Dangerous Chemicals: A Global Problem on Its Way to Global Governance*

Gerd Winter**

I. Institutions and Earth System Analysis
II. Chemicals – A Global Problem
III. States, Introverted
1. Risk Management
2. Risk Evaluation
3. Risk Information
IV. Transnational Societal Self-Regulation
V. States as Global Trustees
VI. Transnational Administrative Networks and Cognitive International Organisations
VII. Re-Imbedding Informal into Formal International Law
VIII. Conclusions

I. Institutions and Earth System Analysis

It is a truism that the human impact on the environment has become a global problem. „Global" can mean 3 things: (1) the ubiquitous replication of a specific kind of damage, such as soil degradation, (2) the long-range dispersion of single damages as transfrontier industrial pollution, and (3) damage to the mechanics of the biosphere as a whole, for which climate change is the outstanding example. In order to understand these and other aspects of global change, natural sciences propagate earth system analysis as a specific tool.

* The author wishes to express his gratitude to the laureatus for many years of (in the two meanings of the word: critical) support. The paper ows much to *E. Rehbinder's* own work on chemicals law. It is based on a lecture at a conference in the Tokio National Museum of Emerging Science and Innovation in April 2005.

** Univ.-Professor, Dr. iur., Lic. rer. soc., Forschungsstelle für Europäisches Umweltrecht, Universität Bremen.

Law and other societal institutions both cause and mitigate global environmental problems. On the one hand, by opening up national borders for transnational trade and direct investment the law incites economic growth and, through this, the exploitation of natural resources. On the other hand, by introducing regulatory tools the law strives to protect natural resources against over-exploitation even when situated outside national jurisdictions. The study of law and institutions must therefore become part of earth system analysis.

International lawyers and political scientists might claim that they have thought in global terms for long by studying and promoting international regimes. However, international regimes[1] develop at a very slow pace and are difficult to implement and enforce. Given the urgency of environmental problems, more levels than the international must be considered as sources of global governance. The states' and regional organisations' potentiality of developing solutions must be re-evaluated. Although confined to their individual jurisdiction they may act as trustees of the global community and may also spread their achievements through horizontal diffusion of legal concepts. Intergovernmental networks of expert bureaucracies may evolve as one more generative structure of globalised regulation. Self-regulation by private actors completes the overall picture of multilevel global governance.[2]

Multilevel governance is understood by some as a kind of postmodern plurality of regimes which emerge, change, interact, and address problems posed to them without any structured pattern. This is not the view taken in this paper. This paper will show that multilevel governance is indeed based on certain structures, and that it is worthwhile to explore patterns which allow predicting what kind of problems can be handled on what levels of governance.

This "question of scale"[3] shall be posed taking dangerous substances as a case study. The aim of my paper is therefore twofold: (1) to demonstrate a methodology of global institutional analysis which might allow conclusions as to what task can or should be tackled on what level, and (2) to show how the problem of toxics is currently being solved and how this could be improved.

II. Chemicals – A Global Problem

There are about 100,000 different chemical substances (called existing substances) traded in the world at a significant volume,[4] and about 1,000 substances (called new substances) being added every year. Dangerous substances have be-

1 The term "international regime" as used by political science is broader than the term „international organisation". Other than an international organisation a regime may sometimes be based on mere soft law and informal bodies rather than on formal law and organs. It must however be operating *de facto*. The emphasis is therefore on effectiveness, not on forms.

2 See for an approach that integrates the different levels the contributions in and introduction to *G. Winter* (ed.), Multilevel Governance of Global Environmental Change, Cambridge: Cambridge University Press 2006.

3 See *O. Young et al.,* IDGEC Science Plan, IHDP Report No. 9, Bonn: Köllen Druck 1999, p. 54 et. seq.

come a global problem in all of the three meanings mentioned before: They are used everywhere, they travel around the world, and they may affect basic mechanisms of the earth system. The more immediate burden many of them cause is civilisation diseases such as cancer, allergies, and disabilities, as well as environmental deterioration such as water, soil, and air contamination. The long-term impact affecting the fundament of life is the possible impairing of the reproductive capacity of living organisms. *Albert Einstein* is said to have worded this danger into a concrete example through commenting on the intoxication of bees by pesticides: Without bees humanity has only four years to survive: no bees, no pollination, no plants, no animals, and hence no humans.

Control of chemicals is therefore necessary. It is in part already existing but still highly ineffective. Adequate control would require three things, i. e.

(1) the production of risk information, i. e. the generation and submission to public authorities of data regarding risks of these substances to human health and the environment
(2) risk evaluation, i. e. the assessment of intrinsically potentially dangerous properties of the substance, and the assessment of exposure of end-points to the substance
(3) risk management, i. e. taking decisions on the classification of the substances according to risk categories, informing the users of the risks, and the ban or restriction of substances in case of otherwise uncontrollable risks.

These modes of control will have to be applied to all chemical substances used at a significant quantity. Such administrative work must be based on rules that by themselves must be elaborated and promulgated. Thus, the overall task to be completed in a global dimension would consist of the following 5 elements:

Table 1: Taxonomy of risk control

	risk information	risk evaluation	risk management
rule-making	1	3	5
rule-adjudication	2	4	6

What levels of governance have thus far been employed to establish such means of control? Commonly one would distinguish just two levels – states and international organisations. However, the globalisation of economic transactions has brought about a more complex plurality of legal strata and structures generating them, including in particular, industrial self-regulation and transnational

4 This number is extrapolated from the about 30,000 substances traded on the EU market, taking into account that many of the substances traded in the rest of the world will overlap with the EU substances. Other estimations such as that of CHEMCATS go up to as many as about 11,000,000 commercially available substances (www.cas.org/cgi-bin/regreport.pl, visited 6 June 2006). However, many of these substances can be grouped together for their convergent chemical structures and properties, and others are traded at an insignificant volume.

administrative networks. Four levels of global chemicals control should therefore be taken into consideration:
- states
- transnational industrial self-regulation
- transnational networks of expert administration
- international organisations

The combination of levels and tasks results in the following scheme of potential ways of allocating tasks to levels:

Table 2: Taxonomy of matching tasks and levels

	risk information		risk evaluation		risk management	
	rule-making	rule application	rule-making	rule application	rule-making	rule application
states						
industry						
admin. networks						
int. organisations						

In practice, the levels of states and international organisations can bear very different characteristics. States can expose an inward-looking attitude in a given issue area or time period, while also being able to expose an attitude of global trusteeship in other areas or at other times. Some of the international organisations (such as the OECD) have a primarily cognitive orientation, i. e. they aim at enhancing international knowledge, whilst others (such as the UN) are destined to prepare and make binding decisions.

Chemicals control has developed in a sequence that brings all of the levels into play at different stages and with different characteristics. As will be concretised in the remainder of the paper I suggest five stages of development of global chemicals control spreading over the four main levels introduced above:
- states, introverted
- transnational industrial self-regulation
- states as trustees of the globe
- transnational networks of expert administration, assisted by cognitively oriented international organisations
- international organisations with a regulatory orientation

These stages and levels must be distinguished from each other because all of them have had a peculiar potential of governance. But they must also be seen as interlinked, building on or contributing to each other. To name just two examples: (1) the informal rules elaborated by transnational bureaucracy networks are often referred to by formal national law, and (2) the allocation of property rights by formal law is a basis for transnational industrial self-regulation.

III. States, Introverted

To the extent that chemicals control does exist, the main level has traditionally been that of states and regional communities such as, notably, the European Community, which can be regarded as state-like in this context. This is attributed to the fact that its regulation of existing chemicals has since the early 1990s been highly centralised. The overall approach of states has for many decades been rather introverted, i. e. in relation to chemicals they have concentrated on domestic problems and domestic measures.

1. Risk Management

States have introduced national *risk management* measures. The number of such state based measures is difficult to assess because much depends on the definition of measures. If one only counts measures banning or severely restricting the placing on the market of substances, in the EU the number of substances regulated amounts to about 50.[5] Since the more common practice is not to restrict the placing on the market of the substance altogether but to fix thresholds for individual exposure scenarios in many different areas of its use, the number of such restrictions can be substantial even for one single substance. If one includes also restrictions which according to common definition would not be termed severe the number of measures increases exponentially. Since many of them differ (for e.g. concentration thresholds for toxic substances in products are fixed at diverging levels) the number of measures must be multiplied with the number of states with different standards.[6]

All in all there is a plethora of national risk management measures many of them are different in terms of scope and severity. For international trade this means that products must be designed differently according the specific requirements of the individual national market. On the other hand, in spite of the great quantity of measures the number of substances that has carefully been assessed and regulated is dramatically low if compared with what may lie hidden in the bulk of un-assessed substances. Assuming that 1 per cent of the 100,000 marketed substances are candidates for severe restrictions,[7] the number of 50 restricted substances – achieved by the EU – amounts to only 5 per cent (i. e. 50 out of 1,000). Hence, the overall result of state based risk management is flawed

5 Annex I Directive 76/769.

6 The legal file of UNEP Chemicals lists 53,000 legal documents concerning 10,000 substances. International instruments are included but constitute only a minor part. See www.chem.unep.ch/irptc/legint.html (visited 6 June 2006).

7 The estimate of 1% is an extrapolation from the practice of risk assessment of prioritary existing substances in the EC. For 28 (out of 121) assessed substances with full risk assessment (i. e. 23%) the conclusion was that restrictions were necessary (see website cited in previous footnote). Given the fact that the selection of prioritary substances implies a bias in favour of dangerous substances the percentage 23% must be reduced. 1% can be regarded as a conservative estimate.

in two respects: due to the difference of standards it is economically inefficient, and due to the paucity of standards it is ecologically ineffective.

2. Risk Evaluation

'No sound restriction without a sound risk assessment'. States have for a long time also been the only level on which *risk evaluation* was conducted. Risk assessment is a process ideally comprising the following steps:

- hazard identification (i. e. the indication of the adverse effect which a chemical has an inherent capacity to cause)
- dose-response assessment (i. e. the estimation of the relationship between dose, or level of exposure to the substance, and the incidence and severity of an effect)
- exposure assessment – (i. e. the estimation of the concentration or dose to which human populations, e.g. workers, consumers and persons, exposed indirectly through the environment) or environmental compartments (e.g. aquatic environment, terrestrial environment, atmosphere) are or may be exposed. This estimation entails the determination of the sources, emission routes and degradation pathways of the chemical.
- risk characterisation, i. e. the estimation of the incidence and severity of the effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a chemical

Although these steps are widely accepted, states have developed significant differences in putting them into practice. For instance, in the US the assessment is surrounded by public controversy,[8] whilst in the EU it is rather influenced by member state expert bureaucracies and their domestic risk perceptions.[9]

However, the two flaws innate in approaches based on introverted states – incompatibility of national approaches and slow action – reappear. For instance, the definition of the danger classes varies greatly such that a substance labelled as toxic in one state may be taken as non-toxic in another. Overall, the number of substances which have been subject to a risk assessment and properly classified is dramatically low. To take the keenest regulator, the EU, as an example: Since the start of the existing substances regime in 1993, the national and EU authorities have completed the comprehensive risk assessment for no more than 141 existing substances within 13 years,[10] i. e. about 11 full assessments per year. This is an overall yield of just 0.3 per cent substances assessed for risk out of an estimated number of 30,000 substances waiting for assessment in the EU.

8 *K. Harrison/G. Hoberg*, Risk, Science, and Politics. Regulating Toxic Substances in Canada and the United States, Montreal: McGill-Queen's University Press 1994. For Canada the authors found the approach to be to rely on expert judgement and limited public debate.

9 *G. Winter*, Drei Arten gemeinschaftlicher Rechtssetzung und ihre Legitimation, in: G. Brüggemeier (Hrsg.) Verfassungen für ein ziviles Europa, Baden-Baden: Nomos 1994, 45 ff.

10 http://ecb.jrc.it/esis/esis.php?PGM=ora (visited 6 June 2006).

3. Risk Information

'There is no sound risk assessment without elaborate data on intrinsic properties of and exposure to substances'. States have also been the major actors in relation to the production of risk information. However, marked differences between states and an overall slow pace must be deplored once more.

The rules for existing substances established by the major chemicals producing countries– Japan, the US, and the EU – differ significantly. In the US and Japan the public authorities bear the burden of collecting risk data about existing substances.[11] Whilst in Japan government-funded programmes were launched to systematically monitor the environmental fate of existing priority substances,[12] the US government has largely remained passive in generating risk studies[13] – which is fatal because the US government is in high demand for solid data in order to meet the heavy burden of proof which court case law has laid on it.[14] In contrast, in the EU, industry was required to play a more active role. Producers and importers had to submit basic data even for the initial screening. On that basis priority substances were to be identified triggering duties to produce and submit more in-depth data.[15]

In fact, however, even in the EU the system has not worked well, because industry has not been cooperative and no effective sanction was provided for non-compliance. For the individual producer or importer, it paid not to submit the required data, because the more data the more the responsible public authority might be alerted and ask for additional information or propose restrictions. Paradoxically, industry was all the more eager to provide information when it was to contradict critical conclusions up-coming in the assessment process. Practitioners called this drop-by-little-drop-information.[16] A 1999 study made by the European Chemicals Bureau based on 2,465 EU High Production Volume Chemicals (HPVCs, i. e. chemicals traded at above 1,000 t/a by producer or importer) showed that 14% of substances have data at level of the base-set, 65% have data of less than the base-set level and 21% have no data.[17]

11 Royal Commission on Environmental Pollution, Chemicals in product. Safeguarding the environment and human health, 24th Report, HMSO 2003, p. 73 et seq.

12 Royal Commission Report p. 79.

13 Royal Commission Report p. 75, citing a review of the Toxic Substances Control Act carried out by the US General Audit Office in 1994.

14 Corrosion Proof Fittings v. EPA, 947 F. 2nd 1201 (5th Cir. 1991), at p. 1217. *H. Ginzky*, Nutzen und Kosten im Chemikalienrecht der USA, in: G. Winter, H. Ginzky, B. Hansjürgens, Die Abwägung von Risiken und Kosten in der europäischen Chemikalienregulierung, Umweltbundesamt Berichte 7/99, Berlin: Erich Schmidt-Verlag 1999, p. 179.

15 See Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, OJ L 84, 5. 4. 1993, p. 1, Art. 3–8.

16 *J. Ahlers*, The availability of risk information, in: G. Winter (ed.) Risk Assessment and Risk Assessment of Toxic Chemicals in the European Community. Experiences and Reform, Baden-Baden (Nomos) 2001, 69 ff., at p. 78.

17 *R. Allanou, B. Hansen, Y. van der Bilt*, Public availability of data on EU high production volume chemicals, parts I and II, in: Chimica oggi – chemicals today, 2003 p. 59–64 and 91–95.

The introverted approach to the production of risk information has also been highly inefficient because of lack of global division of labour. For the same substance, data sets are requested by many different states simultaneously, the risk assessment being done by the states in the same manner.
Taking the state-based approach to information production, risk assessment, and risk management, altogether we can conclude that the outcome was environmentally ineffective and economically inefficient. The lack of risk information, the retardation of assessment and classification, and the sparse bans and restrictions have allowed environmental impairment to occur. Moreover, the divergence of standards has caused unnecessary costs to industry.

IV. Transnational Societal Self-Regulation

This failure, and in particular the lack of available risk information came to the attention of the global public in the late 1990s. Alleging what they called "toxic ignorance" non-governmental organisations, mainly in the US and later on in Europe, pressed for a fundamental reform.
Industry did not wait for governmental reaction. Encouraged by politicians like Vice-President Gore in the US and alarmed by plans to introduce more severe regulation the International Council of Chemical Associations (ICCA) in 1998 pronounced a self-commitment to voluntarily provide, within 5 years, the required data for 1,000 HPV substances.[18]
This HPV commitment is a marking example for societal self-organisation or, in other words, private governance at a global scale.[19] It stands in contrast to the traditional reliance on state based governance. Its logic of emergence is this: A global problem – toxic substances – is regarded as being insufficiently handled by the states; transnational civil society protests; industry, as transnationally organised, commits itself voluntarily, be this due to its own better insight or in order to prevent governmental intervention.[20]
However important this contribution of private governance is, its shortcomings cannot be overlooked. It is difficult to build joint institutions and implement joint commitments on a global scale not only for governments but also for industry. After all, although sometimes willing to cooperate in the global public interest, companies also compete against each other.
Understandably, a company which may dispose of the relevant risk information is not very keen on sharing this with its competitors. For these reasons, in 2004,

18 ICCA, The HPV initiative: What we set out to achieve, how it works, and where we stand, 2004. Published on http://www.icca-chem.org/pdf/icca009.pdf (visited 6 June 2006).

19 A similar instance of self-commitment had already earlier been tried in the eighties in Germany, when a technical body called Consultative Committee on Environmentally Relevant Existing Substances (Beratergremium Umweltrelevante Altstoffe, BUA) was set up with intensive voluntary involvement of the chemical industry. This body has since 1982 elaborated risk assessment documents for about 330 substances.

20 See more generally *M. Herberg*, Private authority, global governance, and the law, in: G. Winter (ed.) op. (cited above, footnote 2) p. 149 et seq.

i. e. after 5 years, only 26 per cent of the promise was fulfilled.[21] Moreover, the envisaged 1,000 substances although quantitatively constituting an alleged 90% of the global chemicals production[22] leave tens of thousands of other chemicals unnoticed. In addition, the submission of hazard data they have promised is only a first step towards chemicals control: Risk assessment and risk management are still to be worked out. Therefore, NGOs and the political arena insisted that a governmental response remained overdue.

V. States as Global Trustees

Such governmental response was once more envisaged at the level of states rather than of international law and organisations. But this time, solutions emerged and are still evolving at a pace going beyond the traditional introverted approach. States came to regard the problem as global and to see the need for global trusteeship.[23] The lead was taken by the EU. In contrast, the US-government decided to trust in the self-regulatory potential of industry whilst Japan which was not much affected by the critical campaigns stuck to its traditional concept.
The EU decided to strengthen the governmental clout elaborating a very ambitious concept of systematic registration, evaluation and authorisation of all chemicals (REACH). Among other improvements the REACH concept aimed at introducing an obligatory and strictly enforceable registration duty for existing and new substances, a streamlined procedure for the restriction of substances, and authorisation requirement for certain highly dangerous substances.[24]
The process of forming and introducing REACH has incited a worldwide discourse which includes the Japanese and the US governments and industries. The reason why the world outside the EU is discussing REACH in spite of its limited jurisdictional scope is both environmental concern and economical interest. Two lines of argument deserve closer inspection.
One critique raised by US and other industries outside the EU is that EU producers may gain a competitive advantage because they can sell their chemicals as "REACH-tested" not only in Europe but even more worldwide. The external industries were afraid of being compelled to adapt themselves to the stricter requirements and, for reasons of economies of scale, to adopt REACH standards also for those substances which they place on markets outside the EU. Understandably, environmental NGOs have welcomed such side-effects or – as it is

21 See the ICCA report, cited above, footnote 18.

22 See the ICCA report, cited above, footnote 18.

23 See for a general concept of state based trusteeship *Peter H. Sand*, Global environmental change and the nation state: sovereignty bounded? In: G. Winter, op. (cited above, footnote 2) p. 519 et seq.

24 Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Com (2003) 644. The European Parliament has issued its Opinion on 17. November 2005) EP Document No P6_TA-PROV (2005)0434). The Council has politically agreed on its Common Position (Council Document No 15921/05).

called by economists: trading-up[25] of the regulatory regime. Foreign governments may feel encouraged to even formally adopt the core elements of REACH as their own legal standard. The reasons for such "horizontal dissemination" of pioneering solutions can be manifold. The reception state may be led by environmental concern, it may strive to press its industry towards product innovation, it may even be pushed by transnational industry willing to "trade-up", or it may, following its general practice, simply copy legislation from states it regards as acting reasonably. Horizontal diffusion of this kind is a potentially powerful mechanism because it operates by non-contractual means.[26]

By contrast, the EU based producers (not retailers, though, because they are interested in safe products) raised opposite concerns. They predicted that the states outside the EU could as well decide to reject REACH altogether. External producers might realise that the strict European regime can be circumvented by stopping to export substances and substances in preparations to the EU but by continuing to export substances as components of articles.[27] They claimed that this would be fatal for EU industry. The chemical producers serving the world market would, because of the EU registration requirement, have a competitive disadvantage compared to the external producers who act under more lenient control regimes. Downstream users would have difficulties in supply of chemicals they have thus far imported from external sources.

It is impossible to say which side will be proven right. In any case, the EU basically stood to its approach thus showing the willingness to act in the global public interest. Nevertheless the controversy was so heated that it has taken as many as 15 years to enact REACH, and the implementation of its regulatory tools will take more time. Even more time will pass until the REACH approach – if at all – will horizontally be disseminated to become the global model. In the mean time, chemicals continue to be produced and used, and they continue to pose (widely unknown) risks to human health and the environment.

VI. Transnational Administrative Networks and Cognitive International Organisations

The slow pace taken by states and regions moving towards global trusteeship has left expert bureaucrats in the field impatient. Rather than waiting for politics and

25 *D. Vogel*, Trading Up – Consumer and Environmental Regulation in a Global Economy, Cambridge, MA: Harvard University Press 1995.

26 *K. Tews*, The diffusion of environmental policy innovations, in: G. Winter, op. (cited above, footnote 2) p. 227 ff.

27 According to Article 6 of the REACH proposal importers have to register substances in articles only if the substance is intended or known to be released during its use. The European Parliament wants to extend the registration obligation to any dangerous substance contained in an article and not yet registered in the EU. The Council has however expressed itself to follow, with some exception, the Commission proposal. It does not regard the possible discrimination of EU producers as significant. For the sources see footnote 24 above.

legislation to proceed they have formed transnational administrative networks to push things further.

The networks active in the chemical field have received administrative and political support from a number of international organisations including in particular OECD and WHO. These international organisations can be characterised as cognitive because, at least in the environmental realm, they operate as collectors and disseminators of information rather than as regulators. Although they provide valuable assistance also in the chemicals area, the bureaucracy networks heavily rely on personnel from national ministries and technical agencies. Their performance very much depends on the commitment and on a kind of 'transnational professionalism' of the participating individuals. They often also involve the relevant transnational networks of industry. Sometimes, manifestations of the general public and technical input from NGOs also contribute to networks formation and performance.

Transnational networks of this kind must therefore be analysed as a distinct source of global governance[28] besides the pioneering and dissemination of state based concepts and the self-regulation of private actors. Their product – informal codes of conduct and concise appreciation of facts – is often referred to by national law, and formal agreements and decisions by regulatory international organisations may at some later point be built on them, but only after long phases of informal cooperation.

Informal bureaucratic networks and the subsequent transposition of their work into more formal systems have also contributed to risk management, risk assessment and the generation of information in relation to chemicals.[29]

An initial step with regards to *risk management* was taken in the seventies when two soft law agreements were signed by many states: the UNEP-based London Guidelines on chemicals and the FAO-based Code of Conduct on pesticides. They established a voluntary system of listing banned or restricted chemicals and required that exporters of chemicals must, prior to the exportation, inform the importing state and ask for its consent (PIC – prior informed consent). Due to the fact that an institutional infrastructure was established (the International Register of Potentially Toxic Chemicals) the endeavour was quite successful.

For the generation of *risk information* and the elaboration of *risk assessment,* a great number of transnational networks of expert bureaucracies have been formed. The most important have acted in the framework of OECD. They developed Guidelines for the Testing of Chemicals and Principles of Good Laboratory Practice. Another network drafted the criteria for the classification of dangers for the UN based initiative to establish a globally harmonised system of chemicals classification and labelling, the so-called Globally Harmonised System (GHS).

28 See generally *A.-M. Slaughter*, Global Government Networks, Global Information Agencies, and Disaggregated Democracy, in: K.-H. Ladeur (ed.), Public Governance in the Age of Globalization, Cornwall: Ashgate 2005, p. 121–156

29 See for the following *M. Warning*, Transnational bureaucracy networks: a resource of global environmental governance?, in: G. Winter, op. (cited above, footnote 2) p. 305 ff.

Apart from making technical rules of this kind, transnational networks have also committed themselves to collecting risk data on individual substances. A worldwide effort of this kind is the International Programme on Chemical Safety (IPCS), which was established in 1980 based on a Memorandum of Understanding between WHO, ILO, and UNEP. The cooperating national administrative agencies elaborate so-called Environmental Health Criteria (EHC) Monographs collecting available information on the intrinsic properties of a substance as well as exposure. In Concise International Chemical Assessment Documents (CICAD) this information is summarised for private and public use. IPCS has elaborated so-called EHCs for about 220 substances and CICADs for about 60 substances.

VII. Re-Imbedding Informal into Formal International Law

Although the transnational informal networks have been successful in elaborating *harmonised technical rules on risk assessment and risk information*, their conclusions have not remained purely informal. Many of the informally consented technical rules have been made binding by international organisations and referred to by state law. For instance, the testing guidelines elaborated by an OECD based administrative network were formally adopted as an OECD decision and later referred to by EC chemicals legislation. The GHS document was approved by UN ECOSOC and will soon be transposed into national laws.
As to the *generation and assessment of risk information in individual cases* the modest yield of EHC monographs and CICADs shows that transnational administrative networks are far too slow to also be employed as institutional blueprints for global case by case administration. The relevant activities will probably be renationalised in the future. A crucial question will then be if the essence of national data collection and assessment is made accessible for the international public. One such instrument is IUCLID (International Uniform Chemicals Data Base) which is run by the European Chemicals Bureau and was accepted as the data exchange tool in the OECD framework.[30]
Finally, with respect to *risk management*, the history of the codes of conduct on chemicals and pesticides provides more proof that soft law is often converted into formal law if the informal practice had a chance to evolve for a time and was supported by an institutional infrastructure.[31] In 1998 the London Guidelines and the FAO Code of Conduct were put on a formal basis – the Rotterdam PIC-Convention. Although the PIC-approach is a mere procedural tool which does not necessarily remove the substance from the market a culture of requiring import permits and refusing the import of certain substances developed. Following this experience the Stockholm POP-Convention was concluded in 2001. It aimed

30 See http://ecb.jrc.it/existing-chemicals (visited July 30, 2006.)
31 *D. Shelton* (ed.) Commitment and Compliance: the Role of Non-binding Norms in the International Legal System, Oxford (OUP) 2003.

at the phasing out of certain particularly dangerous substances, the so-called POPs (persistent organic pollutants). Successful as this institutional career may appear, the outcome is however still very modest: Only 12 substances, the dirty dozen, were banned in the first run. Pioneering initiatives by national states acting as trustees for the global public interest will therefore remain crucial.

VIII. Conclusions

In conclusion I hope I have shown that many different mechanisms of governance, including industry self-regulation, states pioneering as global trustees and dispersing concepts by discourse rather than contract, transnational administrative networks, and international law and organisations have contributed to the achievements of global chemicals control, but that each has also had its share in the tremendous shortcomings still prevalent.
When devising improvements, the whole range of institutions should be taken into consideration rather than looking towards – and waiting for – supranational institutions to act. The crucial question here is what mechanism is appropriate for what task or function?
A methodological interjection is necessary at this point. A sociological inquiry would ask for explanations why in the past certain functions were taken up by certain levels, and why this was successful or failed. A normative inquiry would search for an optimal model fitting functions and levels together. My attempt is practical; it is looking for a normative but realistic model, i. e. one that takes conditions of realisation into account.
There are some aspects to be kept in mind when devising such realistic model: One is professionalism: What level provides the best quality of chemicals control? Another is time: What level has sufficient manpower to complete substantial loads of work involved in chemicals control? A third is reliability: How can be ensured that promises are held? A fourth is legitimacy: What level ensures that those who are affected by chemicals can voice their concern? A fifth is realisability: Is the level which is optimal for a task available in the foreseeable future? Applying these criteria results in the following suggestions (Table 3).

Table 3: Matching tasks and levels, applied

	risk information		risk evaluation		risk management	
	rule-making	rule-application	rule-making	rule-application	rule-making	rule-application
states	B		B		H	H
industry		A		A, C		[I]
admin. networks	E		E	D		
int. organisations	[F]		[F]		[G]	

Data generation and risk assessment concerning the individual substances is the genuine business of industry itself (A), but that self-regulation must be embedded in a framework of formal law. Although in many cases industries do generate data and assess them for their own purpose, incentives to submit these data to public control have been lacking. Therefore, rules establishing that risk information must be generated, assessed and submitted to public authorities should be based on binding and enforceable formal law. Absent international harmonising efforts such law will be state based for some time to come (B).

Some measure of harmonisation can be achieved if the REACH-approach enters into force and is "horizontally diffused", i. e. adopted as a model also by other states.

However, the introduction of a *transnational division of labour* on data generation and risk assessment will need more than state based legal framing. Rather than multiplying the work for the same substance, industry must join forces each taking a number of substances and handling the data collection and assessment for all of those who produce or market the same substance. To create willingness for data sharing and to organise the allocation of substances to "sponsor" companies necessitates transnational organisational capacity. The example of the worldwide self-commitment of the chemicals producers shows that the industrial actors are willing and capable to cooperate through their transnational industry associations such as ICCA ([C]). But pressure from the organised public sphere is indispensable to keep self-commitments long-lasting and effective, all the more so because the parallel data collection and assessment activities of the national agencies must also be coordinated. Absent international organisations with adequate power informal bureaucracy networks can play an important role in this respect (D). Of course, the progress could be accelerated significantly if an international agency was established acting as an information broker. But this is probably wishful thinking.

The case related administrative work must operate according to common technical rules such as *rules on assessment methodology, testing, good laboratory practice, classification, and labelling*. Such rules should be elaborated, as before, by transnational administrative networks assisted by cognitive international organisations (E). International and state formal law should however adopt or refer to these documents and thus make them binding ([F]).

For *risk management* internationally harmonised restrictions based on binding international law would certainly be optimal ([G]). However, the slow progress of international agreement on bans and restrictions of chemicals and the more proactive mood of some states show that decision-making on national levels will be the most reliable source of protecting human health and the environment for the foreseeable future, and especially so if they act as trustees of the global society (H). Given the current state of international integration, entrusting global institutions with regulatory competence is a promising first step but everything must be done to avoid a counterproductive effect, namely that the scaling-up of regulation to the international level provides nation states with a good excuse not to take pioneering steps. In the "shadow" of strict national and gradually international powers of restriction industry may then be induced to voluntarily withdraw substances from the market in order to avoid transaction costs ([I]).

Generally speaking there remains a need for binding law, for reasons of quality, efficacy and legitimacy. For the introduction of such law, there is no other actor available than the state acting as a trustee for the globe and, incrementally, international law and organisations. But this law must be alerted to the fact that self-organisation by transnational private and public networks is an important source of governance. It must provide a basis and incentive for self-governance, a source of control against abuse, and a link to transfer informal law into binding legal practice.