

MANIFESTO FOR SMARTER REGULATION

Executive Summary

'Smart Regulation' is en vogue. Commission President Barroso's decision to make smart regulation a priority of his second terms has revitalized the better regulation agenda of his first term. Not only has he decided to move the smart regulation policy to the Secretariat General and thus under his direct authority but there is also a number of recent Commission Communications which contain interesting ideas how the smart regulation initiative would be better implemented if it was to bring concrete results.

Cefic's legal department has drafted a Manifesto on smarter regulation, as a response to the amount of legislation in the environmental and more specifically the chemicals sector.

The Manifesto examines the progress made so far by the Commission and the other institutions, assesses the latest Commission Communications on Smart Regulation and Industrial Policy and the recent report from the Court of Auditors on the impact assessment system from the institutions and makes a number of recommendations with concrete examples for improvement.

The Manifesto mainly requests that the regulatory framework should be more consistent (to avoid inconsistencies we are facing, for example, with REACH and RoHS, the Toys Directive or the Ecolabels Regulation) and that this should be checked prior to a legislative proposal but also during and after its adoption. It suggests amendments to the current impact assessment system and calls for better consultation of stakeholders. It concludes with the proposal for a 'quality check' for clusters of legislation which should systematically address a number of criteria and legal principles.

INTRODUCTION

The European Union aims at a high level of protection of health, safety, the environment and consumers and developed policies and rules regarding the Chemicals industry. They stand as one of the most regulated and complex policy frameworks in the European Union. However, divergence of procedures and implementation requirements at European or national level should not have an unnecessary impact on costs or innovation dynamics of chemical companies exposed to international competition.

Too often the applicable legislation is complex if not obscure; procedures deriving from it are cumbersome representing a huge cost for chemical companies to comply with. This may endanger their competitiveness in keeping their substances available on the market for the consumer at a reasonable price. As a conclusion, legislation both at EU and Member States levels need to be improved in terms of volume, simplicity, quality and workability.

The Better Regulation Initiative from 2005 onwards

« Les résultats du droit de l'environnement et de la politique éponyme demeurent pour le moins mitigés. Nonobstant le succès rencontré par certaines mesures, les objectifs poursuivis par de nombreuses réglementations (réduction des pollutions industrielles, par exemple) n'ont pas été atteints, sans doute en raison des phénomènes d'accumulation, résultant d'une consommation de masse, apparemment sans limites. Aussi chaque progrès obtenu sur le plan réglementaire est-il rapidement dépassé par l'apparition de phénomènes nouveaux, voire de risques insoupçonnés (biotechnologie, nanotechnologie) »¹

Addressing administrative burden, the EU Commission launched the Better Regulation Action Plan in March 2005. Cefic members submitted proposals but the results - reflected in actions of the Commission - were limited. The obligation to conduct an impact assessment for each new legislation is the most noticeable one. However, a recent assessment of the Commission's impact assessment system by the European Court of Auditors² shows several areas of concern and improvement, mainly the fact that impact assessments are not updated and amended during the legislative procedure.

Cefic also contributed to the High level Group on Chemicals where it made 7 recommendations for better legislation, some of which were encroached in the High Level Group's Final Report. Other papers from the Commission followed: Roadmaps, Action Programmes, the Commission's Work Programme for 2010 which introduced the notion of 'fitness-checks' of regulation and finally the Commission Communication on Smart Regulation from 8 October 2010³.

Communication on smart regulation from 8 October 2010

In this Communication the Commission analyses what has been achieved so far with regard to better regulation and announces to address 3 key issues in the future: to manage the quality of regulation throughout the policy cycle, to insist on the fact that it is a shared responsibility of all three institutions and also the Member states and to strengthen the voice of citizens and stakeholders.

We noticed that the Commission refers in its Work Programme 2011 to this Communication as a 'new phase of smart regulation'⁴. However, we had expected more from this Communication, especially as the Commission's President Barroso took direct responsibility for better / smart regulation at the start of his second mandate, and are missing concrete actions.

¹ Professor de Sadeleer, Environnement et marché intérieur, 3ième édition 2010, p.9

² European Court of Auditors Special Report No 3/2010: Impact Assessments in the EU institutions: do they support decision-making?

³ COM(2010) 543 final

⁴ Commission Work Programme 2011, point 5.2

Communication on EU industrial policy from 28 October 2010

We therefore welcome the recent Communication on EU industrial policy⁵ which lists ten key actions for European industrial competitiveness, thereof the first two on smart regulation. The Commission announces to:

- Undertake an explicit and thorough “competitiveness proofing” of new legislation where the impact on competitiveness of all policy proposals will be properly analysed and taken into account, and to
- Conduct “fitness checks” of existing legislation which will identify the potential for reducing the cumulative effects of legislation so as to cut the costs for business in Europe⁶.

These elements are not new as both an ex-ante and ex-post assessment had already been announced in the Work Programme 2010. What is however new is the clear link of bad regulation to the effects on competitiveness and the announcement to improve the quality of legislation. We have been insisting on the fact that the different pieces of legislation have to be seen in the complex context. The acceptance of the harm of potential spillovers on industrial competitiveness and the cumulative impact of legislation is an important step. Our Manifesto contains concrete proposals how this could be done.

Evaluation of initiatives

Other efforts were undertaken to reduce the regulatory burden but addressed mostly forms and formalities at EU and national levels. Even if some Member States announce targets up to -25 % of the amount (of pages?) of legislation, these actions rarely address the questions of legal consistency.

A High Level Group for the reduction of administrative costs also inquired about some legislation due for review. Cefic pleaded for more consistency of the directive on Restriction of Hazardous Substances (RoHS) with REACH, especially for the selection of substances to be covered by this waste legislation, but the Group neither wanted to address REACH, nor the question of consistency.

In order to reach its goals, these initiatives should identify more the fundamental problems industry encounters. It should not limit itself at restructuring regulations. It should also identify which are possibilities for reducing compliance costs and should also include the implementation stage. It should be prevented as much as possible that there is extra cost arising of national implementation.

There should also be more focus on the real, more detailed problems industry faces. Companies, especially SMEs take the law for granted and look on ways how to comply with it. So it is difficult for them to indicate which are the right issues for the Commission to focus on. This could be improved by more reviews of the national laws, as it has been the case for the Environmental Liability

⁵ Communication on an Integrated Industrial Policy for the globalisation era putting competitiveness and sustainability at centre stage, COM(2010)614

⁶ Footnote 5, point 3.1

Directive. The Netherlands have recent experience with small groups, which go into details of a certain law with the stakeholders and in the end they try to find a solution under the lead of a high level person. He/she puts very direct questions to the different stakeholders, whether industry or government to come to a solution.

Today renamed Smart Regulation, the policy should set competitiveness objectives to the regulatory framework of Industry. The Commission's work programme for 2010 lists smart regulation among its 5 priorities. The Commission announces to make effective use of existing policy instruments and to pave the way for their modernisation.

As regards forthcoming proposals, the Commission announces to examine

- If there is a clear EU value added in a project of legislation
- if the proportionality principle is safeguarded
- better apply the smart regulation instruments
- better coordinate the inter-institutional work
- extend the existing impact assessments system to comitology measures and to
- improve the transparency of impact assessment work by preparing roadmaps

As regards existing legislation, the Commission will

- conduct a systematic post-evaluation to ensure consistency
- undertake a 'fitness check of legislation to identify excessive burdens, overlaps, gaps, inconsistencies and/or obsolete measures'

We hope this is the result of an ex-post assessment of the Better regulation policy and that this project will be realized. Pilot exercises were announced to start in 2010 in four areas of which the environment is one. So far, it was not possible to know if the chemical legislation would be part of this check. Would the Commission consider our sector, the chemical industry is always prepared and eager to undertake this kind of pilot evaluation.

In 2008, Cefic insisted and was finally allowed to submit to the High Level Group (HLGC) on the Competitiveness of the Chemical Industry some proposals to support innovation by reinforcing intellectual property and to improve the consistency and the efficiency of the European chemical legislation. However REACH, just started, remained out of the scope of the HLGC.

The HLGC identified regulation as having a significant impact on the organization and operation of chemical companies and agreed:

- On the need of "favourable internal **economic and harmonized regulatory framework conditions** that foster the efficient functioning of markets and rapid take up innovations."
- That "**Impact assessments** for chemicals legislation need to be based on high quality scientific information and solid evidence collected in a transparent and verifiable manner."

- On the need of “extensive **consultation with stakeholders** to encourage preparation of high quality input, the consultation process should start early, the information requirements be clearly formulated and sufficient time given to respond.”
- That **Improved communication** by authorities is needed, since “full and accurate information is especially important following adoption of new legislation.”

A real step towards Cefic expectations is the decision of the Commission to prepare the review of Reach in 2012 by comparing the scope of 165 “chemical “ legislations and looking for inconsistencies to be corrected on this occasion.

Companies subject to these legislations have a daily experience of their different requirements and hope that this initiative will lead to more harmonization between the texts, the principles they refer to and the instruments they use. This would streamline the **EU “chemical law”**, putting Smart Regulation in action.

1. THE EU REGULATORY FRAMEWORK OF THE CHEMICAL INDUSTRY SHOULD BE CONSISTENT

« Les normes d’harmonisation ont été empilées les unes sur les autres sans vu d’ensemble. A la différence de certains Etats membres qui se sont dotés de codes de l’environnement (Suède, France), le droit dérivé reste à ce jour composé de cadres juridiques hétéroclites, comme en témoigne la diversité des bases juridiques retenues. »⁷

According to the Directory of European Union legislation in force, there are to date (1.09.2010) 113 legislations regulation directly chemicals, 365 legislations in the wider area of pollution and nuisances and a total number of 1321 in the broader field of the environment.

The above mentioned study of the Commission will check the consistency of 165 chemical legislations with the scope of REACH. This project not only confirms the size of the “chemical law” but also refers to REACH as a framework and a methodology that could guide the selection of substances to address in any kind of regulation.

REACH was presented as a framework legislation replacing 40 earlier ones. It will require twelve years of efforts to register, evaluate and authorize chemicals. Specific uses and situations may of course still be adequately regulated but it could be expected that REACH would be the reference for future legislations that could align on the same principles and tools, such as the procedure of selection of substances to authorize. The objective of consistency with other policies is explicitly mentioned in the Explanatory Memorandum accompanying the proposal for the REACH Regulation from October 2003 where the Commission describes that ‘*In preparing its proposal, the Commission has been careful to avoid duplication of the provision of other legislation (...)*’⁸.

However, subsequent legislation already seemed to ignore REACH:

⁷ Professor de Sadeleer, p. 117

⁸ Explanatory Memorandum, page 8

- The Toys Directive (Directive 2009/48) introduced another substitution system than the REACH authorization and restriction system (“Ban, except if”)
- The Ecolabel Regulation ((EC) No 1980/2000)) allows the EU Eco Labelling Board to make its own selection of substances, raising questions about this procedure. Proposed criteria referring to risk assessment and REACH were recently rejected
- The ongoing recast of the RoHS Directive (Directive 2002/95/EC)⁹ may require a separate assessment of substances, despite an announced alignment of RoHS and REACH in the Commission proposal. The Parliament and the Council could adopt a different regime for the selection of substances which would mean that industry will have to seek exemptions under 2 pieces of legislation in the future, which introduces administrative burden for those having to comply with both legislations

Consistency should be a founding principle of this exercise binding steps of the legislative procedures, starting with the different Commission services that often ignore what the neighbour did before, or prepares. An often fundamental difference between the proposals from the Commission and the amendments in the Parliament or in the Council lead to these discrepancies. Our industry, being subject to all these legislations, experiences them and has to carry the weight of double or more procedures. No need to say that this is in opposition to the principles of proportionality and of effective administration.

Impact assessments do not seem to prevent such inconsistencies. A broader analysis of a draft legislations and of the previous ones on nearby topics could help. Cefic would like to propose this as an objective for the “Smarter Regulation” policy.

2. AN IMPACT ASSESSMENT IS NOT SUFFICIENT

Mandatory for all new legislative proposals from the Commission, Impact assessment is embedded within a formal six steps framework for policy making:

- problem identification,
- definition of objectives,
- development of options,
- analysis of impacts of options,
- ideas for monitoring,
- and evaluation.

The quality of impact assessments is overseen since 2006 by the Impact Assessment Board which may ask for improvement or return a proposal (R Meads, European Risk Forum).

⁹ Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Reports are public which is important for transparency. The co-legislators are informed and so are the stakeholders. We however consider that the current scope of impact assessments is too narrow. The experience shows that the analysis is mainly economical and political and does not prevent inconsistencies with other legislation. This is also criticized in the recent analysis from the Court of Auditors¹⁰.

3. THE QUALITY OF A LEGISLATION MUST SYSTEMATICALLY BE CHECKED

Cefic considers that the qualitative aspects of the content of legislation are currently not sufficiently taken into consideration in the impact assessment procedure. The current amount of EU legislation addressing chemical products and manufacturing is a historical addition of rules that could be simplified. *« Ces tendances exacerbent la lourdeur de normes rédigées davantage par des techniciens que par des juristes. Qui plus est les régimes de protection s'arriment à des actes relevant de politiques diverses, adoptés en fonction de procédures spécifiques, poursuivant des finalités distinctes, élaborés sans aucune vue d'ensemble. »*¹¹

If (and when, as the flow continues) more requirements are added, it is seldom in place of earlier ones. They come in addition and sometimes overlap with earlier ones, creating unnecessary burdens. This is why the check should go beyond a single piece of legislation. A consistency check should therefore apply to a “cluster” of related legislations, and not to only one. An analysis of the draft regulation in relation with “neighbour” legislation could lead to more unity in the EU chemical law and step by step to a codification of “clusters” of regulation, as initially done and considered again for Reach.

The proportionality check should also be made systematically to make sure that no unnecessary burden is created to reach the objectives of a law: is it sustainable and effective for the achievement of a legitimate objective? Is it necessary to achieve this objective? Is it reasonable and with effects and costs not disproportionate to its aim and benefits?

*« Le contrôle de proportionnalité relève davantage de l'empirisme que d'une méthode bien précise qui impliquerait un examen successif et systématique des différents critères. »*¹²

Other principles of EU law could also be at stake and, if not respected, be sanctioned by the Court of Justice.

For example, the original Biocides legislation which is 10 years old did not yet produce a single final authorization but instead led to products deselection and even to the bankruptcy of a company before even having its case to have its intellectual property on its data recognized by the European Court of Justice.

An impressive example of dysfunctionings leading to serious damages: property rights ignored, inefficiency of the system, right to be heard...This legislation is currently reviewed.

¹⁰ See footnote 2

¹¹ Professor de Sadeleer, p. 331

¹² Professor de Sadeleer, p. 400

4. LEGISLATION SHOULD BE CONSIDERED BEYOND THE PROPOSAL

The texts the Impact Assessment Board considers are not final. The Parliament and the Council will amend them afterwards and the co-legislators can overlap and ignore each other. Both the Commission in its recent Communication and the Court of Auditors in its recent Report confirm this. The same check should therefore be made at the level of these institutions. Inter-institutional negotiations already considered impact assessments for amendments. Without underestimating the difficulty, these checks could inform the legislators about both costs and possible inconsistencies of a future legislation.

Nevertheless, the initiative becomes a catchword if the concept breaks down when implementation measures are added to legislations. According to the new articles 290 and 291 of the Lisbon Treaty (TEU), the Commission is empowered to take delegated or implementation measures, but has not currently to submit them to the Impact Assessment Board. Considering the importance of these measures in the case of technical legislation like REACH or the Emission Trading Scheme, this control is clearly missing.

The so called “Comitology” procedure for adoption of implementation measures being now more than ever the responsibility of the Commission, the Smart Regulation policy should extend the obligation to submit the “significant” implementation measures to the Impact Assessment (and therefore to the Board?). The chemical industry supports these proposals.

5. THE EFFECTIVENESS OF A LEGISLATION MUST BE REVIEWED

Member States are in charge of the application of EU legislation, which is sometimes difficult to implement and enforce. On the other hand, directives are sometimes badly transposed or “gold plated” by Member States with additional constraints. Such cases are detrimental to the objective of a harmonized internal market and distort competition. The Commission realizes this in its recent evaluation of the effectiveness of the Environmental Liability Directive where it notes that *“The framework character of this Directive resulted in a broad divergence on several key implementing provisions amongst the Member States(...).”*¹³ It is because of the divergent national transposing rules that the Commission announces to start the evaluation of a possible earlier introduction of amending measures ‘without delay’ and before the review foreseen for 2013/2014¹⁴

A lack of harmonization on inspection is unfavourable to the Chemical Industry; In this regard there is a distinction to be made between the inspections by the Commission, verifying whether implementation has been formally achieved and the inspections by national authorities. Only enforced laws will lead to a real harmonization and an internal market. Moreover the lack of uniformity in applying definitions and guidelines should be improved, as was the case for waste and in the ETS definition.

Feasibility checks at early stage and efficiency reviews some years after a legislation entered into force should be conducted.

¹³ Report from the Commission (...) on the environmental liability , COM(2010) 581, page 3

¹⁴ Report from the Commission (...) on the environmental liability , COM(2010) 581, page 10

“Ex post” evaluation should become systematic. If a piece of legislation cannot or is not well implemented, it should be revised. Terms should be planned for review in any new legislation. “Fitness checks” will start in 2010 for existing legislation i.e. in environment and industrial policy fields (Commission Work Programme 2010). We support these proposals and give 3 examples to illustrate our request.

- **IPPC / IED Directive:** The recast was necessary because the Directive was only fully implemented as of 30 October 2007. The final BREFs, and in particular the BREFs concerning the chemical industry, were only actually adopted by the Commission in 2005-2006 and no translations were provided. Even if BREFs were only a tool to know which BATs are available, it added uncertainty.
- **Environmental Liability Directive:** The Environmental Liability Directive had a long history of preparation and discussion before it entered into force on 30 April 2004. Member States had three years time to transpose it into national law. The problem was that diverse opinions and political compromises in the Council and EP Plenary had resulted in a text that leaves a lot of discretion to the individual Member States in the following crucial areas: whether to allow permit and state-of-the-art defences, whether to apply proportional or joint and several liability in a case with more than one polluter, how to regulate financial security schemes, on the extend of the biodiversity which should be protected and on the definitions of damage and remediation targets. The result of this is critically assessed in the commission’s report (see above).
- **REACH scope review:** According to the REACH Regulation (Article 138(6)) by 1 June 2012 the Commission shall carry out a review to assess whether or not to amend the scope of this Regulation to avoid overlaps with other relevant Community provisions. On the basis of that review, the Commission may, if appropriate, present a legislative proposal."Resorting to such a proposal, the REACH Regulation and other pieces of legislation (e.g. Biocidal Products Regulation, Classification, Labelling and Packaging Regulation) could be amended in view of a better consistency. Based on the results of that first assessment, the above-mentioned review is also expected to bring changes of the REACH Regulation it-self, which might significantly impact REACH implementation.

6. WTO COMPATIBILITY AND INTERNATIONAL BENCHMARKING OF NEW LEGISLATION ARE A MUST

The following points should be elaborated in this new chapter:

- New EU regulations should be subject to an examination of their impact on trade and investment and a WTO compatibility test. The objective should always be to choose the least trade restrictive form of regulation in line with the WTO.
- The EU should frequently *benchmark* its regulatory approaches, especially for new regulatory issues, to ensure that they are not diverging from the approaches of major trading partners. Otherwise, business will be put at a competitive disadvantage and policies to promote regulatory convergence with major trading partners will be difficult, if not impossible, to achieve.

7. TRANSPARENT CONSULTATION AND REMEDIES AS PRACTICALITY CHECK

Citizens and associations may contribute to the quality of legislation with their proposals and even with their criticisms. Consultation and transparency are part of EU rules and the Commission even finances some NGOs in this regard.

Cefic appreciates discussing the initiatives of the Commission. Such meetings lead to more understanding for the cases to be dealt with but we regret they are more and more conducted in form of questionnaires.

As far as consultations are concerned, the Commission announces in its recent Communication to extend its consultation periods from 8 to 12 weeks from 2012 onwards. In parallel, it will review the consultation process and especially the quality of the documents on which it consults and which have often been criticized as being unclear¹⁵. Cefic considers the length of the consultation period is not the problem but the question if the contributions to a consultation lead to a result.

Stakeholders generally have the opportunity to give their opinion but some parts of the legislative procedure, i.e. comitology, could however be more transparent. The option between delegated (290 TEU) or implementing acts (291 TEU) is relevant in this regard.

Some bodies however remain untransparent such as the the EU Ecolabelling Board, who did not set criteria for its decisions.

In case of disagreement, citizen's last remedy in front of the authority is to ask a judge to interpret the law. However, access to Justice is sometime difficult or impossible (direct and individual interest (art 263 TEU) is difficult to demonstrate against a general legislation), and always expensive and time consuming.

We therefore continue to ask for the possibility to be heard in an "administrative appeal" by the superior of the person or the committee in charge of a decision and ask that this practical solution becomes part of the decision making process.

8. PROPOSAL

The chemical industry, being heavily regulated, was particularly interested in the announcement of the Smart Regulation Initiative.

It should ensure an objective of quality of legislation:

- Consistent with the policy goals related to competitiveness and employment
- That can be implemented by Member States and companies , big and small
- Uniformly enforced

¹⁵ Commission Communication on Smart Regulation , COM(2010) 543 final, p.10

As a methodology, we propose to add a Quality Check to complete the scope of the impact Assessment procedure and include this check to the role of the Impact Assessment Board.

The European Chemicals Agency (ECHA) uses general appraisal criteria for decisions:

- Effectiveness : attainable objectives , targeted measure, cost effectiveness
- Proportionality: Are the costs proportionate to the benefits?
- Practicality: clarity of the obligations, implementability, enforceability and monitorability
- Consistency: Is the content of the legislation predictable and legally certain

We can align on these criteria and propose that a Quality check for all chemical legislation include more precisely the following 4 questions under 4 different points of view presented in a matrix:

Questions:	To be scrutinised under the 4 following points of view :			
	scientific advice: quality of evidence and of interpretation	consultation: ask “users “about their experience of the regulation	international benchmarking : compare with legislation abroad / WTO compatibility	simplification achieved (including incentives , ,voluntary alternatives)
Consistency of the proposal with related EU and other legislation:				
Proportionality				
Effectiveness				
Practicality				

Deficiencies should be communicated with proposals for improvement to the co-legislators and be accessible to the public. Consultation should be organized on this basis.

We believe this process would help improving the quality of legislation

Tests could be made on pending legislation:

- RoHS
- Biocides
- Results of the study on the scope of 165 chemicals legislation