European Regulatory Science and National Arrangements : The Making of European Chemicals

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European Regulatory Science and National Arrangements: Making Chemicals European

Henri Boullier

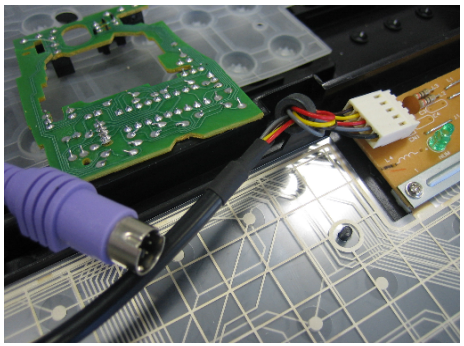
21 June 2012

Regulatory Agencies as Sites of Regulatory Knowldge

Presentation of Trichloroethylene (TCE), before REACH

- First synthesized in 1864
- The first shared instrument to the common market of chemicals is consequently a European classification system
- The various directives and regulations adopted in the sixties and eighties reveal that obligations and other barriers to their placing on the market mainly involve chemicals whose toxicity is certain or probable
- The beginning of collaboration between experts from different countries, routinely introduced by these directives, was not enough to have TCE regulated

The « Sniffing » issue: impossible problematization of TCE

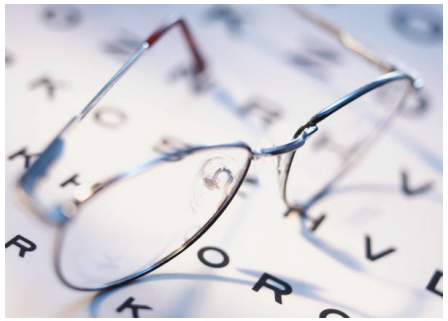


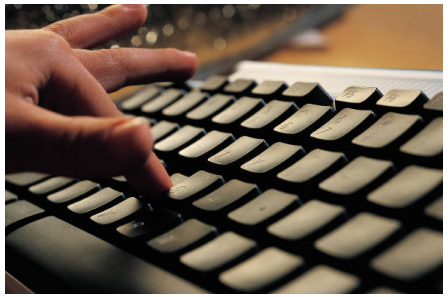
- TCE does not have a "public trajectory" like asbestos, lead, benzene, glycol ethers, PCBs, and some others
- In 1984, TCE's sale was banned for minors because of its use as a recreational drug
- The French Senate then discussed the possible generalization of the ban…
- …but it targeted TCE used as a drug
- In the early 1990s, TCE seems neither perceived as an environmental risk, an occupational hazard, or as a public problem

The European response to an orphan risk?

- However, the situation changes significantly during the 1990s
- In 2001, TCE is classified as probable carcinogen in Europe
- Fifteen years after the French parliamentary discussions, the trade or sale of TCE to the general public is prohibited at a European level
- the framing of TCE as an occupational hazard can be seen as an effect of the Europeanisation process
- **European integration can lead to institutionalizing occupational safety in some MS**
- **Europeanization is a mechanism that leads to institutional isomorphism across MS**

Adoption of the REACH regulation: 2006





- The 1 500 substances potentially involved in the procedures of authorization and restriction are substances placed on the market before 1981
- As REACH was adopted in 2006, the "head of network" role of the French agency AFSSET (*French Agency for Environmental and Occupational Health and Safety*) became highly criticized, for not having in-house expertise
- Merger of AFSSET and BERPC in 2009
- The adoption of REACH consequently represents the opportunity for the French health safety agency to claim for in-house expertise

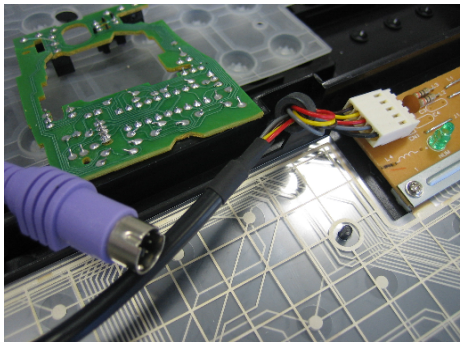
Intepretation procedures by AFSSET

- An examination of the French experts' practices shows the bounded rationale of the identification, selection, evaluation and implementation of actions on chemicals
- The monitoring of these procedures indicates that the identification, selection, evaluation and implementation of actions concerning TCE are largely borne by the French agency
- The emerging nature of these procedures also allowed the French agency to "put forward its preferred options"

A routine framing or an *upload* of precedents?

- The TCE dossier is used by an organization, AFSSET, to impose its way of understanding and defining a problem outside of the politicization channels generally taken by Member States
- This is not simple delegation or isomorphism
- These procedures have been examined to identify, in practice(s):
  - The fact that the TCE dossier is taken over by AFSSET
  - some limits of Europeanization as delegation

Conclusion



- AFSSET enjoys backstage discretionary power in the implementation of the REACH procedures
- REACH Regulation, that helped to establish AFSSET as legitimate and powerful despite a modest staff.
- The expertise of AFSSET and the spectacle of TCE on the scaffold could they then be seen as a democratization of European integration
- ECHA isa site for validating regulatory knowledge

Thank you!

French actors for priorisation

In France several important institutions are entrusted with the obligations to work on setting forward new SVHCs: **Ministry of Environment** (MEDD), **French Agency for food, environmental and occupational health safety** (ANSES), the **Committee on Chemical and Biocidal Products** (CPCB).

The Ministry of Environment has an umbrella role in the process as it provides strategic impetus to the priority-setting. ANSES as executive agency under the auspices of MEDD plays a scientific role, organizes scientific meetings (CES) and comes up with the first proposal.

This is followed by CPCB's stakeholder meetings and opinion which, finally, serve as the basis for a formal decision by the French government to embark upon a new Annex XV dossier.

Annex XV dossier in France

The REACH CES' work, and this is the case with many other member states as shown by my investigations on other competent authorities, first relies on an informal list of 500 substances candidate for identification as SVHCs prepared by six member states in 2009 and never disclosed (but that circulates informally between stakeholders). Taking as its starting point the substances in this list, the selection of the REACH CES is then based on the criteria listed in Articles 57 and 58 (3):

- "the CMR 1 A or 1 B character is proven (inclusion in annex I to directive 67/548/ EEC) or PBT/vPvB character recognized by the TCNES (*Technical Committee on New and Existing Chemicals*)",
- the tonnages produced/consumed in Europe and by year, are at least of 10 tonnes,
- one or several occupational exposures have been identified,
- one or more consumers exposures have been identified,
- one or more environmental exposures identified,
- "one or more uses recognized as widespread or dispersive