Precautionary Regulation of Chemicals

Addressing contemporary regulatory challenges of scale, uncertainty, complexity and innovation

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Outline

1. Chemicals as a regulatory target

2. Four inter-connected challenges that traditional legislation has failed to address:

a. the problem of scale (lots of stuff)
b. the problem of toxic uncertainty (the difficulty of assigning probabilities of outcomes)
c. the problem of complexity (interactions between parts of a system, requiring continuous monitoring and adaptation)
d. the challenge of innovation (developing interesting new stuff)

3. The roles of precaution in REACH

4. Conclusions

Chemicals as Regulatory Target

- Key industry for the EU → regulation must target not only 'negatives' (risk and impediments to the international market) but also 'positives' (competitiveness and innovation);
- Industrial processes are diverse and complex → sector-wide standards are not feasible;
- Influential industry association → regulators can enlist this association to help mobilize regulatees as co-regulators;
- Environmental performance relatively transparent → regulators can enlist the public in the quest to secure compliance.

Four Preconditions for Effective Regulation of Chemicals

- Find an appropriate response to *the scale* of the regulatory challenge at hand;
- Acknowledge and then appropriately deal with *scientific uncertainty*;
- Acknowledge and then appropriately deal with (environmental) *complexities*;
- Avoid regulatory lock-in and stimulate *innovation*.

Connecting with the problem of scale

The ‘problem of scale’ *quantitatively* refers to a high number of substances, or high volumes of a single substance (e.g. a million tons). For example:

* 66 million substances in CAS registry, approximately 15,000 new substances are added each day.

* About some 30.000 substances we know very little or nothing as they were classified as ‘existing’ substances under the old regime;

* Also: substances behave differently once certain quantitative thresholds have been exceeded

Connecting with the problem of uncertainty

A state in which possible outcomes are clear (such as specific degrees of harm or benefit) but in which it is impossible to quantify the probability of such outcomes actually materializing. For example:

* Combined effects and Interaction between substances;

* Cumulative effects;

* Dose/response relationships;

* Long-term effects.

Connecting with the problem of complexity

a *qualitative problem* that stems from intricate relationships between parts of a larger system. Interactions between those parts are complex, as changes in one part of the system impact on the system as a whole, as well as on any or all of its individual parts. For example:

* ecological systems;

* the (human) genome;

* climatological phenomena

* the human brain, etc.

Stimulating innovation/avoiding lock-in

Innovation: novel combinations of knowledge, resources etc. subject to attempts at commercialisation (or carried out in practice).

Lock-in: a situation in which (often poor) technological choices are perpetuated, not rarely as a direct consequence of regulation.

* In respect of ‘new chemicals’, a time consuming and costly notification procedure used to apply, deterring potential competitors from entering markets with new and possibly less harmful products.

The Essentials of REACH

- *'no data, no market' principle* → it is the responsibility of private actors manufacturing or importing chemicals to demonstrate safety by collecting and providing pertinent data (Art. 5);
- *principle of substitution* → when safer alternatives exist, so-called 'Substances of Very High Concern' (SVHC) need to be phased-out (Art. 55);
- *Chain regulation* → *all* private actors in the supply chain are obliged to ensure the safety of substances they handle (Titles III and IV);
- *Volume based system* → stringency of (mostly procedural) regulatory requirements increases with volume;
- *Principle of prioritization* → SVHC need authorization irrespective of volume

REACH and the problem of scale - 1

- *Volume based system* with corresponding generic procedures and standards that come to apply depending on three categories based on volume; (1-10 t/y; 10-100 t/y; > 100 t/y).

Correctives to this over-simplification

- Substances of Very High Concern *always* require authorization ; (Arts. 56 and 57):
  - Step 1: SVCH *may* be included in Candidate List
  - Step 2: Substances from that list are prioritised for inclusion in Annex XIV (Authoriisation list)

- Restrictions to deal with 'unaceptable risks to human health or to the environment' ;(Art. 68)

REACH and the problem of scale - 2

- *The burden to prove safety lies with private actors* (manufacturers, users, importers), thereby enlisting firms as co-regulators

Correctives to deal with reluctant co-regulators

1. *Law*: (strict) liability regimes (environmental and product);
2. *Society*: transparency and access to information;
3. *Markets*: labelling regimes

REACH and the problem of uncertainty

- The precautionary principle underpins REACH;
- For as long as safety has *not* been shown by applicants, precautionary measures can be taken;
- Annex I instructs to acknowledge information gaps;
- *Potential* effects must be taken into account;
- The open standard of *'adequate control'* helps accommodate a deliberative process aimed at securing the appropriateness of standards, taking into account scientific uncertainty.

REACH and the problem of complexity

- REACH represents a reflexive and responsive regulatory approach translating, *inter alia*, in:

  1. Review and temporary validity of authorisations;

  2. Review of core criteria for prioritizing and testing chemicals;

  3. Monitoring requirements apply to private actors, national authorities, and the EU.

  4. Member States can take provisional measures to protect human health or the environment.

REACH and innovation

- *Principle of subsitution*: an authorisation for SVHC can only be granted if it is shown that the socio-economic benefits of authorisation outweigh the risk to human health and the environment, and if moreover there are no suitable alternative substances or technologies. (Art. 60(4)).

- *Principle of proportionality*: Prioritization for SVHC, volume based system, authorization may proceed if the social benefits of authorization outweigh the costs of rejection.

Some first achievements:

- REACH is starting to deliver
- Publication of Candidate List serves as driver to innovate and substitute SVCH
- For half of substances included in Annex XIV no applications for authorization have been submitted
- Public consultations have provided new information on alternatives
- Downstream users are involved in substitution plans

Some implementation gaps:

- System of co-regulation is not accompanied by enough control mechanisms and sanctions
- Move from hazard based approach to risk based approach
- Responsibility to determine levels of safety has been reverted back to public authorities
- The role ECHA is ambiguous

Conclusions

- REACH bears the hallmarks of precautionary regulation;
- The precautionary features of REACH serve to organise a regulatory response to

  - the problem of scale
  - the problem of uncertainty
  - the problem of complexity
  - the challenge of innovation

- However, The ultimate effectiveness of this response depends on the regulatory environment within which REACH operates, and is currently sub-optimal

Many thanks for your attention!

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