

## Cefic Manifesto towards European chemicals law

### INTRODUCTION

*On 10 October 2012, the Commission announced its intention to undertake future horizontal “fitness checks” for sectoral legislation (COM (2012)582 final). We asked for a check of the legislation on chemicals but it was decided at the last minute not to choose our sector for this exercise. We believe that even if “chemicals law” is broad, it can nevertheless be addressed in parts using the ongoing or planned reviews of chemicals and chemicals related legislations. To achieve this objective, Cefic endorses smart regulation (SR) principles and methodologies announced by the Commission in its 2010 communication (COM (2010)543 final).*

*While waiting for a fitness check to be undertaken for our sector, we make recommendations on how to progress step by step towards a more consistent framework for the production and use of chemicals in Europe. The coming reviews of numerous legislations should be used to cross-refer these legislations, creating a common reference system. This would help compliance and save costs.*

*The chemical industry is a major industrial actor in the economic and social environment of Europe and the world. It is key driver of progress of sciences, technologies and innovation and is a committed contributor to sustainable development<sup>1</sup>. Being at the source of essential components and products, the chemical industry interacts with practically all other sectors of industry meeting the expectations of society for high quality and performance.*

*To remain competitive, this industry requires an appropriate, affordable, clear and consistent legal and regulatory framework, to achieve the objectives for smart, sustainable and inclusive growth set out by the Europe 2020 agenda. The European chemical industry has demonstrated its robustness in the recent years of financial and economic turmoil, but its future is largely dependent on its own ability to meet competitive challenges, as well as on the quality of the legal and regulatory environment in which it operates.*

*The present manifesto intends to focus on the REACH regulatory system as a central piece of chemicals law, which requires evaluation and improvements. It also seeks to address aspects of its interface and needed consistency with other or more specific legislations. Addressing difficulties and inconsistencies will help companies, both small and large, to successfully operate in the European chemical regulatory environment.*

*We make or support the following overall recommendations to improve the European legislative process:*

- 1. The pre-legislative and /or policy review consultations should be effective and guided by SR concepts. They should be as open and complete as possible in order to base decisions on information from relevant and representative sources. Formalistic consultations, for example, made through too simplistic and obvious questionnaires, should be avoided. The Commission should always provide feedback to stakeholders and report on how their contributions to the decision-making process have been used. In other words, a real dialogue must take place with the relevant representatives of stakeholders.*

<sup>1</sup> See Cefic report 2011-2012 «[the chemical industry in Europe: towards sustainability](#)”

2. *In line with impact assessment methodologies, the process of consultation should effectively conclude between alternative political choices to be made in the regulatory process.*
3. *The SR process should apply to the full policy and legislative cycle (“cradle to grave” approach), as announced by the Commission in 2010. This means:*
  - *when policy options are presented at the beginning of the legislative process;*
  - *when the Commission presents its proposal to the Council and to the Parliament;*
  - *when the Commission undertakes a review of the adopted legislation.*
4. *In particular, a full and effective impact assessment should apply to the proposed final legislation, and not just to the general policy options initially reviewed by the Commission, before adoption of the legislative act, as substantial differences might exist between the two.*
5. *Powers delegated to regulatory authorities - whether at European or national levels - can be considerable and might have a far reaching impact on citizen and companies. A full and effective impact assessment should apply to delegated and implementing acts of EU legislation. The procedure should require regularly applying SR in a more transparent manner in “comitology” activities and decisions. This should be the case even more for the large number of “atypical acts”, which include communications, white and green papers, roadmaps, action programmes, guidelines and guidance. The legal nature of these acts is unclear, but they can have the effects of a regulation<sup>2</sup>.*
6. *“Fitness checks” assessing whether the overall regulatory framework for a whole policy area is fit for the purpose should be organised on the occasion of the review of legislation.*
7. *Continue improving impact assessments by giving special attention to competitiveness-related aspects of new legislation, as announced by the Commission in 2010 and consequently developed in the competitiveness-proofing toolkit.*
8. *A consistency analysis between the proposed policy and / or legislation and existing policies and or legislations should always be done. Special focus should be given to the question of consistency and simplification of the regulatory burden, including resolution mechanisms for unforeseen complex cases.*
9. *Quality checks of the text in progress should be made during the legislative procedure. Too hasty compromises may lead to huge costs. Correcting deficient legislation might take more time and energy than adopting the right one from the beginning.*
10. *Member States should avoid additional burdens when transposing directives into national law (“gold-plating”). Also, the reports on the state of the environment show serious implementation concerns in key areas, such as biodiversity, water, waste and air. Better and more consistent implementation would help to achieve a level playing field. Effective remedies should be created for resolution of possible conflicts between regulatory provisions, transpositions or enforcement measures.*
11. *A right for administrative review of consultations and decisions of the Impact Assessment Board needs to be established. Stakeholders should have the opportunity to be heard by a higher*

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<sup>2</sup> See for instance the recent example of a sector guidance document on the harmonised free allocation methodology for the EU ETS.

*authority, for instance where their interests have not been taken into consideration, or if an impact assessment has not been made.*

## SECTION 1: SMARTER REGULATION

### a) Work in progress

The current Commission has chosen smart regulation as one of its priorities, and is pushing it further.

Cefic reacted to the initiative with its first Manifesto on “smarter regulation”, in October 2010. In it, we mainly highlighted the need for a more consistent regulatory framework, in view of the amount of legislation in the environmental area and, more specifically, the chemicals sector. We had concluded with the proposal for a ‘quality check’ for clusters of legislation, which should systematically address a number of criteria and legal principles. Our aim is for the burden of regulation - both at EU and national levels - to be alleviated, in order to reduce the cost and time needed to comply with it and to improve efficiency.

In the last two years, we have gained the impression that our core interest for consistency and quality of legislation is being taken up. Smart regulation appears in every important communication (Europe 2020, Integrated industrial policy, Commission Work Programme), and we find many ideas we have been advocating for six years, mainly the idea to undertake a consistency check prior to and after the adoption of legislation. In October 2010, the Commission even issued a ‘landmark’ communication on smart regulation, in which it promises to improve in three key areas: to manage the quality of regulation throughout the whole policy cycle, to align also the other institutions and the Member States, and to improve the consultation practice.

A strong argument for a need to act is the huge amount of legislation affecting our sector: more than 100 legislations regulating chemicals directly (the REACH scope review even covered 165), more than 350 in the wider area of pollution and nuisances, and more than 1, 300 in the broader field of the environment.

Besides this, there are all the delegated and implementing acts, of particular importance in legislation of interest to the chemical industry. The “comitology” procedure, recently reviewed, lacks transparency and should be subject to the same principles of smart regulation and impact assessment.

All these measures have to be consistent to ensure “legislative hygiene”.

### b) Impact of regulation on EU competitiveness

Industry faces a difficult situation in the EU, and we would like Europe to become again the number one<sup>t</sup> place to invest. How can regulation improve EU competitiveness? The EU has to focus on two keywords to enhance the performance of its business: *simplicity and stability of the regulatory environment*. This is an idea in progress.

The Europe 2020 strategy calls for boosting growth and creating more jobs in Europe. The “New European industrial policy – Citizens’ summary” to COM (2010) 614 mentions: *“Europe’s economy represents 500 million people, 200 million jobs and 20 million companies. However, inefficiencies in European and national policy making have made it difficult for industry, innovators, workers and consumers to really fully exploit the benefits such an economy could generate. This is a luxury Europe can no longer afford in a world of tighter international competition.”* Further on, the strategy promises to create *“a more favourable business environment, thanks to less red tape.”*

### c) Regulatory Impact Assessments and Competitiveness-Proofing

Impact Assessments are very important tools to understand the potential positive or negative impact of new regulation. In its previous 2010 communication on industrial policy, the Commission announced its intention to better integrate competitiveness aspects in the ex-ante impact assessments of policy initiatives and legislative proposals. As a result, it introduced the competitiveness-proofing toolkit, which allows for giving special attention to competitiveness-related aspects of new legislation, and hence has Cefic’s full support.

Notwithstanding progress made, competitiveness aspects are still insufficiently taken into account. Most impact assessments do not allow for an objective and transparent comparison of the costs and benefits of different options for all three dimensions of sustainability. Often, the assumptions are unrealistic or the calculation models used intransparent. With regard to environmental or climate policy, the potential benefits of a draft proposal for the environment, society and the economy are generously calculated, whilst the costs tend to be underestimated. The option of non-action is usually disregarded. What is more, excessive long-term modelling (e.g. until 2050) - meanwhile used widely by EU institutions to justify legislative proposals and targets - carries risks from exponentially increasing uncertainties and inherent assumptions.

#### d) Application of the general principles

A smart regulation needs at least to meet the following criteria in order to efficiently attain its regulatory objectives:

- Coherence and consistency
- Comprehensiveness and transparency
- Proportionality

Shortcomings are apparent in terms of proportionality of different regulations, resulting in unnecessary administrative and financial burden for the chemical industry. The following questions should be kept in mind when drafting new rules or assessing their benefits:

1. What is the concrete and legitimate regulatory objective in mind? Is the current / planned legislation appropriate to attain this objective?
2. Does the desired legislation go beyond the necessary, or are there other less restrictive means and measures to reach the same objective?

## SECTION 2: EU “CHEMICALS LAW”

We shall hereafter call “chemicals law” the numerous pieces of legislation addressing chemical substances and their uses, as well as their production and the related environmental law.

In order to ensure coherence and consistency of current and future legislation on chemicals, the Commission and the co-legislators should adopt and follow a firmly systematic and structured approach every time there is a review or revision. Ongoing legislation often does not supersede existing legal provisions but is juxtaposed to them, thereby complicating the legal status quo and jeopardising the regulatory objectives. To avoid this happening, the focus has to be on a broad and extensive approach, to gradually shape an integrated and extensive framework of EU chemicals law.

Smart EU regulation governing the chemicals sector has to be conceived in a systematic manner, with a general piece of legislation covering common and joined-up elements, whilst specific regulatory issues have to be addressed in accessory legal acts:

A first block should concern the **general** chemicals legislation, now dealt with by the REACH Regulation.

It would then be necessary to categorise the legislation relating to the **specific “uses” of substances** (mainly connected to agriculture, food and feed).

Chemistry is also linked to **products** and their health and environmental aspects (RoHS, cosmetics, toys etc.), so it would be appropriate to shape a block of legislation dealing with them, specifying the distinction between general product safety, which concerns every kind of product, and the **specific** products, to analyse their single characteristics and provide a tailored legislation.

Moreover, chemicals are also linked to the **working environment** and require a reflexion on the way in which to protect **workers** and to establish the appropriate preventive measures.

Finally, the **environmental policy** is of high importance, given the impact of chemicals on the environment. It would be appropriate to have common references between environmental legislation

and related chemicals legislation. This would mean categorising on the basis of the specific sector concerned (whether it be air, water, waste, animal testing, or eco-labelling and eco management).

The underlying logic of such a regulatory framework of EU chemicals law, which should ultimately tend towards a codification, can be illustrated as follows:

REACH \* (legislation1; legislation2; legislation3; ...) = Regulation of a specific chemicals sector



Unfortunately, a considerable number of overlaps and double regulations persist between REACH and other legislations. These inconsistencies can be remedied by aligning them to the regulatory system of REACH. To cite a few examples:

- *Residues of Hazardous Substances (RoHS)-Directive 2011/65/EU*: Chemicals are already listed in REACH. Cefic stresses its previous suggestion to merge RoHS into REACH and align the restriction regime only under REACH Annex XVII, in order to avoid double burden.
- *Safety of Toys Directive (EC) 2009/48*: Despite the reference to the general regulatory regime of REACH, some inconsistencies persist. This may concern particularly the introduction of different conditions for the use of CMR (Carcinogenic Mutagenic or Toxic to Reproduction)
- *Persistent organic pollutants (POPs)-Regulation 850/2004*: There is a potential overlapping restriction and thus possible double regulation for substances regulated by the POPs convention and REACH, because both restrictions apply at the same time. This is not only confusing but it contradicts the idea of REACH as the central legislation to deal with all chemicals including POPs at EU level.

### SECTION 3: CASE STUDIES

*Two recent good examples can be quoted to illustrate possible steps leading to smarter European chemicals law.*

#### a) WATER – a positive example of a comprehensive fitness check

As part of its smart regulation policy, the European Commission announced in 2010 that it would begin reviewing selected fields of existing legislation through fitness checks. With this comprehensive approach, the Commission will examine relevance, coherence, effectiveness and efficiency of the water legislation. The coherence of legislation (especially between EU water policy and other policy areas) will

be further analysed and strengthened in the upcoming blueprint for safeguarding Europe's water resources.

A first fitness check has started on freshwater policy. It includes the Water Framework Directive (WFD), the Groundwater Directive, the Directive on Environmental Quality Standards, the Urban Waste Water Directive, the Nitrates Directive and the Floods Directive and some areas where there is no legislation yet. A consultation and a stakeholder workshop at the beginning of 2012 brought first results, mainly the need for a better implementation of some Directives as well as integration with other environmental policy areas (for example environmental impact assessments, biodiversity, chemicals, pesticides, chemicals, environmental liability).

However, the fitness check on water shows that the consistency check is not yet far reaching enough. Although a good instrument, its preliminary findings show that the scope is too narrow, as it concentrates on environmental goals and does not include industrial policy objectives.

## b) REACH

### 1. REACH and 165 other chemical legislations: the consistency check

The European Commission published in May 2012 the study on the REACH scope, analysing possible overlaps or gaps between the REACH regulation and other EU provisions, in terms of exemptions, definitions, risk assessment or risk management methodology, authorisation or restriction regimes or other issues. Cefic and its members, when contributing comments on over 20 legislations, emphasised that REACH is to take precedence over related legislations, existing and especially new ones, unless it is explicitly stated in the vertical legislation that this should not be the case.

The study comes to similar conclusions when it is asserted that "overall, REACH's various in-built mechanisms for avoiding overlap seem to work well. Moreover, the large number of synergies identified between REACH and the various sector-specific legislative acts also demonstrate a high level of coherence" (see point 9.7 of the study). The study also recommends that it would be better to amend as necessary more sectoral legislations and to have REACH as a central reference system. This does not prevent having REACH under regular scrutiny and its being improved.

One important part of the study is the assessment of the water legislations (see above), mainly how the identification, selection and risk management of substances under REACH and water legislations could be aligned in order to improve consistency. The main question is the comparison between the identification of priority substances and priority hazardous substances under the WFD and substances of very high concern (SVHC) under REACH.

We support the other main finding that for some instances of double regulation, a common and searchable database for restrictions would be helpful. This would particularly help SMEs and non-EU companies.

### 2. REACH: the fitness and quality checks

In regard to the application of the principle of smart regulation, the implementation of the REACH regulation provides unequal results.

The ongoing REACH 2012 review exercise, with the analysis by the European Commission of different relevant aspects of REACH and supported by a number of thematic studies, has shown a certain respect for the concepts of "fitness check" and "quality check".

At the same time, the concrete implementation of REACH has also highlighted the lack of a clear legal framework regarding the protection of company data, due mainly to insufficient clarity and quality of the REACH text and to inconsistencies with EU legislation on access to environmental information held by public authorities. In the absence of a clear and explicit mandate by the legislator regarding the disclosure of certain categories of information, the relationship between REACH and the Aarhus Convention, a pillar of EU law concerning transparency and confidentiality, is ambiguous and legally uncertain. Clear and precise parameters on how to strike a balance between the right of ownership and other legitimate interests have been omitted for certain categories of information. Consequently, a

disproportionate trend towards an extensive interpretation of public disclosure, to the detriment of the legitimate right for the protection of confidential business information, has been observed.

More remains to be done to harmonise and balance legislations in this field.

## CONCLUSIONS

**In this regard, the consistency and efficiency of European chemicals law can be improved step by step, using the smart regulation procedures and referring to already existing legislation. We make the following proposals:**

1. Cefic supports the new concept of smart regulation with its two improved tools for consistency checks (competitiveness proofing and fitness checks). It helps to achieve more than just an administrative simplification, as it undertakes a broader analysis of a legislative framework.
2. In this respect, REACH is our reference legislation for chemicals in Europe and, on a global level, to achieve a competitive regulatory environment.
3. Where double legislations occur, these should be abolished and, if, for good reasons, double legislation cannot be avoided, diminished, for example by setting up searchable databases of restrictions (e.g. RoHS, Toys), or guidance documents should be issued. However, REACH should be used in a non ambiguous manner as the reference and systematic basis for sectoral legislations.
4. Where synergies between sectoral legislations and REACH exist, links should be stronger. The reference to REACH databases of substances would improve legal certainty for our industry.
5. For better results with future legislations, the existing checklists should be coordinated (the competitiveness proofing toolkit, the fitness check elements and the impact assessment guidelines) and be supplemented by our suggested quality check. This would lead to a real smart regulation methodology.
6. Every opportunity should be used to make this framework more consistent and transparent, leading step by step towards a simplified and consistent codification of European chemicals law.