HAZARDOUS WASTE POLICY MANAGEMENT – INSTITUTIONAL DIMENSIONS

CHAPTER THREE:
Risk Assessment and Regulation for Hazardous Wastes

B. Wynne

May 1984
WP-84-43

INTERNATIONAL INSTITUTE FOR APPLIED SYSTEMS ANALYSIS
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PREFACE

This paper has been produced as part of IIASA's hazardous waste management work, which is the main component of the Institutional Settings and Environmental Policies project. The overall aim of this work, reflected in this paper, is to systematize our understanding of interactions between institutional and technical factors in policy making and implementation. The influence of institutional processes upon technical knowledge built into policy has been increasingly recognized. However, it has yet to be adequately clarified in comparative research on different regulatory systems. Institutional structures canot be easily transplanted from one culture to another. Nevertheless, through the normal flux of policy, institutional development slowly occurs anyway, in more or less *ad hoc* fashion. Comparative insight may help to direct reflection and adaptation in more deliberate and constructive ways.

This paper forms one draft chapter of an intended book on hazardous waste management. The reader will therefore notice references to other draft chapters in this study which are also being circulated separately, and which are available from IIASA. A full list is given overleaf. At this stage the papers are drafts, and are not intended for publication in present form. They are being circulated for review and revision.

I would like to thank those policy makers and others who have exchanged papers and information with us, and those who generously gave of their time and experience in the many interviews which form a substantial input to this work. A full list of acknowledgements will eventually be published.

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HAZARDOUS WASTE POLICY MANAGEMENT
— INSTITUTIONAL DIMENSIONS

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CHAPTER THREE:
Risk Assessment and Regulation for Hazardous Wastes

Brian Wynne

INTRODUCTION

This Chapter examines the application of risk analysis to toxic chemicals, especially to hazardous chemical wastes. It therefore brings together the more general perspective of Chapter 2 with the specific characteristics of toxic chemicals and their environmental distributions, and with the specific properties of hazardous waste management as an industrial–social–environmental "arena" in which toxic chemicals are produced, moved, transformed and have effects. The particular analytical focus is the dilemma of attempting to plug loopholes by having precise technical standards of universal application, yet to optimize risk management by tailoring regulations to specific waste dispositions and situations. is created by the embedded situational variations and uncertainties of the kind analyzed in the last (and next) chapter, and by the contradictory institutional needs of regulation (varying in different countries) for standardization and third-party accountability.

ENVIRONMENTAL RISK ASSESSMENT

Risk Assessment (RA) has developed and diversified from its earlier focus upon compound mechanical failures and plant emissions; more institutionalized public health concern in legislation and associated regulatory bodies has meant its natural extension into the areas of environmental pathways and human or environmental end-effects [1]. Although some disciplines relevant to the latter — for example toxicology — have long traditions, their ethos has often been clinical and individual, and badly suited to questions of *collective* public health effects. Within RA this has led to fundamental conflicts with younger disciplines such as epidemiology, which have developed their methods and approaches within the new climate of institutional needs and aims [2].

Although formal RA was dominated in the 1950s and 60s by 'mechanical system' analysis, this period also saw the beginnings of more systematic environmental exposure and dose-effect analysis. Indeed attempts systematically to gather evidence and define the risk associated with radioactive exposures had begun with the establishment of the International Commission on Radiological Protection (ICRP) in 1927 [3]. However this began as a concern by clinical radiologists about individual risks to radiologists and patients in clinical X-ray therapy and diagnosis. This effort took on a new impetus and reorganization in the 1950s, following the industrialization of nuclear energy and a shift of concern towards collective public and work-force exposures and risks. Early work in this field was dominated by pharmacology and experimental pathology (as well as the earlier clinical traditions), from which chemical toxicology also developed. The established paradigm was built around the simple concept of a damage threshold as acute doses and associated effects (e.g., gross tissue damage) were reduced. Thus approaches to risk and regulation e.g. in early ICRP standards setting involved short term experiments to establish "no

observable effects levels" (NOEL's) for such gross effects. These were then converted straightforwardly into maximum allowed exposure limits by the application of a safety factor, typically 10 for work-forces or 100 for external dose limits. The implication of this threshold approach was that such exposure limits involved zero risk.

Initially even radiation induced carcinogenesis was also thought to be associated with only gross tissue damage, but with the observation of radio mutagenesis and the somatic cell mutation theory of carcinogenesis (early version of the "one-hit" model of carcinogenesis), the idea became established that the origins of cancer at least lie in more micro-scale damage, unfolding only over long-term into clinical effects, to far more sensitive entities such as genes. This suggested that there may well be no dose threshold for health damage including mortality, so that no "zero risk" standard could exist. However, long latency periods were now associated with observation of effects and risks.

It was through the gradual though contested establishment of this no threshold idea that RA in its presently recognized form developed [4]. In this new form, standards-setting took on a concern for risk–benefit balancing, on the grounds that if no zero risk levels of exposure could be found, and zero exposure to most agents was impracticable, a level of exposure and corresponding risk would have to be set which made an acceptable trade off between risk and the costs of reducing exposures to achieve an acceptably low level of risk. Thus all the procedures of optimization, evaluation of "best available" control technologies, elaborate analysis of low dose-effect relationships for various agents, and concerns for public distributions and acceptance of risk entered into regulatory agendas and processes.

As compared to radiation risk assessment, two major factors further complicated RA for chemicals.

(i) exposure pathways to evaluate doses for radiation are multivariate and complex enough, but at least radiation exposure is to relatively few different kinds of agent (e.g., α-emitters, β-emitters, γ-emitters) from *relatively* few nuclear plants or other exposure events (e.g., A-bomb explosion, or diagnostic/therapeutic programs). These have also often been in discrete events, and sufficiently large and definable populations to provide reasonable epidemiological data for dose-effect evaluation. Chemicals themselves, and their forms of environmental release are so multivariate and diffuse that they present different orders of magnitude of complexity even to identify exposure pathways and populations let alone to begin to attach quantitative estimates to them.

(ii) radiation penetrates tissue and delivers energy in relatively simple, well understood ways, so that specific organ or tissue doses can be calculated from external exposure affects. (Not all is physical penetration and distribution of course — e.g., metabolic uptake movement and residence in the body of particulate radiation, especially α-emitters which deliver highly localized doses, has to be understood.) The same is far from true for most chemicals, so that specific organ or tissue doses cannot be calculated even from known *exposure* levels.

When we consider chemicals exposures from wastes this ignorance and complexity is expanded even more, because the chemical compositions, points of generation and disposal, and subsequent mixing of wastes are frequently badly known at best.

Thus in both dimensions of 'external' RA, exposure pathways (including points and focus of emission) and dose-effect estimations, (including the judgment of which possible effects to explore) hazardous waste management is

severely underdeveloped [5]. Probabilistic estimations have to give way to downright inestimability. Some regulatory purposes can avoid some of these lacunae: for example the ranking of intrinsic hazard of chemicals can proceed without having to analyze situational exposure routes and magnitudes, and evaluating different disposal options and exposures for the same chemical can assume the same dose-effect relationship. On the other hand ignorance within each may multiply; for example if an existing inhalation pathway for a given chemical is not identified and inhalation creates more damage than say ingestion because of different metabolic uptake, then the mistake begun by ignorance in one dimension is multiplied by ignorance in the other.

One can put the state of development of chemicals RA in perspective by observing that it has had far less attention devoted to it than nuclear radiation RA, and is far more diverse and ill-defined an area [6]; yet even with this relatively huge attention devoted to it, for decades, the low dose radiation risk issue defies scientific definition and consensus. Thus in its review between 1976 and 1980 [7] the US National Academy of Sciences, Biological Effects of Ionising Radiation (BEIR III) Committee in the end split irreconcilably over carcinogenic risks, and had to conclude that ignorance was still so deep that no single clear inference was scientifically warranted at doses beneath 10 rad, the very area of public health and regulatory concern.

The environmental–biological side of the field is therefore in its infancy — indeed in certain respects it becomes more infant as time passes, because the rate of new chemicals and mixtures arising, combined with the rate of 'new' exposures from 'old' chemicals (e.g., past dumps) is greater than the rate of adequate knowledge generation to understand better their environmental and health implications. At the Love Canal waste dump for example, after a colossal analytical program involving over half a million data points [8], over 400

different chemicals were eventually identified, with the following characteristics:

	% of total
mutagens	11
carcinogens	13
embryo toxicants (teratogens)	7
hepato toxicants (liver)	10
neurotoxicants (brain)	16
renal toxicants (kidney)	10
pulmonary toxicants (lung)	9

as estimated from a cursory literature survey on animal and *in vitro* testing.

However over 50% of the chemicals identified had no research record against them at all — their properties were simply unknown, even though they had been produced and disposed of up to 30–40 years ago. Even the data on the rest were so uncertain that the EPA's Carcinogen Assessment Group judged that only 4% (15 of 400) of the chemicals found could be given reasonably secure individual risk estimates.

The field is in a kind of intellectual 'poverty trap' in that, because it is so far behind and demands for knowledge are nearly always created under conditions of urgency, the kind of 'research' performed is closely tied to those urgent, retrospective regulatory demands. This draws attention and resources from more carefully conceived fundamental research which just because it is pitched at a more general level, when it does advance may solve problems in larger classes — it is more *anticipatory*. There is an understandable tendency for regulatory bodies (and regulated bodies for that matter) only to be concerned with 'science' which corresponds to their immediate legal and regulatory needs, but this is not necessarily equivalent to the best RA or science for policy generally.

In principle one can employ the same kind of 'fault,' or event-tree analysis to clarify different branching pathways, probabilities and potential doses and

effects in this "environmental and health" domain as in the more traditional 'mechanical domain.' Although the balance of analysis shifts towards more biological, chemical and behavioral factors, these are not absent in "mechanical system" risk analyses (e.g., containment of biological hazards in enzyme detergent or other biotechnology plant). However the regions of uncertainty ignorance and heterogeneity, including range of diverse behavioral–institutional factors, become generally even larger in the chemicals domain, than before. The number of potential end points let alone exposure routes to analyze even just for human health is huge.*

One basic complication about hazardous waste management is that it involves a flexible *range* of various behavioural processes and mechanical systems (in treatment, transport and disposal technologies and infrastructures) but these only *begin* to open up at the point where *natural* process environmental and health RA begins for conventional dispersive waste emission, namely at the point of *waste output* from other industrial plant. Furthermore except in a few places (e.g., Bavaria, Denmark) the T & D technological structure is not under the design and control of regulatory bodies performing or applying RA.

This leads us to consider the different regulatory nodes where regulatory information might be gathered and control applied [9]. We will then examine the possible decision-levels at which regulatory decision making (even if in practice made by industrial management, it may be under specific regulatory influence) might in principle use RA.

The various possible points of regulation and monitoring in hazardous waste management are indicated in table 2. It is immediately apparent how much the overall picture is complicated by the fact that unlike conventional pollution, hazardous waste is *packaged* waste, therefore controlled and transferred by human intermediaries.

* See for illustration, Table I.

TABLE I. Examples to show range of potential human health end points to examine in chemicals risk assessment (non-exhaustive).

REPRODUCTIVE

- Sexual dysfunction
  - decreased libido
  - impotence
- Sperm abnormalities
  - decreased number
  - decreased motility
  - abnormal morphology
- Sub-fecundity
  - abnormal gonads, ducts, or external genitalia
  - abnormal pubertal development
  - infertility (of male or female origin)
  - amenorrhea
  - anovulatory cycles
  - delay in conception
- Illness during pregnancy and parturition
  - toxenia
  - hemorrhage
- Early fetal loss (to 28 weeks) and stillbirth
- intrapartum death
- death in first week

Decreased birthweight

Gestational age at delivery
- prematurity
- postmaturity

Altered sex ratio

Multiple births

Birth defects
- major/minor

Chromosome abnormalities (detected in early fetuses, through amniocentesis, in perinatal deaths, in livebirths)

Infant mortality

Childhood morbidity

Childhood malignancies

Age at menopause

Many of these categories interact in different ways, e.g., observations at one level may by symptoms of 'observations' at another.

NEUROTOXIC

Various tissue toxic attack — axons, neurons, myelin, glin, blood vessels

Distal axonopathy — various sites

Vibration sensation
Motor nerve conduction
Peripheral neuropathy
Sensory conduction

Cranial, spinal, lemniscal and thalamo-cortial nerve activity

Toxic encephalopathy — convulsions, hallucinations

Inflamations

(Pigmentation changes)

Tremor

GENETIC

(biochemical)
altered protein electrophoretic mobility
altered enzyme function
lactic dehydrogenaze isozymes

(chromosomal)
sister chromatid exchanges (different cells and parts of cell cycle)
chromosomal aberrations and breaks
micronuclei formation

(sperm)
abnormal morphology

CARCINOGENESIS

Various sites and kinds of tumour

"ASYMPTOTIC" DISEASES

Reduced performance of normal functions — perceptual, memory, motor skills, reflexes, balance, intelligence, problem solving, attention levels, sleep, etc., etc.

Many of these categories interact in different ways, e.g., observations at one level may by symptoms of 'observations' at another.

POSSIBLE DECISION-LEVELS

1. *Product and process design — integrating waste disposal implications into new investment decisions.*

Ideally, a Risk Assessment scheme for chemical wastes would begin far 'upstream' from normal points of application, at the stage of industrial process-design (see Figure 1, chapter one). Thus not only conventional input factors (materials, capital, energy) and commercial product compositions and yields would be calculated, but also all potentially harmful entailments, either as by-products from the process, or after use (including possible transformations) and discarding of the commercial products themselves. This approach is recognized as the ultimate regulatory ideal. It is also accepted by some [10] as in industry's best interest, since it might prevent some hazardous materials (e.g., PCB's or 2,4,5-T) from ever becoming downstream 'wastes' where they then lead to regulatory reactions which inevitably threaten by-then established production (and use) commitments. In Hungary the government regularly analyzes 'internal' industrial data (see Hungarian case study), but in less centrally-planned economies industry strongly resists even external information-gathering, let alone external direction of plant and process decisions.

The main problem with a regulatory strategy at this level is that the more comprehensive the attempted risk-analytical net, not only the more political conflict does it draw in (e.g., direct interference in industrial decision making), but the more ignorance and uncertainty there is about the key decision factors — possible consequences of different upstream decisions.

TABLE 2: Regulatory nodes, information and instruments for hazardous waste management.

REGULATORY NODE	MONITORING OR ANALYSIS	INFORMATION NEEDED	REGULATORY ACTION POSSIBLE
PRODUCTION PROCESS	Inputs, process design, aste streams, intermediates	Composition and interactions in process, to estimate waste streams	Dictate process choice and design Tax/waste costs enough to influence process decisions.
WASTE ARISINGS - FACTORY GATE	Volume, composition, (e.g., packaging) of waste arisings - internal treatment - external treatment		Prohibit production of some wastes Waste tax Classify and tag some wastes to minimal levels of T & D
TRANSPORT SYSTEMS and SPECIFIC CONSIGNMENTS	Monitor consignments, frequency volume, composition reported and actual destinations	Actual vs reported final destinations Intermediate transfers re-loads, mixing, storage, etc. Prohibit some combinations	Regulator acts as transporter Licence transporters Specify design standards for transport
T & D PLANT RECEIPTS	Analyze waste receipts at T & D plant	Conposition, volumes, origins physical state of wastes received	Licence plants to receive only specified wastes
T & D PLANT OPERATION (+ DESIGN?)	*Plant emissions* – air, water, (leachate, surface), soil, operators	Emission rates to air (stack monitors); composition of leachate, surface water, operating environment	Specific plant performace (& design) criteria, e.g., discharge limits + *prohibition* of some wastes.
ENVIRONMENTAL MEDIA AMBIENT	Analyze which media most indicative, monitor	Contamination levels of media, physical and chemical process	Ambient concentration limits – air, water, soil, etc.
SPECIFIC ENVIRON-MENTAL END-POINTS e.g. AQUIFERS, POPULATIONS	contamination of these.	of environmental movement and distribution.	Specific concentration limits calculated, e.g. as human dose limit equivalents (+ safety factor) "derived working limits" DWL's
HUMAN DOSES & EFFECTS	Monitor potentially affected populations or critical groups	Full range of health effects possibilities (see Table 1); (incl. workforce)	Dose-limits – individual or population maxima. specific tissue and organ contamination limits.

Thus, for example whilst it may be in industry's best interest in principle to know before it makes any more commitments, whether a given process being contemplated at a conceptual design stage will produce unacceptably hazardous materials, in reality there are so many uncertainties and options in the passage from conceptual design and early risk indicators, to eventual effects. Furthermore these uncertainties are both technical ("further tests may show it as not so bad"; "we may develop a neutralization or destruction technique") and social ("we can influence the regulatory interpretation of technical data, or political attitudes to regulation"; "we can trust landfill operators always to perform carefully").

The interested party is very influential in the social management of such uncertainties and intermediate downstream decisions. Therefore it may well decide in private, that early, at-that-stage inevitably ambiguous risk indicators showing possible hazards, may be gambled against the potential commercial benefits of the new process or product, and the calculated possibilities of achieving a happy regulatory outcome

In any case the point is that it is impossible to delineate downstream effects of various upstream decision options because the downstream branches of each upstream decision diversify enough to potentially overlap and mask any clear discrimination between effects of different upstream options. (This is a re-statement of the truism that policy is always made in incremental steps [11]. It cannot always be assumed that this is a less rational response to uncertainties than the approach which demands extensive analysis as the determinant of every decision.)

2. *Production adaptation to reduce wastes or specific toxicities.*

This is effectively a special case of 1, since there is no clear-cut line between a wholesale production change, and large adaptations. Smaller

'adaptations' may range all the way down to e.g. in-plant waste-stream dewatering to reduce waste volume and mobility. Adaptation however implies a prior commitment to a given product and process at the level of conceptual design. Waste RA here could mean enlarging normal optimization decisions about plant details to include differential costs (if any) associated with different hazardous waste implications of the options alongside the conventional cost benefit factors. This would remain an in-house issue for industrial management and the upstream effects of any external, downstream signals from regulatory bodies would be complicated and diffused by the other dimensions of concern to industrial decision makers.

Quite apart from confidentiality problems, industrial processes are usually not unitary but produce multiple waste streams, and even within regular daily operating conditions a process's waste composition will fluctuate quite significantly ("some waste streams go into and out of the hazardous category several times per shift" [12]). Therefore the degree of specificity and accountability of this level of RA is always likely to be limited. Many industrial processes are simply not amenable to other than crude prediction of what chemical wastes they will produce; and by the time empirical examination can be made, for a full RA, commitments to the process are established — the familiar technological risk dilemma.

3. *Given a certain waste arising, what treatment and disposal option should it receive*?

At this level, (as it were at the factory gate with the gate closed and all inside an inscrutable 'black box'), the aim is to determine the 'intrinsic' properties of the waste as it stands, and match its hazards to the cheapest effective technical option calculated to reduce those hazards to 'acceptable' levels. As already noted, even knowing *what* is there is a big problem.

Risk assessment for 'intrinsic' hazardous characteristics has to be complemented by risk assessment of different T & D routes to evaluate if those intrinsic hazards can be acceptably reduced (at 'acceptable' cost), and if so,what is the most cost-effective means. There are two basic loopholes in this approach:

(i) even assuming risk analysis could evaluate clearly the optimal T & D route for a given waste, it does not consider the risks of the designated routes not being fulfilled; [see 5. below];

(ii) a general problem with risk analysis, that the uncertainties in the costs and effects of different options dwarf anything but crude comparative information, so that in practice, management of the interpretation of risks and costs can determine what is 'analyzed' as optimal; in other words the large uncertainties allow 'analysis' to be manipulated (not necessarily deliberately) so as to give apparently objective justification to more pragmatic prior commitments to different T & D options.

Two immediate situational factors give rise to a special case of level 3, namely:

4. *Given a certain waste arising in a certain place, what practically existing treatment and disposal option should it receive?*

Whereas 3 might be used, ideally, for planning a T & D infrastructure, 4 may more reflect real decision situations. The US EPA, which is committed to the greater use of formal RA in regulation, has been developing an integrated model which attempts to match and optimize combinations of Waste-Environment-Technology (WET Model) for different risk/cost objective functions using linear programming [13]. The model's developers recognize that in aggregating many factors (for example to score all possible human health effects for an initial 140 different chemicals on a single scale), this risk

assessment model is a very crude cut. Nevertheless it is intended that it will systematically identify combinations of wastes, environments and technologies where regulation should increase or decrease in resolution, and at the limits, where total prohibitions or non-regulation should occur. As "a broad policy planning tool...incapable of developing and revising specific regulations," [14] the WET RA is essentially the first, crude step of a step-wise regulatory strategy trying to see where analytical attention should be focused in a situation where regulatory attention and resources are far outstripped by the magnitude and complexity of the available problems.

In principle, WET matching should optimize the *situational* conditions (treatment, transformation and disposal, containment, isolation, etc.) and hazards from the *intrinsic* hazards of a given waste, thus refining the risk-cost trade off. In practice of course, the apparent specificity of such an analysis and decision is impossible because there are far too many and too varied wastes arising (let alone possible environmental dispositions) for each to be subject to control by clear-cut risk-cost assessment rules. But it is necessary to remember that however it is structured in different systems, this is the implicit aim.

Thus regulatory approaches have attempted to establish accepted frameworks for evaluating wastes for their intrinsic 'hazard,' then 'control' their routing towards 'hazard-limiting' T & D options. This can be done in various ways and to different levels of determinism or specificity. One option is to allow complete freedom of choice for the operator to dispose of his wastes once classified, but only within a given menu (which may be very large indeed, including export) of T &D operators whose facilities are licensed to received a variously limited range of wastes. This involves a significant measure of risk 'control' from the T & D licensing end (the back end), with a minimal 'intrinsic'

hazard classification of wastes, from the generator end (the front end) and a large mediating middle ground of free enterprise. Insurance is attempted against ignorance of waste arisings by placing control emphasis at another, downstream regulatory node. RA here is essentially a complex mix, of *minimal conditions* at each end of the match — initial waste, and final T & D — but allowing normal commercial processes in between, to optimize for all other factors (and perhaps more besides) which a risk management decision would include. This is the least deterministic form of regulation. In putting regulatory emphasis on T & D plant licensing but not upon what wastes *arise*, it is also institutionally most distant from production process innovation, and least able to influence that phase. This kind of balance is in principle most nearly approximated by the UK, which has probably the least elaborated hazard classification for wastes, and the most strongly expressed dependence (even if decentralized, and in reality variable in quality) upon T & D site-facility licensing [15].

Two ways in which this balance can be changed are (i) by more elaborate front- end attempts to classify hazardous wastes, even to tag specific wastes to direct them to specific kinds of T & D (or even specific T & D facilities). This is being tried in Austria, and is the subject of moves to establish it in FRG*; and (ii), to centralize licensing of T & D facilities to be more elaborate and specific in the kinds of wastes they are allowed to treat. The US EPA began in 1978 by considering that it would issue centralized criteria of T & D plant design and performance, but had to relax these in 1981 to 'best engineering judgment' in case-by-case manner, requiring *operators* to perform justifying risk assessments [16]. The uncertainty of this approach for operators has caused EPA to retreat to general standards, this time for *environmental* performance of T & D facilities.

* In effect it is partly established already in Bavaria and Hesse.

Both of these regulatory moves (i) and (ii) push the front and back ends of the system together, thus reducing the ill-defined middle. In theory this would increase determinism, control and effective regulation. In practice it would reduce the coordination of the system, which* is only viable if a large degree of freedom, thus regulatory indeterminism, is allowed to private enterprise in matching specific wastes to specific end-points.

A key dilemma is whether adequate freedom to allow self-coordination in the middle does not also in practice inevitably entail too much freedom for industrial actors to interpret too variably the conditions (e.g., definition of "waste", or threshold concentration) of hazardous waste classification and facility licenses which are the bases of regulation. The EPA WET model for example [17], does not seem to have any components for evaluating different behavioral responses of free operators to different regulatory strategies and signals (e.g., monitoring versus notification; taxes and subsidies, etc.). Yet these perceptual and behavioral differences may be critical to effective regulation.

5. *Given a certain waste and a certain designated T & D facility, what are the risks of its not arriving, in its proper form?*

This could be broken down into accidental or purposive "misdirection." The former could involve accidents and spillage, unsafe mixing at an intermediate collection point (e.g., cyanides with acids, which could release HCN, or physical or chemical changes within the same waste during transport or storage.

It is interesting that some regulatory bodies such as the UK feel that hazard lists and classification schemes are *only* necessary for the transport phase — although they have not taken steps to license hazardous waste transport operators [18]. Trip-ticket notification systems are supposed to address

* except perhaps in comprehensive local systems (see chapter five)

this "effective designation" problem, but it is widely accepted in practice that: the sheer volume of paperwork and coordination necessary; the dislocations between brief, unit paper descriptions and real world transport arrangements (e.g., 'season-tickets' aggregating many loads into one recorded consignment): and the time lag between actual transport and receipt of all copies of the paperwork by an agency; all mean that trip-ticket systems can *at best* be a retrospective information gathering exercise, and not a form of real-time regulation.

A further dimension of this RA level, also a part of the previous one, is that if transport is a significant risk-generating phase, either through spills or diversions, optimization of risk should contain an element of reduction of transport distances *and* frequency of transfers and handling. This happens to coincide with the fact that transport is a significant part of overall T & D costs, so it becomes prominent in T & D decisions (unless costs differ widely between different T & D operators, as they sometimes do).

This transport reduction factor has to be played off against the need to get a given waste to an 'adequate' facility, and the (technical and economic) benefits of large scale regional facilities against smaller local facilities, which implies longer average transport distances. This kind of regionalization option may further imply regular one-way cross-border flows of wastes, with consequent unpredictable political difficulties as well as extra possibilities of lack of coordination, so that many decision factors at other levels begin to dominate the transport issue. Thus as with other levels of Risk decision in this field, the boundaries of the problem crumble even as one tries to define its internal structure. Thus far, in practice, with few exceptions,* most decisions about disposition of different kinds of T & D facility have not even been made on any coherent policy grounds, let alone ones including systematic risk assessment.

* e.g., Denmark, Bavaria, Hesse and the planned Hungarian network.

They are more the accumulated result of 'separate' *ad hoc* commercial calculations.

6. *With a given set of wastes produced with a given geographical distribution, what site and what design of T & D facility should be established?*

Assuming that a decision to build a certain kind of T & D facility in a certain region has been made, siting and design (including license conditions) become issues for regulatory involvement. Apart from the stage of general hazard classification lists, this seems to be the field in which risk assessment could be most useful. Siting and design issues interconnect because for example, lining, leachate collection and treatment, monitoring systems and other design aspects of a landfill will depend upon its precise site in relation to geology, hydrology, etc. An incinerator's siting may depend upon the nature of its aerial emissions, etc.

The principle underlying the approach is to reduce the intrinsic hazard of any given waste to acceptable levels, by transforming its intrinsic character, by physical or chemical immobilization, or other forms of isolation so that human or other exposures do not occur. "Acceptable levels" will often be conventional environmental media standards — air, water, MPC's or derived working limits in specific sensitive media (e.g., food-crops, fish, etc.) — but they may also involve plant emissions limits or even specific design requirements.

As indicated earlier, unless a system is structured institutionally so that waste *arisings* fall under the positive designation of the T & D facility management, there is no guarantee that a risk assessment at this back end will be effectively used in harness with other economic and technical judgements.

7. *Risk assessment of past dumps.*

This is a somewhat separate issue from regulation of present hazardous waste management even though there are overlaps in terms of public attitudes, landfill analytical and monitoring techniques, environmental movements and public health effects. There are also direct interactions from the soil clean up programs for past dumps where large volumes of incinerated soils stripped of most but not all of their contaminants still need to be landfilled at controlled sites, thus taking up capacity needed from currently generated wastes. In general however, risk assessment for past dumps clean-up is only at the first step of a stepwise process, attempting to develop criteria for prioritizing those sites most in need of desperately limited clean up resources [19]. In view of the difficulties experienced in mobilizing designated funds, and the huge escalation of clean up costs now that they are based on some initial experience rather than hopeful guesses [20], this selectivity of prioritization has become even more severe. As the Love Canal case illustrated [21], the same dominating ignorance and uncertainties pervade this aspect as real time management, but the way in which past dumps are discovered makes the social trauma of the uncertainties more immediate and dramatic. As will be discussed in chapter 7, for past dumps there is less mediation and containment by regulatory bureaucracies of the surprises inherent in such ignorance than there is in the case of 'real-time' hazardous waste management.

There are several basic issues threading the question of what role RA might play in regulation for hazardous waste management. The main ones revolve around how intrinsic hazards are managed into specific 'situational' ones, and where responsibility/autonomy rests for doing this. A related issue is the way in which decision rules for RA and regulation are expressed — how formal and specific are they, or conversely how informal, discretionary and situationally flexible? These questions take us into the heart of how authority is managed

through the use of formal scientific knowledge or less formal judgment in RA for regulation. This balance in turn relates, on the one hand to *institutional* structures of scientific advice, regulation and policy, and on the other to public attitudes and reactions.

IGNORANCE, JUDGMENT AND STEPWISE TESTING

As indicated in chapter 1, even where it is most elaborate, regulatory attention for hazardous chemicals focuses upon only a small proportion of the available problem domain. Various factors combine to reduce the area of attention, especially the vast and growing excess of chemicals and potential effects over available analytical resources. As analytical techniques become more powerful and refined, e.g., chromosome damage techniques and various neurological field techniques [22], they ironically expand uncertainty because they move further ahead of the ability to interpret the meaning in terms of causal factors and recognized health risks, of the new observations they produce [23].

In the RA of chemicals and chemical wastes therefore stepwise or tier-testing schemes have become normal currency, although their structure is far from fully defined [24]. It is also important to distinguish initially between: (i) ***tier testing***, which is designed to bring rational priorities to the question of what to subject to more refined, more expensive and time consuming risk analysis; and (ii) stepwise ***hazard classifications***, which attempt to create a hierarchy of increasingly strict regulatory control for increasingly hazardous materials, or combinations of materials and situations.

These two phases overlap, but are in principle distinct because the first ought to be only a preliminary to the second. In reality, RA often advances no further than the first phase, but is then confused with the second.

Tier Testing

Given that only a small fraction of all potentially harmful chemicals can be properly tested, the aim of tier testing is to first perform cheaper, more rapid and more crude screening tests on a wider range, in order to try to find out what to test in more detail. One very important pragmatic limitation of the scope of such schemes is that they usually only apply to newly introduced commercial chemicals [25]. Therefore those already in circulation or created anew in wastes are exempted unless particular ones are arbitrarily "chosen" and brought to attention dramatically, thus demanding analysis, as with PCB's, or at Love Canal, Gouderak and other dumps. Tier testing therefore by passes a first, greater level of ignorance, particularly true of hazardous wastes, which involves not even knowing what chemicals are where, in what form, to even screen for more detailed risk testing.

Given the daunting range of potential adverse health effects to test for, and the lack of reasonable scientific connection between rapid, acute effects and chronic, low level effects testing, the ordering of tests is scientifically rather arbitrary. Whereas regulators present it as a rational means of optimizing regulatory knowledge within very limited resources, industry sees it as a rational means of cutting down regulation and thus costs of introducing new products [26]. Many different schemes have been proposed or used. A typical scheme is that proposed for the US Toxic Substances Control Act by a "consensus group" of industry and professional environmental bodies, convened by the Conservation Foundation [27]. This is organized into four Tiers, the first being a review of primary chemical and physical properties such as chemical structure, volatility, purity, solubility, partition coefficient, adsorption/desorption, stability. The second tier begins biological tests e.g. for acute toxicity (oral inhalation, dermal) in mammals, birds and fish. Given that

each LD_{50} value* is a statistical determination needing many data points, this already implies a lot of laboratory experiments. This tier also entails plant and seed toxicity tests, analysis of transformation and degradation processes, and short-term mutagenicity and carcinogenicity tests such as *in vitro* cell transformations. These include further tests with metabolic activating agents. Already, in addition to escalating costs, requirements for standardized experimental designs and reproducible methods are involved. These are by no means easy to develop and establish in practice, even between technically experienced practitioners, and require elaborate development involving inter-laboratory comparisons and exchanges, thus further multiplying costs and time scales.

The third tier expands upon the second, if tests at the earlier level indicate the need. This goes into greater detail and "longer-term" typically 90-day tests, for subacute, chronic and teratogenic effects *in vivo* and *in vitro*, in a range of species and cell cultures. Biodegradability, bioaccumulation and other environmental movement/transformation tests are also required at this stage, so as to develop a picture of potential exposures under different conditions.

If indications from the previous tier suggest it, the final tier involves lifetime chronic toxicity tests in at least two mammalian species, with associated histopathological examinations, and further mutagenicity tests. Neurological tests in various species, life-cycle plant growth/reproduction tests are also involved. Metabolic and environmental transportation studies are required to include more examination of the by-products of such transformations, since these may be toxic even if the parent chemical is not.

As a pragmatic necessity, some kind of escalating set of tests such as those outlined above is inevitable. However inevitability should not be confused with rationality (and risk control) in any stronger sense. Merely listing the

* Mean Lethal Dose to 50% of subjects tested.

escalating tests in this way gives no sense at all of the vast array of large-scale and detailed experimental and interpretive uncertainties at every point. Furthermore the structuring of the burden of proof in the stepwise screening process means that a chemical is exonerated from further tests unless it gives some positive indication in the earlier tier. But earlier, acute tests and effects for example, may not relate to chronic effects, which occur by different metabolic pathways, and act upon different entities and functions from acute effects. Thus, such tiered testing schemes and experimental protocols are not a substitute for experience and judgment, nor will they overcome interpretive conflicts containing policy overtones despite the fact that this is the way they are often viewed [28].

This is especially so when as often happens, tier tests are framed as numerical scoring systems from risk assessment models which fit bureaucratic needs by assimilating various results of different test batteries into single weighted aggregate scales which are automatically calculated. Thus for example one such RA model [29], attempting to distinguish degrees of hazard for wastes, has "a single value represent all types of effects from different types of cancers to different kinds of graded responses such as liver damage. The conceptual link ... is the probability of an incident per unit dose. A score of "2" on our scale, for example, is intended to represent roughly a 1 per cent risk of either contracting cancer or having an adverse effect from consuming 1 mg of pollutant per 1 Kg of body weight per day.... The model assumes ... that most reported MED's, or minimum effective doses correspond to a risk of about 10%."

Such bureaucratization into one simple numerical dimension of basic qualitative differences and diverse and interacting uncertainties is encouraged by organizational realities and a felt need for the "objective" authority supposed to emanate from models [30]. However this method of harnessing science may

actually obstruct rather than encourage the development and integration of *better* more mature and discriminating science in RA. Some experts have criticized the hyper-mathematization of biology in bio-statistics with the same concerns in mind. It is typical to find that many of the experimental tests, let alone interpretations of results have to be [31] "done in the hands of a master" to mean anything at all. Another widely acknowledged expert, MacKay, has criticized the whole framework of stepwise testing and ranking in RA as a misbegotten attempt to substitute for experience and judgment [32]:

> Undoubtedly, "scoring," or "rating," or "prioritizing" numerical schemes will be developed, allegedly to assist in identifying the most hazardous substances. It is the author's opinion that such schemes are usually misleading and are often pursued only because of intellectual laziness. There is no substitute for the careful gathering and assimilation of reliable, physical-chemical, biological, and industrial data by a broadly experienced group of well-informed and well-intentioned individuals who can then make a balanced judgment in which all the issues have been weighed subjectively.

This defense of science as craft skill, incorporating many dimensions of tacit experience, intuitive judgment and subtly negotiated intra-expert agreements is often counterposed to formal models and methods. Yet formal models, ranking schemes and approaches also require implicit, informal judgments and inputs to be viable, and attempts to model may make more, not less demands upon less accessible and accountable judgments. This issue arises again below and is discussed later in connection with risk assessment decision rules.

Stepwise ranking schemes for hazardous chemicals including wastes extend in two directions from the kind of scheme outlined above. Firstly, even to enter the *first* gate, selection has to be made. Thus for example the Interagency Testing Committee (ITC) for the US Toxic Substances Control Act was required in 1979 to provide a scoring system to meet a six-month congressional deadline, for the full repertoire of 70,000 or so chemicals already in commercial circulation. This was to determine which of these should enter into a

more careful scheme akin to that outlined before. The group which conducted the scoring was itself forced to use a series of crude gates and selection principles established ad hoc [33]. The key one was simply to borrow lists from existing regulations in the hope that these had more definitive origins. Furthermore, for all its heroic attempts to be definitive and explicit, the group repeatedly had to bridge huge gaps of ignorance and uncertainty with subjective judgments.

Secondly, the starting point for ranking of hazardous chemical goods is *relatively* well defined compared to hazardous wastes. The quantitative ranking process for hazardous goods either takes the approximately 500 new chemicals per year, cuts them down first to about 40, then down to the three to six per year which can actually be subjected to full STAR* testing; or as in the exercise above, it selected 900 from the 70,000 starting number, and worked these down in a similar way. Hazardous chemical wastes on the other hand are much less well known because, socially defined as wastes, their chemical compositions and purity have no positive economic value; they may also therefore be mixed and vary indiscriminately with unknown chemicals resulting from uncontrolled interactions. As Finnecy has noted [34],

> Firstly there are many thousands of possible constituents in a waste, and waste is *very* rarely even an approximately pure substance. Secondly waste is rarely ever completely analyzed by anyone. Rather, analyses (or estimates of one sort or another) are made of a few 'significant' components while the rest of the waste is largely unidentified in anything other than general terms.

When one adds to this the myriad, often unknown starting points of wastes, and their complex, also often unknown life cycles, the problem for a central regulatory body of knowing where and what to begin screening is larger still.

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* Scientific & Technological Assessment & Review

Even leaving aside for the moment this extra dimension of ignorance for hazardous wastes, it is worth quoting at length the reflections of a scientist involved in the ITC ranking exercise [35]:

> I would draw several conclusions from this exercise ... that the scheme that was used incorporated a very significant degree of scientific judgment at every step. At each screening step, the chemicals screened out were examined manually by experts and the scoring involved at least as much scientific judgment as the use of objective data. ... that the scoring system which considered 15 factors and had a range of 0 to 3 or 0 to 4, was at least as complicated for each of the factors as was justified by the available data. It may in fact have been too complicated. It may have tried to divide the chemicals more finely than our knowledge would justify. Frankly I believe that any reasonable scoring system can handle hundreds of chemicals with no finer subdivision than 0 to 3, or zero, low, medium and high. ...that the screening process was limited primarily and very severely by lack of data on most chemicals. In fact, I would say that, if for each of the 900 chemicals we had placed information on the seven factors into separate boxes, at least two thirds of the boxes would have remained empty. My conclusion is that the scoring process was not limited by scoring methodology or by any other screening methodology. It was limited by the lack of data. I would therefore suggest that elaborate scoring systems are not justified at the present state of our knowledge. Until we have such more extensive data on most of the factors for which we have to screen, there is no point in developing elaborate scoring systems because they cannot be used.

This expert recognized not only that schemes and rankings apparently controlled by formal criteria actually required *more* informal judgments rather than less, but also that RA ranking systems may *conceal* ignorance rather than better define and systematically reduce it. The kind of streamlined "scientific knowledge" which such classifications require is easily confused with the more fundamental scientific knowledge which embodies open gaps and conflicts, normal qualifying dimensions, situational adjustments, and so on. Because it tends to bury uncertainty, it cannot easily develop strategies to overcome or adapt to it. Regulatory systems may have to act *as if* knowledge existed and ignorance were bounded. But the institutional processes concerned may confuse this necessity for regulatory "as if" confidence and associated 'knowledge' with real scientific knowledge.

DEGREES OF HAZARD AND SITUATIONAL RISK OPTIMIZATION

Although RA begins with estimation of 'intrinsic' hazards, either of engineered plant or chemicals or both, various situation-specific factors enter into regulatory risk management. The basic aim is simply to refine regulation to correspond with degrees of hazard in real cases rather than with blanket worst-case scenarios. This RA refinement parallels the regulatory attempt to use risk benefit optimization* in that in trying to make regulation more 'efficient,' by tailoring defined risks to varying specific situations, margins for uncertainty and error and thus of safety, are also naturally reduced. This therefore implies the need for a greater regulatory ability to define the specific controlling properties of such varying situations. Such an assumption is highly problematic.

'Intrinsic' risks of a chemical or nuclear plant might be probabilities of given release rates of harmful agents. Situational factors such as environmental attenuation, siting (proximity of populations; other sensitive entities such as drinking water); typical particle size, chemical form, etc., of releases: affect estimations of actual situational risks. In the case of large scale plant, such as liquid gas terminals, the releases and environmental pathways to be considered as situational risk-qualifiers may be very few, usually to do with atmospheric dispersion characteristics of vapour clouds (liquid gas plant) or particles (chemical and nuclear plant).

The definition of any specific risk situation is basically identical to the problem discussed earlier, of defining the relevant structural characteristics of a technological risk system. The examples of LEG terminal facilities and the use of 2,4,5-T as a herbicide were given in Chapter 2. For hazardous wastes the

* Though risk–benefit trades off decreasing risk/increasing containment against costs of achieving such decreases, degree of hazard schemes do not always proceed to the second stage of defining containment costs of situational risk reductions.

risks of understating uncertainties and variations are greater because of scientific ignorance and greater situational variation in this case.

Various possible approaches exist to defining situational risk qualifyers and organizing these into regulatory degree of hazard schemes [36]. The usual assumption is that more situation-specific risk definition identifies risk-*reducing* features which allow the severity of centralized regulation to be relaxed to a minimal base line, supplementing it with the risk qualifying factors introduced by more autonomous, situation-specific *operator experience* and good management practices. The former may be 'directly' regulated with specific rules etc., whilst the latter may be only indirectly regulated (e.g., by economic incentives) or merely assumed to take place.

However (as the 2,4,5-T case illustrates) it should be noted that it is not necessarily the case that situational realities *reduce* risks. Whether laboratory experiments with individual pure components capture the "real, intrinsic" hazards of chemicals in environmental circulation is questionable, and as mentioned earlier, the distinction between the "intrinsic or natural" hazard of a substance and its situational hazard is not an objective distinction free from social determination and variability. Often, what is defined by one party as an *intrinsic* hazard already contains unrecognized assumptions about institutional factors which appear as natural to that party, but which others see as questionable or false.

Different regulatory systems construct different distributions of regulatory direct constraint and autonomous responsibility between 'universal' risk characteristics, and flexible situation specific realities [37]. For example if one inserts at the beginning of a RA scheme, the criterion "volume of production" or "potential exposure," only subject to this prior evaluation making any assessment of toxic and other 'intrinsic' hazards, this may produce a different

profile of relative risks from a scheme which first evaluates intrinsic hazards, then begins to introduce situation specific qualifyers. Different regulatory systems may also draw the line of specific control at different levels, for example:

(a) listing for universal control (e.g., registration) hazardous wastes with intrinsic hazardous characteristics, then taking account of say, volumes produced, physical form, typical concentrations of hazardous constituents, professionalism of industrial management, siting, etc. only in separate local decisions (e.g., plant licensing) about specific T & D practices; or alternatively,

(b) exempting from primary listing those wastes, even if intrinsically hazardous, which are: not produced in large volumes or concentrations; produced perhaps only by large, technically well-endowed companies; or arise in aqueous form if they are mainly an inhalation risk; [38] etc.

The regulatory argument in favor of this latter approach is that it slims down primary regulatory lists, thus allowing more attention to focus on the more intense hazards [39]. This coincides with the industrial interest in more autonomy from regulation. Thus for example Dow Chemicals' critique of EPA hazard listings was that it was based upon estimated intrinsic hazards of constituents only [40], hypothesizing for this purpose that waste would be improperly managed. Dow proposed instead a stepwise degree of hazard scheme which placed estimated real exposures (including production volumes) at the front end, thus reducing the apparent risks in an "equivalent toxicity" measure. Likewise the European Chemicals' Industry Toxicological Research Institute, ECETOC, has advanced a three-tiered degree of hazard approach which combines intrinsic toxicity criteria with [41] "exposure conditions which correspond to those in man or where the relevance of the exposure conditions

can be deduced." Thus again, situation specific factors are incorporated into the same standard degree of hazard regulatory scheme as intrinsic factors.

This is typical of general European institutional processes which compound "intrinsic" scientific factors with extrinsic factors in informal mechanisms and imprecise, flexible 'technical' criteria [42]. These institutional mechanisms may involve joint advisory committees which deliberate in private and negotiate the particular weaving together of scientific and extrinsic factors, or implementation processes which allow case-by-case negotiation between regulated interests and enforcement bodies.

In the UK, situational risk-qualifying factors for specific waste have been identified, such as [43]:

- where it is
- quantity
- concentration of hazardous components
- physical form
- detailed environmental disposition (e.g., if a fine powder, is it open to wind dispersion; is it adsorbed strongly by clay surroundings)
- sensitivity and number of targets exposed to it

and lastly:

- "how damaging the hazardous effects are to the target," i.e., intrinsic hazards of the chemical constituents of the waste.

The apparently "intrinsic hazard" list for regulatory control in Britain actually already incorporates informal judgments of many such situational factors, and provisions are made for automatic testing to *de-list* specific wastes [44]. Whereas the US system specifies a list of controlled wastes and adds as a catch-all, several tests which all *unlisted* wastes must also pass in order to be

exempt from control [45], the UK system specifies a (much more compact) list, but gives several tests which wastes containing such listed compounds must fail in order to be *included*. Whereas the US system is designed to automatically *include unlisted* hazardous wastes, the UK system is designed to automatically *exclude listed* wastes which in their specific circumstances are not deemed hazardous. (Although there is a procedure for de-listing wastes in the US, it is dauntingly elaborate and contains criteria of proof sufficiently stringent to intimidate most companies from even trying.)

Situational Variables — Natural and Social

In addition to the extra uncertainties and narrowed error margins of situational variation, a further complication with the UK system and others which attempt to incorporate situation specific factors in actual hazard rankings, is that they risk confusing naturalistic risk factors with socially determined ones. This point is crucial and deserves close examination:

It is common to talk of the "life cycle" of a hazardous waste as it passes from generation, via various phases including transformation, to "final" dispositions (see Chapter 1). In emphasizing the need to incorporate situational risk qualifying factors for example, it is observed that [46]:

> "hazardous waste may be hazardous in only one phase of its life cycle. Acid waste for example, may be hazardous only up to the point where it is neutralized before final disposal. Organic solvent waste may pose a hazard only until it is burnt in an incinerator."

Notice however that these examples of "life-cycle changes," and situational risk reductions are not natural transformations such as biodegradation with time into harmless products. They are the results of deliberate human interventions. It is precisely these which regulatory controls are there to first, define as necessary, and, second, enforce. In much of the policy discussion

there is a tendency to confuse such behavioral components, which we cannot assume will occur naturally, with genuinely "natural" factors which may in some situations reduce exposures and risks from intrinsic 'worst cast' levels by attenuation or benign transformations. Even many of these however, must also be activated by deliberate human action, (e.g., to site a landfill on thick clay and to allow only certain compounds to be filled), and are thus *not* natural in the sense that they cannot be assumed automatically to take place without regulatory control to ensure good management.

As accumulating empirical research on real environmental regulatory implementation is showing, such proper management is not even ensured when 'direct' regulatory statutes and bodies exist to "enforce" it [47]. Yet degree of hazard schemes incorporating situational factors often mix questionable assumptions about ideal behavior by the complex sets of actors involved in hazardous waste, together with genuine physical environmental factors which may reduce real exposures (and thus damage) below theoretical worst case possibilities.

Much hazardous waste policy analysis argues that environmental factors which (it is assumed) reduce exposures from 'worst case' possibilities should hold a more prominent place in risk assessments for regulation [48]. Underlying this argument is a feeling that widespread publication of disquieting *laboratory* evidence of toxic damage from a whole host of chemicals in the last decade or so has encouraged exaggeration of real risks and consequent over-regulation based upon "worst case" assumptions which neglect exposure-reducing realities. The following arguments are typical [49]:

> Perhaps the most direct approach ...[is]... to assemble a list of toxic effects, along with a list of tests that establish the presence or absence of those effects.... Such an exhaustive approach has been commonly required for food additives, pesticides, new human drugs and animal drugs.

> ...While such an approach may define the biological effects due to a substance, it is necessarily incomplete, since such information is only a part of what we need to know to define the *actual* hazard to health or the environment.
>
> ...it is generally less expensive, more technically appropriate, and equally protective to evaluate the potential environmental impact to the degree necessary to make decisions on the degree of containment control based upon actual expected impact, rather than treat routinely for worst case conditions in which it is assumed that the toxicity associated with a particular source extends for considerable time and distance.

Reflecting this concern to modify an intrinsic risk approach with environmental risk attenuation/dilution factors, data frameworks stress criteria such as:

- production volumes, places, and durations
- modes of dispersion
- physical form and containment
- environmental transformation, absorption, partitioning, etc.
- proximity of populations (including eating and habits of environmental usage)
- food-chains and other possible exposure routes and limiting factors
- likely exposure levels and durations.

Risk analysis models and data frameworks combine exposure-related hypotheses and calculations with intrinsic effects estimates. At the same time strong arguments are made to incorporate such dimensions in formal regulation. These are supported by optimistic claims that [50]:

> there is emerging a capacity to predict the environmental fate of newly introduced chemicals by means of techniques such as...evaluative models. Such techniques predict the likely compartments of the environment into which the contaminants will flow and accumulate, thus exposing biota and humans to toxic effects.

However the insecure foundations of such beliefs are indicated by the fact that the same author admits later that this same area "contains a vast number of species with varying and poorly understood interdependencies" in which yet again, "scientific knowledge severely lags behind regulatory needs" [51].

Even considering the physical-chemical and biological unknowns in the domain of environmental movements and exposures therefore, there are severe difficulties and *risks* involved in trying to optimize RA and regulation to varying situations, without destroying or over-stepping safety margins. This is true even for relatively pure, well-analyzed chemicals. For hazardous waste one must add to these the extra complications of badly known and more variable waste compositions, and semi-autonomous, ill-defined behavioral factors sharply affecting their physical dispositions and thus environmental conditions. The risks are especially sensitive to some of these behavioural factors.

Thus the whole issue of regulating risks characterised by such variety, in determinacy and regulator-ignorance may invite reconsideration of the optimization approach in this particular policy field. One institutional alternative may be the absorption of the risks, wastes and T & D management responsibilities by regional public authorities which are essentially also the regulators. This will be the subject of Chapter 5. In the next section we illustrate that even in the highly controlled and artificially simplified context of scientific testing ignorance and indeterminacy of situational variations are too great to allow credible standardisation.

STANDARD TESTS AND SITUATIONAL RISK ASSESSMENT — the EP Test As a Case Study

Conventional scientific disciplines routinely have to reconcile the variability of specific cases and situations with the search for universal underlying constants and relationships. Regulation must manage a similar reconciliation, but

the principles and purposes of standardization for regulatory knowledge are different from those of science, even if they overlap. Conflicting pressures and contradictory strategic aims are exposed at the heart of regulatory science.

If regulations embody key definitions of materials for control, such as "hazardous," "special," or "controlled," these are defined either by lists or properties or both. In order to define whether a given waste has a given property, clear criteria must be defined for each property, and standard, reliably reproducible tests established. For properties such as flammability, corrosivity, etc., relatively simple indicators can be defined, e.g., flash-point, or pH (though even these are not always valid). However it is for characteristics such as toxicity or carcinogenicity that the major difficulties arise.

The first area of difficulty is identical to that discussed above for all chemicals, even with well-defined compositions, that any standardized hazard criterion

> is not technically valid for assessing the environmental hazard associated with solid wastes primarily because the transport and transformation (environmental chemistry) of the solids-associated contaminants can be markedly different for each specific environment, and usually play a dominant role in determining the hazard associated with the introduction of solid into the environment. The environmental chemistry of contaminants is influenced by many factors...and must therefore be evaluated on a site-specific and solid waste-specific basis [52].

It is important to note that these situation specific arguments apply not only to the particular environmental conditions surrounding a waste in any given site, but also to the variable condition of wastes themselves. Wastes which are given the same name in a hazard classification or list and which are thus in regulatory terms identical, usually vary in composition and physical form both between plants performing the same process, and even from the same plant over time. These variations may cause significant changes in risk characteristics, e.g., leaching properties for hazardous constituents. Even if

the chemical composition of different wastes was identical, changes in physical form such as particle size distribution, degree of aeration, etc., may radically affect the release of hazardous constituents (and thus risks) in the same environmental site.

Despite the force of these arguments, regulatory bodies have understandably been tempted by the opposite appeal of a single universal criterion and a corresponding standard test, at least to characterize wastes initially as hazardous before going on to consider situation-specific variations. An apparently simple example of such standard criteria are concentration thresholds for listed constituents of wastes, with "standard" analytical methods for tests. A regulatory test for toxicity in the US is the elutriate procedure, or EP Test, which is formally designated as a standard, statutory test to bring wastes which fail it under regulatory control [53].

The EP test is designed to test the leaching rates of potentially hazardous waste-constituents into water, so as to simulate releases from landfill sites. A "representative sample" of a waste is mixed with a solution (pH 5 acetic acid) supposed to represent typical landfill conditions, and the leachate separated from this mixing is then analyzed for certain listed constituents. If these are present above a specified concentration, the waste is officially hazardous. So far the listed constituents are 14 chemicals or elements taken from water quality regulations under the Clean Water Act. The concentration thresholds in the leachate are set at the standards for acceptable drinking water quality multiplied by an arbitrary factor of 100. This large situational factor is to allow for assumed further attenuation or dilution between leaching and escape from a waste-site, and possible eventual contamination of drinking water.

As one expert has remarked [54]:

> The primary requirement of a method to be used in making such an inherently expensive decision as whether or not the leaching from a waste is hazardous or whether a disposal method is safe, is repeatability. Not just that one technician in one laboratory can run three replicates, and get the same answer. Ten technicians in ten laboratories must be able to.

Inter-laboratory precision and repeatability is absolutely vital to regulatory use of such standardized hazard classification tests. The regulations therefore stipulate detailed methods which are obligatory for conducting such tests. Even so, the possibilities for methodological variations, *even on the same sample*, are very large and still undefined. Some of the factors which produce variable results are very subtle, and maybe not even consciously recognized as elements of method by practitioners themselves. These factors include the following [55]:

1. Leachate
   (a) precise purity and composition
   (b) redox conditions (e.g., dissolved oxygen)
   (c) temperature,
   (d) pH, including buffering
   (e) method of preparation and storage
2. Batch or column (continuous) test
3. Volume of sample
4. Leachate — solid waste ratio
5. Method, vigour and duration of agitation
6. Method of addition of solution to solid waste sample
7. Mixing vessel material, design and even exact position
8. Contact — agitation time

9. Sample preparation, e.g., grinding, homogenization
10. Organic contents of waste sample
11. Particle-size distribution, porosity, etc.
12. Number of elutions performed per waste sample
13. Leachate-solid separation method — centrifuge, settling, filtering — and time
14. Preservation of samples before leaching
15. Preservation of leachates after mixing and before analysis — freezing, drying, light exposure, time, etc.

This is not an exhaustive list, but it already presents formidable difficulties for precise repeatability. Some of these experimental factors have been specified in the standard test protocol, others have not. Even with the standardized method, an interlaboratory evaluation program in 1979 found poor reproducibility even from standard laboratory samples. (In other words, all the severe variations in sampling a real waste have been excluded.) Thus for example the EP test on sample fly ash coal burn waste for Arsenic leaching found a mean concentration of 0.227 ppm, but with a standard deviation of results of ± 0.226, i.e., ± 100% uncertainty [56]! Chromium fared somewhat better at ± 50%. Other standard tests, all involving apparently precisely controlled statements of method, also showed such poor reproducibility that *even for the same laboratory sample*, it has been concluded that the EP test is highly unreliable as a regulatory instrument. Sampling variations introduce an even further dimension of variability and uncertainty into the attempt to define the 'intrinsic' hazard of a waste.

It is important to understand the several levels of variability which accumulate:

1.

(a) Is the 'standard laboratory sample' a representative sample of a real waste?

(b) Is the 'standard sample' taken by any given laboratory the same as the 'standard sample' taken by another laboratory?

(c) Is the 'standard sample' taken by a given laboratory the same as that taken at another time by the same laboratory.

2. Laboratory methods and detailed practices affecting leaching — the same three questions as for 1 apply.

3. Chemical analysis of a standard leachate from the experimental leach test is also highly variable, especially at the low levels of concentration relevant. The same interlaboratory program mentioned above [57] found that with the same leachate sample and the same analytical technique, *analytical* results could vary by ±100% in this concentration range.

As Collins and others have documented, experimental reproducibility even for 'simple' experiments involves many tacit, craft aspects of detailed laboratory practice which are barely, if at all specifiable [58]. Thus reliable standardization for consistent and secure regulation is far more difficult than usually recognized, and in practice prohibitively expensive, even if achievable in principle.

The potential variations outlined above incorporate two separate kinds of uncertainty. Firstly there is that resulting from variation in detailed laboratory practices, including sampling and analysis. Secondly there is the uncertainty as to whether the standard *laboratory* test conditions laid down in the attempt to gain clarity and reproducibility bear any resemblance to the real

conditions in a waste. This is not only a question of representative sampling,, but also of whether e.g. a specific agitation method and duration mandated for the test is a realistic simulation of solid–liquid mixing and leaching in a real landfill.

Clearly, a laboratory test protocol to be practical must simplify conditions from its real-world counterpart; and to be valid it must identify the factors and detailed experimental conditions which match the key real factors affecting real leaching of hazardous constituents from a landfill. Yet these are poorly understood even in general, let alone in the fantastic variety of specific sites, their particular properties (which vary within one landfill and over time), waste inventories and management practices. Nor do the possible differences between laboratory tests and real conditions always produce over-conservative regulatory results. The leachate pH specified in the EP test for example, is 5, to represent what is thought to be a worst-case scenario, of disposal of an industrial waste with municipal waste. Yet compounds of some toxic metals for example arsenic, selenium and chromium are more soluble, therefore subject to greater leaching, in the alkaline conditions which prevail in some landfills. Other landfills are much more acid than pH 5. The range of pH found in a study of US landfills was 1.5 – 9.5 [59]. A variety of other uncontrolled and poorly understood factors in different waste-site conditions could similarly lead to under-estimations of real risks by the standard testing protocol.

To summarise, even attempts to standardise central regulatory criteria fail because of situational variations in the highly controlled process of laboratory scientific testing. Yet this is an artificially simplified sample, and science is supposed to be definitive and controlled by clear and precise rules. If situational variation is a problem even here, we must multiply the problem manifold for the real world of wastes and situations.

Formal Science, Informal Science and the Allocation of Authority

This brief review of the EP test illustrates a fundamental dilemma in the use of science for this kind of regulatory instrument. Efficient, optimal and defensible risk assessment requires that methods for measuring risks match real risk situations. The wide variability of such situations even for the major single treatment and disposal method — controlled landfill — would thus require the modification of test methods and experimental parameters to match particular cases. This has been widely, and vigorously advocated by industry and other bodies, but such diverse, ad-hoc modifications destroy the basis of uniform and accountable regulatory management. Furthermore it is inherently impossible to distinguish between legitimate situation-specific test adjustments, and adjustments which affect the consistency and reproducibility of the tests.

It has been estimated that developing just one of the several extraction tests from which the EP test was chosen cost $1.5 million to one of the central research bodies [60]. The EP test is an example of a formalistic caricature of science. Its regulatory establishment changed the orientation of research away from developing adequate predictive understanding of leaching mechanisms under different conditions, towards the more mechanical and relatively superficial problems of experimental reproducibility and classification under standard conditions artificially defined by an extreme institutional need to regulate using science [61].

The test represents an expensive attempt to use science to reconcile a deeper institutional conflict. The technical conflict between a fictional standard situation and widely variable real situations embodies an institutional conflict between central, standardised control and industrial autonomy. Central standardisation implies that regulators do not trust industries to devise

and do their own tests and allow for local factors in a responsible way. Apparently, no intermediate position is conceivable in which *guidelines* are cen trally issued, and uncontrolled industrial autonomy in their use is restrained by more substantial local regulatory institutions. These could have a better chance of understanding local realities, but still retain and ??? the overall central regulatory philosophy goals and guidelines. The level of uncertainty and error in the EP test and the extent of its shortfall on reality, is a function of the resolving power expected of such a test. If it is so unreal and little, more robust criteria and tests could defocus from attempted scientific precision, and place the curden presently overloading the scientific domain upon adapted institutional processes. Analysis of the technical problems therfore reveals questions about the institutional structure of regulation, (and ultimately about political cultures).

It is instructive for comparison to look at a similar test in the UK. This is the main criterion of toxicity used in the UK to define specially controlled wastes. The test is 'simply' that if any 5 cm^3 sample of a waste would cause acute toxicity ("death or serious tissue damage") if ingested by a 20 Kg child, it is to be designated special waste [62]. Although the technical basis and the ambiguity of this test has been criticized and it has been described as offering a potential field day for lawyers [63], its institutional role and surroundings in the UK system render it relatively uncomplicated to administer. Responsibility for case by case interpretation in practical regulation is allocated to the discretionary wisdom of government experts advising those with statutory responsibility for control, namely local authorities. Although explanatory guidelines are offered for advice, these are still rich in the need and opportunity for situation-specific judgment, which in principle allows more efficient tailoring of regulatory classifications to real-world variations. The remarkably relaxed, col-

laborative flavor of UK regulation and the non-interventionist stance of central bodies is exemplified in the official guidance for evaluating toxicity such as the following [64]:

> Where a waste producer does not have access to such [suitably qualified] staff, guidance may be available from certain of the larger specialist waste disposal contractors: failing this it is suggested that the waste producers and waste disposal authority (and other parties as appropriate, e.g., a water authority) should hold joint discussions to establish the status of a particular waste.

In lacking universal, clear decision rules, the approach thereby offers less means of third party access, review and accountability*, but it is impressively economical in its demands on formal public science. Informal expertise buttressed by institutional arrangements and broad rituals which stress this elitest "craft" image of scientific expertise in the UK replace the elaborate public use of formal precision and 'public' science in the US. When appeals to formal science for authority begin to escalate beyond a certain ill-defined but strongly influential (and rather low) threshold, these are superceded by implicit, or if necessary explicit appeals to accept institutional norms of authority (e.g., "competent industries and local authorities acting in good faith should reach a socially negotiated consensus which weighs technical judgment with economic and other factors; third parties should accept such consensus as a legitimate balance of appropriate expertise and relevant social interests"). It is when these fail that major rituals (such as public or parliamentary select committee inquiries) reemphasizing such norms are performed [65].

INSTITUTIONS, FORMAL DECISION RULES AND INFORMAL JUDGEMENT

One of the most rigorous attempts more constructively to define different kinds of decision rule in the interpretation of science and policy for RA was that

* There are also problems to do with local authority resources, including expertise (see Chapter 6).

of the US NRC Committee on Risk Assessment in the Federal Government [66] This study proposed a distinction between scientific risk assessment, risk assessment policy, and risk management. Risk management would consider the conventional economic, social and other situational factors extrinsic to science which are weighed in decisions upon "acceptable" risk standards. Scientific risk assessment means the conventional fields of science unsullied by policy considerations.

The interesting dimension is the middle one. Here there are often found questions of a scientific nature which are nevertheless strictly unanswerable by science, either because of uncertainty due to gaps in science, or to *inherently* trans-scientific properties of the issue. Any one of several scientific inference bridges or decision rules could be legitimately used to reach across the gaps and allow the construction of policy relevant scientific knowledge — each might be consistent with, but not determined by, existing scientific knowledge. Yet each may have its own policy implications, so that the choice of decision rule is inevitably partly a policy matter. A good example is the choice of extrapolation rule for low dose toxicity or carcinogenicity effects in humans, when what empirical data there is rests upon high doses, in animals or sometimes, in humans. Choice of a linear, quadratic, linear-quadratic or threshold low dose-effect relationship is more or less equally legitimate according to available high dose data, but the choice often dramatically affects the estimated effects e.g. excess cancers, depending upon the constants employed. It seems to be necessary for policy to make an inference bridge, but which *scientific* inference rule to choose as "risk assessment policy" is legitimately a matter of *policy* choice.

There are many other such examples, with policy implications which vary in clarity and importance. The conditions laid down for the EP test as described earlier are also a form of policy mandated scientific decision rule, or "risk

assessment policy". In this case the rules are more "blind" in the sense that the choice of standard scientific test condition, e.g., leachate pH, will certainly affect the estimated risk and thus, logically, the regulation, but it is not clear which way it would affect it. In other cases such as low dose-effect extrapolation, or whether to include benign cancers as effects, the implication of the choice for regulation and policy is quite clear. These influences and influence-processes whose policy implications are clear are not the only problem because a deeper fund exists of those whose policy implications are obscure, or which can be changed from obscurity to clarity by normal processes of debate.

The reasoning behind the NRC study's proposal formally to discriminate between scientific risk assessment and risk assessment policy, or policy determined scientific inference rules, was to insulate proper science from insidious invasion by implicit policy interests and concerns. Thus a new, hybrid arena was separately defined with its own norms and principles The choice of inference rules would be guided as much as possible by current science, and scientists would judge whether the state of knowledge justified equal policy choice between inference options, whether new evidence suggested transfer of such a rule out of the policy domain and into the purely scientific, etc.

The practical problem with this has already been implied in this chapter. As one reaches into science for policy implications, they can be found extending deeper and wider, even if — as mentioned — the precise way their policy consequences fall becomes less clear-cut. And the solid ground of science free from judgments and inferences which are not fully determined by logical rules and unambiguous facts recedes as it is closely examined [67]. The *appearance* of natural solidity is created by legitimate, institutionalized social agreements and judgements of scientists to ignore unexplained anomalies, to resolve an ambiguity one way rather than another, etc. Scientists are comprehensively

socialized into particular institutionalized sets of such judgments and inferences, and thereby become committed to them as if they were utterly determined by nature and logic. For example, whether benign tumors should be counted as malignant effects or not depends upon a scientist's theories about the ways in which benign tumors may develop into malignant ones, which may correspond with different schools of thought in various disciplines — pathology, biophysics, molecular biology, immunology, genetics, etc. Even whether an inference option is in the "scientific" domain or the "risk assessment policy" domain is hotly contested. Likewise the different options for human low dose-effect extrapolation from short term, high dose animal data are not accepted by scientists themselves as *equally* implausible and thus open to equally weighted *policy* choice.

When one presses each option in detail, one finds each one has its own proliferating networks of supporting theories, inferences and *a priori* methodological commitments which are supported by deeper level commitments, and so on in a kind of self-supporting circle [68]. Without some ultimately arbitrary, but pragmatically necessary *institutional* restraint, the regulatory demands upon science in relevant fields for formal justifications pertaining to risk assessments could allow endless encroachment upon scientific judgments by regulatory concerns framed as "risk assessment policy" or (externally determined) "inference rules." Once the scientific inferential judgments are so pervaded by policy concerns, the whole problem orientation and epistemology of a discipline may be taken over and emasculated by regulatory purposes and principles determined by a given administrative and political culture. The formalization of decision rules recommended by the NRC study and its underlying rationale unwittingly risks this kind of encroachment — the very process it was intended to preempt. Contrary to the study's faith, there is nothing inherent in *science*

to prevent it, but there are different institutional buttresses.

CONCLUSIONS

In this chapter we have analyzed the extent of misfit between diversity, ignorance, instability and uncertainty surrounding all the various dimensions of hazardous waste management, and the need to regulate *as if* the uncertainties involved were narrowly limited and thus credibly manageable within unidimensional, quantitative boundaries. RA as a technical activity is expected to reconcile this fundamental contradiction in a way which is credible and authoritative to a wide array of different actors and institutions with their own interests and perceptions of the issues.

A balance has to be maintained between too little structuring of the risk framework, in response to the authentic unknowns and lack of definition of the field, and over-elaborate, artificial bounding of ignorance, in response to demands for definitive risk-benefit knowledge by which to regulate. The former emphasis runs the risk of lack of effective control, and lack of pressure to develop consistent technical and evaluative knowledge for regulation; the latter runs the converse risk of actually obstructing its zealous search for more precise regulatory knowledge. It risks concretizing the *artificially created* limitations and standardized frameworks upon the unknowns in the field as if these creations were reality. Although *individual* regulators may recognize this distinction, the system still may be constructed and run as if no such distinction existed.

The strategic aim must be to find a dynamic position in which centralized, standardized knowledge both yields to its own ignorance and *local* flexibility, and also allows room for appropriate adaptation of regulatory standards and practices to relevant technical knowledge as it emerges from the existing unk-

nowns. This is in principle true for all environmental regulation, but the problem of finding such a three way balance between: universal knowledge — 'universal' ignorance — local variations; is exacerbated by the extra complexities and new dimensions of hazardous waste life cycles compared to conventional pollutant emissions. It is important to note than uncertainties due to differing perceptions and problem-definitions amongst hazardous waste practitioners enters into all three levels, not only into 'local variation.' Public attitudes and expectations also interact in complex ways with the above three dimensions, so as to further reduce the feasibility space for policy processes and options within this domain.

A major point of this chapter, embodying what we claim as two important distinctions in risk assessment of technological systems, is that:

(i) what is usually regarded as technical uncertainty embodies two fundamentally different kinds of uncertainty; (a) ignorance of deterministic events and chains which in principle are knowable but which require more extrapolation, calculation, modeling and judgment to make up for incomplete knowledge; and (b) *genuine* indeterminacy in a system. This factor takes on extra importance when those components of the policy system are autonomous human beings in diverse social and cultural settings very different from those of analysts or regulators, and when they are a prominent, but ill-defined dimension of the overall system as they are especially for hazardous waste. These behavioral components although indeterminate, are not arbitrary.

(ii) apparent technical uncertainty and divergence in risk analysis (and science/for policy generally) often masks what are in reality different, socially constructed definitions of a technological system. These range from detailed 'technical' differences to radically differently

> even contradictory frameworks apparently describing the same system. The regulatory impulse is to regard such uncertainties and differences as purely results of technical immaturity, to be resolved by more precise, more standardized 'science.' This may be counterproductive especially if as is often true, it suppresses the recognition of diverse equally objective social perceptions and definitions constituting a risk–regulatory arena.

Both these distinctions imply a reconsideration of the balance between regulatory emphasis upon science as a surrogate policeman or arbitrator, and upon complementary institutional mechanisms of mutual control, compromise and voluntary compliance which might restrain unrealistic demands for precision from science.

We have emphasized the combination of structural uncertainties in the real behavioral and technical domain of hazardous waste, with pervasive needs for informal judgment in science even in "well-defined" fields and "simple" tests. However the objective in emphasizing this point is not to suggest that attempts to formalize knowledge for regulation in RA frameworks should be abandoned. Our aim instead has been to emphasize how extremely vulnerable is a regulatory process which bases itself upon scientific knowledge unsheltered by various institutional supports which expressly or more subtly limit its public exposure to pure scepticism and unrealistic formal criteria of definitiveness.

The extent and significance of tacit conflicts and unknowns, the actively strategized nature of uncertainties, and the pervasiveness of informal judgmental knowledge within even orthodox well-developed sciences let alone those struggling to catch up with ill-defined environmental and regulation problems, must somehow be articulated in the *public* dimensions of regulation (and not only in intra-expert seminars). Otherwise RA and regulatory authority is easily

open to self-destruction when the uncertainties, conflicts, artificial constructs, and non rule-determined conclusions which it harbors are eventually revealed.

The degree of elaboration of RA and the extent to which it remains true to underlying unknowns and institutional processes underlying such uncertainties, is therefore a key parameter in the maintenance of regulatory credibility. This is a function of institutional structures, not a matter only for technical judgment. Different balances will of course be struck in different national settings with their characteristic institutional arrangements and cultural styles. But an underlying constant may be the internal contradiction, of public expectations of central government management and definitive scientific authority from regulatory knowledge, which pushes for a standardized RA framework of some kind, and expectations of definitive justifications in specific cases, which because of the factors mentioned above, often cannot be delivered from that knowledge.

It is our argument that the full significance and complexity of the interactions between bureaucratic processes and public expectations and attitudes — a field touched upon but not adequately covered by the new discipline of risk perception — has yet to be recognized in attempts to use RA and science to develop effective regulation. This will be discussed further in chapter 7.

A tentative conclusion of this chapter, supported by some policy experts in the field [69], is that for this issue at least, the variabilities and ignorance are so great (and intractably so) that attempts to establish formal scientific degree of hazard discriminations are likely to result in either extravagant waste of scientific resources for artificial and futile regulatory purposes, or severely reduced safety margins due to badly understood real exposure and effects mechanisms, or both.

One possible institutional response to this dilemma is that examined in chapter 6, namely the effective takeover of risk management and evaluation by regulatory authorities which are also operators of 'total' T & D systems. Such approaches have been long-established for example in Bavaria, Hesse and Denmark, where public authorities in coalition with regulated industries, run central multipurpose facilities which take all waste from the region. In effect the "community" transforms the technical uncertainties by internalizing the risks and liabilities into a unitary representative institutional framework of responsibility. They then effectively reduce risk assessment to routine operating management decisions as to which in-plant process a given waste should be directed to.

In the next chapter we examine one important phase of RA for hazardous waste in more comparative detail. This is the first and most basic phase of most management/policy frameworks, namely the attempt unambiguously to define what materials are hazardous wastes.

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