



high level dialogue for a globalised world

AECA Round-Table on “Dealing with Regulatory Burden” on January 14th 2016

AECA MEMBER INPUT TO MR. BEN SMULDERS

INTERNATIONAL PAPER

The increased burden of EU Climate Change policy impacts FDI decisions in the region resulting in indirect carbon leakage. 2030 EU targets are very ambitious given our relative emission global impact. European Parliaments discussions on previously agreed targets with the intent of increasing them (Greenhouse gas emission reduction set at -20% by 2020 and then afterwards Parliament openly trying to raise that to -30%)

Tinkering with EU ETS to increase the price of carbon which was originally established as a “market based mechanism”.

These are a few of the “burdens” we have to deal with. Competitiveness begins with confidence. Increased regulatory burden that creates an uneven playing field in a globalised world destroys investor confidence in the EU.

See attachment “IP input to Smulders office”

P&G

It would be interesting to hear Mr Smulders’ perspective on:

- Provisions included to increase transparency on trilogues in the recently agreed IIA on better decision-making.
- Main changes he expects from the new IIA on transparency to be negotiated in 2016

AFORE CONSULTING

» What link does he see between the better regulation agenda and the wider package being negotiated with the UK on the EU UK relationship? How will the better regulation agenda feature in any communication around the referendum?

» A litmus test will be whether the Commission will in fact be willing to withdraw proposals on which either Council or the Parliament have, for partisan reasons, been unable to make any progress in recent years. Should there be no progress on the following two financial services files by summer 2016 could he foresee the Commission considering to withdraw these? The two files are the bank structure proposal and the proposed rules on money market funds.

» New technologies have the potential of revolutionising many EU industries. How would the EU decide on adopting the appropriate policy response (legislation, non-legislative) and within which time frame?

DEUTSCHE POST DHL

See attachment “AECA DPDHL contribution Jan 2016”

DIGITALEUROPE

Many argue that the result and process for concluding the General Data Protection Legislation didn't match up to the standards and ideals of Better Regulation in at least 3 ways:

Harmonisation – The overall objective of the Regulation was to fully harmonise a fractured set of laws in an effort provide legal certainty for companies and lower their costs. While it still is a Regulation, the final text includes numerous carve outs/exemptions for Member States (impact assessments, Data protection officers, etc.).

Assessment – The impact assessment was flawed. The UK and NL governments both came out with their own impact assessment where they showed the negative (rather than positive) impact that the Regulation will bring to the European economy. The impact assessment did not balance different interests and the normative framework (fundamental right to privacy) took precedence over market economy considerations.

Content – The Regulation failed to address the question of data processing within the modern context. It took an approach to data processing from the 90s is not fit for the Big Data/Analytics world. It will lead to higher compliance costs and/or companies deciding that it is simply not worth doing their R&D product development in Europe. In the end Europe will continue to do what the EC says it wants to stop doing.....importing technology developed in 3rd countries.

EUROPEAN ALUMINUM ASSOCIATION

As European Aluminum is dealing with a broad range of legislative proposals and reviews, we consider that there are two important elements to be strengthened before policy and legislation is developed and adopted:

1) Transparency: proper and in-depth impact assessments covering multiple aspects and impacts of new legislation. We have identified one important dossier for us (i.e. anti-dumping regulation review which could grant Market Economy Status to China) where informal and political discussions took place within the Commission services with few or limited discussions among key stakeholders. Could you elaborate on how transparency for this particular dossier will be ensured and whether a full impact assessment will be unveiled before considering to grant MES to China?

2) Holistic approach and structured consultation: with Juncker's Presidency, the European Commission has implemented a series of organisational changes with a clearer distribution of portfolios and roles. These changes are welcome by us. Also, we have noticed that different Commission DGs are working together (with the support of Secretary General) in critical dossiers which should increase the horizontal cooperation when it comes to developing policy and legislation. Could you tell us if this model is working effectively to develop a more holistic policy for strategic sectors? In this line, do you see a possibility to develop a more structured policy framework for industrial value chains? How do we maximise and structure the input of key stakeholders with several DGs working on one particular legislation (i.e. Circular Economy)? New fora, new methods needed?

PFIZER

REACH, the EU regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals, came into force in 2007.

Whilst medicinal products and Active Pharmaceutical Ingredients (APIs) are exempted from REACH, other substances (such as processing solvents) used in API manufacturing are not.

Since coming into force, the focus of the regulation was to Register, Evaluate and Classify thousands of chemicals. Now the focus is shifting to the next phase in the process, which is to decide which of these substances, classified as substances of very high concern (SVHC), should be authorised (and need to be substituted) or restricted.

Substances currently used in API manufacturing are subjected to 'Authorisation' today or could be in the future (Triton, DMAC, DMF, and NMP are on the candidate list. NMP is considered for going into the restriction list. The rest are being considered for inclusion in the authorisation list- on hold right now.)

When a substance is put on the 'Authorisation List', companies using it need to apply to the European Chemicals Agency (ECHA) for an authorisation, so that they can continue using it for a period of time, until they find alternatives.

Authorisation is potentially an expensive, uncertain process whose ultimate aim is to substitute or eliminate the use of these substances. Also the period for authorization is short (5,7 or 12 years) so impact sourcing decisions.

API manufacturing processes are optimised to handle and control current substances. A substitution of those substances will lead to changes to manufacturing processes may impact the supply, safety and availability of medicines. Potential impacts from delays, additional safety and efficacy concerns and shortages of medicines should not be discounted.

The risk associated to the use of the substance is already regulated by existing EU legislation governing occupational exposure limits and environmental quality standards (Chemical Agents' Directive and Water Framework Directive respectively). A REACH Authorisation would not bring any additional protection or benefits. The Authorisation process is potentially uncertain, costly and discourages competitiveness.

Even if an Authorisation is obtained and a substance is substituted, it is possible that the new alternative will soon be subject to an authorisation and will need to be substituted too. Solvents/reagents used in the manufacturing process are commonly substances of high concern, but cannot be omitted for their unique chemical characteristics in order to produce APIs. An authorisation is granted for a limited period of time after which it must be reviewed again by ECHA.

Competitiveness: As these substances are not found in the final API and as REACH Authorisation only applies to EU-based manufacturing, this places companies with operations in Europe at a competitive disadvantage. It will also create an incentive for companies, in their considerations of future sourcing decisions, to consider production outside Europe.

We know that DG Grow acknowledges that Authorisation procedure will mean an additional level of cost and admin burden, although exact numbers are unknown at present. If not possible to exempt processing solvents used in pharmaceutical APIs, and if substitution is not feasible, it should be possible for industry to obtain longer authorization timelines than current stipulated. In order to maintain business in Europe this should be 25+ years.

Would he care to comment.

MOODYS

How is the new Commission structure working in the delivery of legislation?

Can the EU develop more flexibility in its legislative framework so that the need to re-open level one to meet evolving situations can be avoided? Some jurisdictions in the EU and elsewhere have agencies with rule making powers and with powers to issue “no-action” letters.

What is the Commission’s view on the balance between regulation and enforcement in the EU?

Will there be any changes to the way the EU deals with the burden of third country rules?

METROPOLE HOTEL

Each European country should have a Minister really responsible for the simplification of all regulatory burden.

In some countries, there is such a Minister ... but without the appropriate background (eg : 10 years’ experience in this field in the private sector, instead of the political nomination of a charismatic person) and/or not spending much time on the problem.

The very difficult and heavy social rules seem to be the main difficulty for Europe to compete with The Americas and Asia ... (very high cost of labor but, also, all the many qualitative difficulties related to the labor market)

DOW CHEMICAL

o How the Better Regulation package is now being implemented by the Commission. What elements are already being implemented now, which ones are still in preparation and when and how will they be implemented?

o What has been the early experience with the implementation so far? Is the new way of working already working? What are the challenges in the implementation?

o What has been the response from Member States? How confident can we be that the ‘gold plating’ measures will make a tangible difference?

o How does the new way of working affect stakeholders? How should they adapt to the new way of working?

o What, if any, are the elements of the ‘regulatory burden’ addressed in the title of the event that the Better Regulation package does not address?

AB INBEV

Is there a trade-off between public interest objectives championed by pressure groups and the Commission’s stated intention of reducing the regulatory burden? Non-financial Reporting and Data Protection are two recent examples where a significant increased regulatory burden was accepted, in practice, to be secondary to overarching public interest objectives.

How does “soft law” fit into the picture (self/co-regulation)? We hear a lot of support in principle, but the approach to soft law still seems ad hoc, half-hearted, and not consensual across policy areas.

ARCELOR MITTAL

Issue: transparency & better regulation (eg transparent & genuine stakeholder consultation procedure, realistic/objective impact assessment, proposal leading to the main aim of the subject):

There is clearly improvement on transparency & better regulation on some issues - eg circular economy - but on some dossiers this is not possible to implement, like on the EU Emissions Trade Scheme plan, nothing changed/improved.

As a consequence this is giving a very high regulatory cost burden in reality.

Can the main principles of transparency & better regulation also be implemented on ETS?

EU SALT

We do have 2 discussion topics, one related to the reform of the ETS 2020 and the burden that has been created to treat direct and indirect emissions differently. Secondly, the theme of Nutrition and the 2 aspects of 1) Nutrient profiles and 2) reformulation of foods. Both aspects relate to negative perceptions on certain nutrients, whilst positive messages on food have much more impact to support healthy food choices. Hence why is there no positive nutrient content formulation requirements instead on reducing contents.

CECCM & JTI

After the publication of the Better regulation package of May 2015 (REFIT), do you plan further changes, i.e. what will be the practical consequence of the “Interinstitutional Agreement” to be finalised soon? Are there any examples of how this could affect or benefit industries?

Do you believe that the current “transparency – better regulations rules” are applied equally to all sectors and stakeholders?

What can stakeholders do if they believe that an impact assessment is needed for some specific Implementing – Delegated acts (ref: par 7. of the “Provisional text of the proposed interinstitutional agreement on better regulation”)?

The Commission is increasingly relying on external studies to prepare legislation (ref: par 22 of the “Provisional text of the proposed interinstitutional agreement on better regulation”). External consultants are selected and should have no conflict of interest when performing their tasks but this may prove difficult. Do you plan to expand the ex ante and ex post evaluation of the potential “conflict of interests” of contractors.

What can stakeholders do if they believe that the EC is overstepping its implementing powers (ref: par 23 and 23a of the “Provisional text of the proposed interinstitutional agreement on better regulation”)?