Without prejudice too the ability of either Party to carry out its regulatory, legislative and policy activities, the Parties commit themselves to ...cooperate.*". Or Article X.5 (Compatibility of Regulations: ... this consideration (striving for compatibility) ... *does not prevent either Party from adopting differing measures or pursuing differing approaches for reasons including different institutional and legislative approaches.....*". For hard obligations on equivalence in sectors (e.g. "shall" accept as conforming to its own standards), we need emergency or escape clauses for 1) temporary suspension of equivalence; 2) renegotiate equivalence in light of new developments accompanied by procedures with consultations etc.