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Regulating Industrial Risks. An Executive Summary of a Workshop

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Regulating Industrial Risks

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An executive summary of a workshop

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RISK MANAGEMENT IN A VOLATILE WORLD

How can an appropriate balance be maintained between industrial progress based on technological innovation and the potential risk from these new developments to health and environmental well-being? Can risk regulation processes be sufficiently effective and responsive to reconcile accelerating technological advances with growing pressures to avoid ill-effects from that progress?

These were the key questions addressed at the Ispra Workshop held at the Commission of the European Communities' Joint Research Centre (JRC) in Ispra, Italy, in October, 1984. Over 25 senior policymakers, advisors, and experts from 10 countries and 21 organizations contributed their expertise to intensive discussions; they were not, however, representing the views of their organizations. The workshop was sponsored by the JRC in collaboration with the International Institute for Applied Systems Analysis (IIASA) and the Man and the Biosphere Program of the United Nations Educational, Scientific, and Cultural Organization (UNESCO).

The focus of the meeting was on brief presentations by contributors to the book *Regulating Industrial Risks: Science, Hazards and Public Protection* (Butterworths, 1985), prepared as part of the JRC's Industrial Risk Program. First drafts of the chapters had been made available before the meeting so that they could be studied in more depth than in the time allowed for authors' presentations.

The purpose of the workshop was to review the contents of the book at an early stage so that the final version would meet the practical needs of the decision-making community. The benefits of the lively and pertinent discussions will be reflected in the published book, which will owe much to the workshop because new perspectives were added; gaps were identified and filled; themes

were explored and expanded; and, most importantly, practical implications were elucidated in the light of the wealth of experience represented at the workshop.

In this *Executive Summary* we review the main observations and conclusions that emerged from the discussions. We also provide information about the book *Regulating Industrial Risks*, which elaborates in more detail the issues highlighted here.

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EFFECTIVE REGULATIONS OF INDUSTRIAL RISKS

The Ispra Workshop helped to identify the main ingredients that determine the effectiveness of risk management policies and provided many practically oriented insights relevant to the establishment of viable regulations. It was recognized that risk management processes are complex and locally varied, and that these issues cannot be addressed by applying simplistic, "universally-applicable" practices.

Innovation is a sensitive issue and the source of potential social conflict, because the risks and benefits of technological advances are often unevenly distributed. While it is possible to reduce hazards, some negative consequences cannot be completely eliminated, particularly as rapid progress in a wide range of technologies is making a proliferating impact on an expanding range of economic, industrial, social, and environmental activities.

The following key observations, which emerged from the workshop, should be considered when developing specific policies.

(1) It is difficult, and usually impossible, to estimate the level of *actual* risk with precision, although techniques, such as those known as *risk analysis*, can provide valuable supporting information for regulatory activities.
(2) In practice, regulations determine the types of hazards and levels of risk that are *acceptable* to those affected. The levels of acceptable risk are even more difficult to determine than actual risks because they always depend upon the specific context and must reflect subjective perceptions of degrees of risk.
(3) Successful regulations cannot be based solely on scientific information, because scientific consensus appears not to be

achievable and the regulatory process has to resolve social and political conflicts that extend beyond scientific considerations. Furthermore, the scientific community may contain divergent viewpoints and sometimes experts appear as advocates of a specific viewpoint.

(4) Effective regulations must not only be scientifically sound, but must be practically implementable and command the respect of the organizations, groups, and individuals affected.

(5) The most effective "style" of regulation, in a particular context, takes account of regulatory experiences elsewhere and is adapted to the deep-rooted political and cultural conventions, as well as to the general administrative procedures in a particular country or region.

(6) Communications media (TV, radio, press) are integral elements in political processes and, therefore, inevitably play a significant role in shaping regulations, in the allocation of resources to regulatory institutions and risk research, and in influencing public support for or against regulations. Policymakers must, therefore, give adequate attention to the media.

(7) The enactment of laws, the establishment of licensing procedures, and the formulation of standards are insufficient in themselves. They must be supplemented by implementation and evaluation procedures, supported with adequate resources to bridge the gap between legislative promise and actual risk control.

(8) Implementation and evaluation of regulations must take into account how people and organizations behave, particularly the principal "actors" in the regulatory process: government departments, regulatory agencies, industrial companies, and groups representing citizens and special interests.

(9) International cooperation and coordination are needed to handle risks that cross national borders, either naturally or through deliberate "risk exporting" by the country in which the risk is created to neighboring countries and other areas of the world.

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REGULATING INDUSTRIAL RISKS: A BRIEFING

WHY ARE REGULATIONS NEEDED?

Technical innovation is a dynamic source of economic growth and social change. It can also be a source of environmental degradation, of risk to human and animal health, and even of catastrophic disasters. The growing use of communications technologies has alerted the public to some potential technological hazards and has highlighted particular instances where harm has been caused by explosions, pollution, drug-induced illness, and other results of technological products or processes. There have, therefore, been increasingly informed, insistent, and sophisticated campaigns from individuals and groups opposed to particular developments. The views expressed by interest groups often represent the deep concern of a broad spectrum of the population.

The pace of both technological developments and of the growth in pressures to provide safeguards against hazards shows no sign of slackening. Advances in different technological disciplines are interacting with each other to create unprecedented rates of change in most social activities. The vigorous campaigning of environmental activists, the strong media interest in reporting challenges posed by new technology, and the increasing political sensitivity to environmental issues are also likely to keep questions of risk and regulation high on the agenda of public debate.

Technological advances have contributed to new patterns of industrialization, with increasing emphasis on the need for industry and business to be more responsive to the rights and well-being of consumers, employees, and citizens, and also to consider the health, environment, and well-being of future generations. Codes of conduct agreed by professional bodies and the desire of some

industrial enterprises to behave as "good corporate citizens" have generated a degree of self-regulation that limits potential risks. Self-regulation alone, however, is insufficient because self-interest may be in conflict with the interests of others or of society at large.

Regulations are needed to provide a coherent framework that takes into account a wide range of interests. Having a consistent set of regulatory conditions for competitive industries provides an equitable business environment. Regulations, and particularly the processes used to formulate, implement, and review them, are also essential to the creation of public confidence that accepts and encourages change and innovation.

WHAT KINDS OF REGULATION ARE NEEDED?

The regulation of science and technology is not new. There are long-established laws, rules and traditions that cope with specific activities, such as road or air transport and drug testing. Since the 1960s, however, there has been a trend toward more systematic approaches that encompass different developments, and there has been a swift evolution in the creation of new regulatory institutions and practices.

Effective regulations must be appropriate to national and regional cultures. The same hazardous situation, with the same technical analysis of risk, has produced very different regulatory actions in different countries because of these variations in administrative style and culture; for example, in regulations covering the transportation and disposal of hazardous waste.

The local culture can exert a strong influence on the topics selected for regulatory action, on the extent and nature of consultations in formulating regulations, on the type of regulatory institutions created, and on the content of regulations (scope, precision, penalties, etc.). Regulations must have the confidence of the public. This requires greater participation by groups and individuals in the regulatory process and good communications between regulatory institutions, risk creators, and those concerned about potential risks, because they either will be directly affected by the risk or are interested in issues of common concern, such as the quality of the environment.

There are a variety of regulatory styles. Some are highly centralized and authoritarian, others involve broad participation by organizations or individuals who represent the general public.

In some cases consultations are based on elite groups of civil servants and scientists, in others regulations evolve from negotiations and consultations involving representative bodies that reflect the views of key interest groups. An adversarial style may predominate, governed by legal debates over which "side" can marshal the "best" arguments.

Whatever style is most appropriate, it is important that it gains public approval and is sufficiently responsive to adapt to rapidly changing circumstances. The following stages of the regulatory process should be adequately provided for:

- *Setting standards* that determine acceptable safety levels and, where appropriate, *licensing* facilities on a one-off or type basis.
- *Monitoring* prescribed activities to ensure that they conform to agreed standards, targets, and licensing conditions.
- *Enforcement* of regulations through warnings and legal actions if regulations are broken.
- *Evaluation* of the results of regulations to assess their true effectiveness and, when necessary, to refine and improve relevant procedures, standards, and rules.

CAN REGULATIONS BE LEFT TO THE EXPERTS?

Uncertainty is a key characteristic of most regulatory actions concerned with risk, because problems are typically discovered as unwanted side effects of a process or product, unintended and previously unnoticed. Decisions are likely to be most urgent where scientific methods are the most inadequate and arguments the most inconclusive. When estimates are made of the level of risks, such as the probability of an engineering failure or the likely effect of exposure to a substance believed to be dangerous, there is bound to be uncertainty.

Science cannot go further than making estimates and, when scientifically possible, these estimates are qualified by a statement of the likely amount of uncertainty in the estimate. The growing social and political significance of technological risk and its regulation in the last 20 years has led to the development of the "science" of *risk analysis* in an attempt to make regulatory decisions less controversial by applying greater scientific rigor to the evaluation of risk.

Risk analysis involves the use of available data, supplemented by calculation, extrapolation, theory, and expert judgment, to define the risks to people due to their exposure to hazardous materials or operations. Initially, risk assessment focused on methods of quantifying risk estimates. When these failed to gain full public acceptance, attention turned to trying to determine how people subjectively perceive risk.

Risk analysis has itself become the subject of dispute and so has not eliminated controversy over regulations. Although the public would like definite answers when disputes arise, at least as a form of symbolic assurance, the inherent uncertainty of scientific knowledge and the volatile social and political context in which regulatory processes act mean that scientific experts cannot be expected to provide them.

Frequently, experts disagree about risk quantification. Also, the perceptions of those exposed to a risk usually differ from those who will benefit from the innovation. Resolving such conflicts requires effective institutional arrangements and a complex web of negotiations between relevant parties and the making of sensitive political judgments. As a study by the US National Academy of Sciences in 1983 commented, "Because risk assessment is only one element in the formulation of regulatory actions, even considerable improvements in risk assessment cannot be expected to eliminate controversies over these actions."

ARE RISKS EXAGGERATED BY PRESSURE GROUPS AND THE MEDIA?

It is true that increased concern about technological hazards has been sharpened by the activities of environmental groups who have mobilized opposition to some developments. Coverage in the mass media of technological accidents and incidents of pollution and exposure to toxic materials has heightened awareness of these issues. There are, however, other important influences.

The escalating use of new technologies inevitably creates more potential risks, some of which become a reality in an intrinsically dramatic way, such as explosions in Seveso, Italy, the release of MIC at Bhopal, India, or birth deformities resulting from the drug thalidomide. Pressure groups are counterbalanced by powerful interests in favor of new developments. The media are diverse and some emphasize protechnology views that counteract claims by pressure groups.

The ability of interest groups to campaign publicly and the freedom of the media to express a range of views are intrinsic and important elements in democratic processes. In the risk regulation context, these processes involve continuing negotiations and interactions between a number of key organizational "actors": government policymakers; regulatory authorities; risk creators, typically industrial concerns; experts; *intervenors*, such as pressure groups; and communications media.

Each actor exerts some influence. The objectives and instruments of regulatory policies should be to maintain a balance between conflicting interests. Otherwise, some hazards may be ignored until disasters occur, important interests may lose confidence in the regulatory process, and resources may be diverted away from potentially significant developments.

HOW EFFECTIVE ARE RISK MANAGEMENT PROGRAMS?

Real-life risk management is concerned with actual hazards, not theoretical assessments of risks, and with managing actual behavior, not just setting abstract standards and enacting formal legislation. Some form of evaluation must take place to determine how the regulations are working in practice. It should be recognized, however, that regulations do not eliminate risks completely and it is difficult to identify environmental degradation or the fatalities and accidents that *did not* occur because of regulations.

To be effective, regulatory agencies must be provided with adequate financial and human resources to monitor and enforce regulations. Information must be openly communicated to risk generators and the people likely to be affected by the risk. This must clearly state the standards that are expected to be maintained, and what actions will be taken if there are violations of regulations. Each risk management program should have an accountability or overview system that specifies how the performance of the regulatory agency is to be assessed. Evaluation procedures, which should be established independently from the agency, should also include explicit mechanisms for taking corrective actions if the agency or particular regulations are found to be ineffective.

Evaluating regulations can be difficult. In some cases, such as those aimed to reduce the level of a certain substance in the air or water, it is possible to provide quantifiable assessment criteria. In many instances, however, assessment involves qualitative judgments of concepts like "appropriate", "unnecessary", or "quality of life".

Ill-effects often become manifest only after a long period. There may be great uncertainty about what effects are being considered. In judging whether regulations have been an unnecessary hindrance to technical and industrial developments, for example, an apparent wasteful delay in the implementation of a new process or of the marketing of a new product may turn out to be of eventual assistance, because safety is improved and the increased public confidence allows for more fruitful long-term benefits. The importance of making effective evaluations and the complexity of doing so means that policymakers should pay substantial attention to this aspect of the regulatory process.

ARE NATIONAL REGULATIONS SUFFICIENT?

There is now increasing recognition of economic, technological, and ecological interdependence between countries. Activities in one country can produce adverse effects in other countries. For example, hazardous waste may be transported between nations; river pollution initiated in one country may be transmited downstream to another; processes in a number of countries can lead to global pollution problems, such as acid rain or changes in the atmosphere; factories carrying out potentially hazardous operations may be sited close to national borders, so that ill-effects are exported across the boundary; or risk creators in countries with strict regulations may sell products or move processes that fail to meet the domestic regulations to countries with less stringent rules and laws.

National regulations are, therefore, insufficient to address transborder issues. Bilateral agreements can be effective if both countries perceive the strong national need for such regulations. As the number of countries concerned increases, the more difficult it is to reach meaningful and implementable international regulations.

International regulations should aim to find an appropriate balance between international harmony and national autonomy. The Commission of the European Communities' Environmental Action Programs, for example, seek to achieve acceptable levels for the quality of the environment throughout its member states, while leaving national flexibility in finding the best means to achieve these objectives.

Complete international agreement is unlikely, given the deep-rooted cultural and political identities of each country. The international nature of the underlying technological and environmental mechanisms, however, demand that there should be continuing efforts to find means of cooperation and coordination between countries, regions, and the whole world.

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ADVICE FOR DECISION MAKERS

The highlights that emerged from the Ispra Workshop to assist in making decisions about regulatory policies are summarized below.

- *Do not regard risk regulation as mainly a technical activity.* Scientific knowledge and methods play a useful, but limited, role in some regulatory stages, such as in setting and monitoring standards. Effective regulations depend on the successful management of broader social and political pressures and negotiations.
- *Seek to gain maximum support for the regulatory process.* To succeed, the regulatory process must have the confidence of the groups most interested in the result. The nature and extent of participation in this process, the openness with which decisions are made, and the clarity and completeness of information made available are some of the crucial nontechnical factors that determine whether or not regulations are regarded as fair and necessary.
- *Be aware of the limits of scientific knowledge.* Science and technology can, at best, offer provisional estimates of risks. The inevitable uncertainties that surround innovations mean that regulators should not believe that science or scientists can offer definite answers to key regulatory problems.
- *Provide sufficient financial and human resources to ensure effective implementation of regulations.* The focus of regulatory activities is often on the drafting of standards and rules and the issuing of licenses. Significant follow-up effort is needed to ensure that risk creators do not slacken safety precautions and operational methods, as well as to establish when regulations have been contravened.

- *Establish an independent mechanism to evaluate the effectiveness of regulatory bodies and regulations.* Little public confidence can be expected in a system in which agencies evaluate their own success or where, as has usually been the case, little attempt is made to assess performance. The procedures and criteria used in evaluations should be clearly understood by all affected parties. This does not, however, preclude the desirability of regulatory agencies integrating plans for evaluating their activities.
- *Keep regulatory processes and regulations under continuous review.* Regulations must be capable of adaptation to research findings, public concerns, and new technological developments.
- *Take an active role in attempts to control international hazards.* If a country ignores the international repercussions of its hazardous activities it could be subjected to political and legal pressures from other countries and international bodies. It should be realized that today's creator of an international hazard could be tomorrow's victim.
- *Above all, maintain a balance between different interests.* The prime objective of regulations is to protect human health and the environment. Successful formulation of regulations would involve all affected parties in a process of negotiation and bargaining that produces results acceptable to all, although each is likely to have made compromises.

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THE ISPRA WORKSHOP

The Ispra Workshop was cosponsored by three organizations.

- *The Joint Research Centre (JRC) of the Commission of the European Communities (CEC).* The JRC is the direct research arm of the CEC. It has four establishments, the largest being located at Ispra in northern Italy with over 1700 employees, where research topics include fusion, nuclear safety, non-nuclear energy, and the environment. The Workshop and associated book are part of the Industrial Risk Program of the CEC's Research Action Program on the Environment.
- *The International Institute for Applied Systems Analysis, Laxenburg, Austria (IIASA).* IIASA is a nongovernmental, multidisciplinary, international research institution, founded in 1972 by academies of science and equivalent organizations from both East and West. Its goal is to bring together scientists from around the world to work on the complex problems of industrial society that are of common scientific and technological interest. It is currently active in examining international environmental issues as one of its programs. IIASA has 16 National Member Organizations.
- *UNESCO, Paris, through the Man and the Biosphere (MAB) program.* UNESCO is the educational and scientific organization of the United Nations. MAB is an interdisciplinary, international program of research launched in 1970. It aims to develop natural and social science methods to assist in the rational use and conservation of the resources of the biosphere. It takes a broadly based, integrated approach to the study of how to improve the global relationship between man and his environment.

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REGULATING INDUSTRIAL RISKS: Science, Hazards and Public Protection

The issues discussed in this *Executive Summary* are explored fully in the book *Regulating Industrial Risks*, edited by Harry Otway and Malcolm Peltu, to be published by Butterworths in 1985. The book's chapter titles and authors are:

1. **Regulation and risk analysis** by *Harry Otway*, Head of the Technology Assessment Sector of the JRC, Ispra, Italy, a founding member of the Society for Risk Analysis, author of about 100 publications on risk estimation, risk perception, and risk policy, and former visiting professor at the Universities of Illinois and Southern California, US.
2. **Approaches to regulation** by *Timothy O'Riordan*, Professor of Environmental Sciences, University of East Anglia, Norwich, UK, member of the Advisory Committee for England of the Nature Conservancy Council, and member of the Environmental Planning Committee of the International Union for the Conservation of Nature.
3. The **international dimension** by *Giandomenico Majone*, who recently moved from being Professor of Statistics in the Faculty of Economics and Social Sciences at the University of Calabria, Italy, to the John F. Kennedy School of Government at Harvard University, and is a former research scholar at IIASA.
4. **Implementation and evaluation of regulations** by *Michael Baram*, Professor of Health Law at the Boston University School of Medicine and Health, Adjunct Professor of Law at the Boston University School of Law, partner in Bracken and Baram, health and energy law experts, and Secretary of the Society for Risk Analysis.

5. **Public participation** by *Michael Pollak*, researcher at the Institute for the Study of Contemporary History at the Centre de la Recherche Scientifique in Paris, a former research associate at Cornell University, US, and invited lecturer at Montreal University, Canada.
6. **Experts in public arenas** by *Arie Rip*, Professor in the Department of Science Dynamics, University of Amsterdam, founder member of the European Association for the Study of Science and Technology, and author of papers and books on issues concerning the relationship between science and public policy.
7. **Risk analysis: scope and limitations** by *Ortwin Renn*, Head of the Technology and Society Program, Nuclear Research Facility, Julich, FRG, author of several books and numerous articles on technology assessment and risk analysis, and chairman of the International Editorial Board of Elsevier's *Man, Technology, and Risk* book series.
8. **The role of communications media** by *Malcolm Peltu*, science and technology writer and journalist specializing in the human and organizational impacts of innovation, 1980 ITT UK specialist technology writer of the year, and former consultant to *New Scientist* and the British Broadcasting Corporation.
9. **A case study: hazardous waste in the European Community** by *Brian Wynne*, lecturer in the multidisciplinary School of Independent Studies, University of Lancaster, UK, who was leader of an IIASA project examining hazardous waste management in five countries, and, previously, a visiting scientist at the JRC, Ispra, Italy.

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PARTICIPANTS

In addition to the book's authors, the workshop participants at Ispra were:

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