Redesigning Joint Responsibility of Industry and Government

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I. Toxic ignorance and slow motion

"Toxic ignorance" – this is the title of a study published by the US Environmental Defense Fund (EDF) at the beginning of 1998 which caused a considerable furore[108]. The study revealed that the authorities knew surprisingly little about the risks of hazardous substances on the market to health and the environment, and that the regulatory mechanism for the control of these substances practically rewards those companies that either do not examine the risks of such substances at all or withhold relevant data. As a result of the publication, the Chemicals Manufacturers' Association (CMA) and the Environmental Protection Agency (EPA) conducted their own investigations which confirmed the correctness of the findings presented in the EDF study. When subsequently Vice-President Al Gore actively involved himself in the matter, the chemicals industry made a self-commitment to provide the required data sets as soon as possible.

At a recent conference organised by the European Commission, a similar situation was highlighted for Europe[109]: for 2 000 of the ca. 4 000 highly problematic chemicals (including 2 500 of which more than 1 000 tons are marketed annually), the most important data are lacking; complete data sets are available for only 300 substances. Moreover, the basic data provide information only on some, not all hazardous properties of substances, and say nothing at all about the exposure of humans and the environment to these chemicals and their complex post-market „downstream" use. The mechanism of national and EC agencies, which prepares detailed risk assessments for each substance, has only managed to process 20 substances in the last five years, that is, four substances per year. For a total of 10 substances, regulatory measures have been proposed; but no decisions have been taken as yet. If things proceed at this at this slow motion, the checking of the 4 000 substances (less 20) should be completed by the year 3000.

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108 David Roe, William S. Pearce, Toxic Ignorance, in: The Environmental Forum May/June 1998, 24-35.

109 On this, see the working document of the European Commission SEK (1998) 1986 final (18.11.1998).

II. Structural failures in chemicals control

An explanation of the snail's pace of events are the structural failures inherent in chemicals control, some of which are mentioned below:

- Reversal of burden of proof: A legal obligation to produce and submit basic data sets arises only when the authorities have reasonable grounds for suspicion regarding the hazardousness of the chemicals. The authorities are thus confronted with the dilemma that the information they are demanding from the producers should already be at their disposal. Moreover, when the authorities have justification for demanding the provision of data sets, they face endless delays. Why? Insofar as the chemicals are already on the market - which is the case for the 4 000 substances mentioned above – producers and importers have no particular interest to fulfil their legal obligations. For those who act in compliance and supply the data as required run the risk of being the first to have their chemicals banned – should these be found to be hazardous. Non-compliance is thus rewarded.

- Non-observance of the precautionary principle: This principle, which has been part of legislation for some years both on the national and European levels, would enable regulation even when there is the mere suspicion of a risk. In practice, however, the demand is for absolute certainty.

- Over-perfection: For each substance, the entire investigative programme is completed before a decision is made. Partial findings are not used for preliminary action. For example, when it is known that a substance causes damage, say in water, at **one** "endpoint" of its life cycle, all the other endpoints are examined before regulation takes place.

- Unsatisfactory priority-setting: Whereas the regulation of existing substances – admittedly for good reasons - prescribes that the prima facie most problematic substances be examined first, the practical approach has been, mainly for bureaucratic reasons of easing the work-load, to deal with the best documented substances in terms of available data first, coupled with a tendency of an excessive preoccupation with them.

- Exaggeration of the costs of regulation for the economy: When, after the laborious gathering of data, risk assessment is finally concluded, its translation into a prohibition of substances is often prevented by the blanket argument that jobs would be lost, although concrete proof of this is rarely provided. Moreover, it is usually overlooked that substance restrictions may well act as incentives to innovation, initiating new

developments and thus creating new jobs. The development of a new type of refrigerator after the prohibition of CFCs is a case in point.

- Lopsided regulation of existing and new substances: New substances going on the market require prior registration and the submission of very detailed data sets, depending on marketing volumes. Although this appears to be a reasonable middle way between a system of prior marketing authorisation and uncontrolled free marketing, much administrative work is still required due to the syndrome of over-perfection which diverts attention away from the regulation of existing substances and indirectly benefits the more hazardous existing substances.

- Perverse effects of speed-up efforts: There have recently been efforts on the legislative and jurisdictional levels to prod the authorities into action. They have been urged to speed up authorisation procedures: should these take too long, liability for damages might be imposed. This push for greater speed has meant that extensive administrative efforts are directed to those substances (e.g. pesticides) whose marketing is subject to prior authorisation. Again, this is having a negative effect on the processing of existing substances.

- Costs of excessive co-ordination: On the one hand, there has been progress insofar as marketing restrictions are now decided by the EC for all states rather than by each state individually. On the other hand, this process is very complex and protracted because consensus is first sought by all member states. As a rule, risk assessment for one substance takes in excess of two years, and the decision on regulation an additional two years, if it materialises at all.

Among the experts as well as in the political sphere, there is a growing awareness that a fundamental reform is overdue. During Germany's current presidency of the European Union, the German ministry of the environment is set to take the initiative in this matter. What is to be expected?

III. Reform proposals

The demand by some environmental associations for a general authorisation requirement for hazardous chemicals holds little promise of success. This would admittedly reverse the burden of proof as authorisation would not be granted unless non-toxicity of a substance has previously been established. On the other hand, a large number of products would have to be taken off the market all at once, creating a situation in which many, possibly vital supplies could no longer be guaranteed. Employment would also be seriously affected.

Even if the number of substances requiring authorisation was limited, the administrative work-load would still be enormous considering the number of necessary authorisation procedures. But a significant increase in staff is hardly desirable and certainly not feasible.

IV. Improvement in the provision of data and risk assessment

There is but one remaining option, namely a radical departure from governmental paternalism towards a greater self-commitment by industry. The maxim of "I will do as I please as long as things are not forbidden" places an unacceptable burden on governments. Civil society is dependent on a voluntary commitment of its members to take on social and ecological responsibility.

1. *Self-commitment of industry*

There are indications that industry is facing up to this task. The European Chemicals Association has pledged to provide the basic data sets for 900 chemicals by the year 2005. Moreover, efforts are under way to include in this task the ca. 4 000 highly problematic substances by involving the multinational companies in a world-wide division of labour under the umbrella of the OECD. This will be an example and a test of the willingness and ability on the part of industry to make a voluntary public self-commitment at a time when globally operating companies can evade the control of individual states and the European Union.

While trust deserves credit, though, control will remain indispensable. In view of potentially dramatic consequences (for instance, the possible discovery of so far unknown effects comparable to those caused by CFCs; currently under review are hormonally operative substances as well as persistent organic compounds), it would be too risky, over a period of several years to trust that such pledges are being kept and then to end up empty-handed with no more than evasive statements that the tests were too costly, the co-ordination too difficult etc.

2. *Register of unknown chemicals*

What kind of control is conceivable that would not immediately call for another complex administrative mechanism? With the "Toxic Release Inventory" in the US, a concept has been introduced whose basic features seem transferable to the European context. This involves a pledge by companies to inform the general public fully about the kind and quantity of substances released by them. This concept of information instead of regulation relies on the action potential of the public, namely of consumers and citizens. Considerations are currently under

way to extend the concept of obligatory information on emissions (exhaust fumes, sewage, waste) to the marketing of toxic products. The following regulation is conceivable:

The European Union publishes a "register of unknown substances" listing the ca. 3 000 substances which, according to established criteria (high production volumes, suspected of being highly hazardous), are considered problematic and for which no or only partial basic data are available. At the same time, it is announced that from 2004 all producers and importers have to make a public statement once a year indicating the amounts of those substances that are still lacking basic data sets they have produced or imported, and explaining the main purposes of their use.

The expected impact could be a potential loss of prestige of companies and a subsequent drop in sales which would force the former to prepare and publish the relevant data. The US experience has shown that many companies go even further, wholly dispensing with the use of those substances for which they are required to provide data. A model along these lines would strengthen the motivation for the non-use of certain substances, the reason being that the provision of data involves substantial costs - ca. DM 200 000 for a basic data set per substance – and that this is too much when the provision of data makes it likely that a substance will be banned from marketing. Thus, the attraction of this approach lies in the activation of voluntary commitments spurred on by an involvement of the public, and in the fact that it works without bureaucratic instruments.

V. Improvement of risk assessment

Obviously, a comprehensive modification of products will not be achieved in this indirect way. But as before, the data – though expected to be received more quickly than in the past – will still have to undergo risk assessment by the authorities. This could be speeded up, if chemicals are not assessed for each and every aspect, but only with a view to the most probable risks (targeted risk assessment), and if proposals for regulation are developed already on the basis of sectional findings.

Before marketing restrictions are imposed, however, an attempt should be made to activate the potential for self-regulation. To give an example from Denmark: The Danish government has published a *"list of undesirable substances"* - substances deemed undesirable after risk assessment and considered as likely candidates for marketing restrictions. The list enables producers and importers to plan for innovations within a certain time span, while consumers can plan their purchasing decisions accordingly. Another concept could be to fix the level of future reductions in marketing volumes of

specific substances, and leave the realisation to the self-control of industry. Such approaches should primarily be realised at EC level. If EC authorities are unable to do so, implementation could take place at the level of member states.

VI. Improvement in risk regulation

A policy that sends out signals for innovations in this way would ease the administrative burden of classical compulsory substance regulation, although it would not make it totally unnecessary. For one would always have to be prepared for stubborn resistance by those who wish to preserve established market niches, a phenomenon that can only be overcome by compulsory command-and-control regulation. But how to improve this complicated decision-making?

1. Simplification of procedures

A simplification of decision-making procedures at EC level is long overdue. Instead of elaborate legislative procedures, individual restrictions on certain substances could be decided by the European executive, namely the Commission in collaboration with the regulatory committees in which the member states are represented. The complex co-ordination process of the Directorates General involved in this process could be simplified by making Directorate General XI, which is responsible for environmental protection, the lead agency for this purpose. In most industrial countries, the ministries of the environment are now responsible for chemicals regulation. It does not seem plausible therefore why the EC should still consider Directorate General III, which is responsible for industry, the lead agency.

A further procedural improvement would be a better co-ordination, both temporal and substantive, between the assessment of the economic impact of the envisaged regulatory measures and the process of ecological risk assessment, which at present begins only after the latter has been completed.

2. Strengthening of the precautionary principle

The material criteria for substance restrictions are also in need of improvement. At the point where risk assessment is being translated into recommendations for action, the precautionary principle needs to be given more room. The usual approach so far has been, despite verbal kowtows to the precautionary principle, to demand reliable data on the hazardousness of a substance and the conditions of its release. This is also reflected by the fact that European law only provides for three conclusions following risk assessment.

(1) The data suffice for assessment, no risk is involved, the substance may (continue to) be marketed;

(2) The data are insufficient, further data need to be obtained, but the substance may (continue to) be marketed;

(3) The data are sufficient, there is a risk, a substance restriction is recommended;

The precautionary principle suggests adding a further, fourth variant, namely:

(4) The data are sufficient only for a preliminary assessment, there are indications of a risk, a temporary prohibition of the substance is recommended, which may be set aside subject to the provision of further data.

3. Reversal of burden of proof for substances with hazardous properties

In practical terms, this would mean that a marketing restriction could refer to specific properties of a substance without the need for further research concerning its various uses which might cause contamination of people and the environment. This is already practised with regard to carcinogenic, mutagenic and teratogenic (affecting reproductiveness) substances: they must not be made available to ultimate consumers. This is a major contribution to health protection. A similar contribution serving the interests of environmental protection is still outstanding. The current discussion is about the possibility of effecting a marketing restriction already when the biodegradability of a toxic chemical poses problems, accumulates in organisms and is mobile. Such marketing restrictions based on substance properties could be combined with a reversal of burden of proof: marketing restrictions are lifted when producers or importers can show that the substances remain within a closed cycle, or do not enter the environment in any way.

4. Cost-benefit analysis – but in moderation

A more rational approach is also needed when different options of substance restrictions are being considered, such as the complete prohibition, the fixing of concentration levels in specific products, labelling schemes, etc.

It should no longer be possible that the frequent and usually quite effective blanket argument, namely that substance regulation involves exorbitant costs, blocks regulation. Rather, there should be an obligatory presentation of facts when it is claimed that the cost of regulation are out of proportion to the anticipated ecological advantages. On the other hand, it would clearly be

illusory, and increase the required investigative efforts to prohibitive levels, to demand a down-to-the-last-detail analysis of costs incurred by the effects of regulation, to compare these costs to an equally detailed calculation of the benefits (in terms of a prevention of environmental damage), and then perhaps balance both in pecuniary terms. Instead, this step should also remain focussed on the principal goal which is to make decision-making transparent. To achieve this, cost-benefit analyses will no doubt be useful. But conversely, decision-making, which is basically political by nature, on regulation measures must not be postponed, concealed or shirked by an insistence on excessively elaborate cost-benefit analyses.

VII. Improvement of the statutory bases

It seems there are many things that need to be dealt with. Much could be achieved by better entrepreneurial and administrative management within the framework of established law, but changes in the law will still be essential. This notwithstanding, there is room for reform on the national levels, such as the proposed list of unknown and undesirable substances. But the greatest efforts will be required on the European level. Particularly urgent is a change in the European regulation of existing substances and the so-called Restriction Directive which contains individual marketing regulations.