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Science and Politics in the Regulation of Chemicals in Sweden

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After the end of World War II, science was a major organizing factor in Sweden's focusing attention on possible health and environmental risks from humans' discharge of chemicals into the environment. For many decades, Sweden has been hailed as an enviable example of how effective environmental policies based on sound expertise can be implemented to the benefit of its inhabitants, and in many respects this reputation is well deserved. For instance, it is now possible to catch salmon from bridges in Stockholm, and a steady stream of delegations from other nations has arrived to learn more about the Swedish model for environmental protection.

However, over the years, as environmentalism passed from scientists' hands to "green" nongovernmental organizations (NGOs) and to politicians eager to capture votes, impartial science

of high quality became less and less important, and the Swedish regulatory machinery devoted more and more of its energy toward eliminating insignificant or hypothetical risks from chemical exposures. Basing its policies on an extreme interpretation of the precautionary principle (PP), this country has imposed some of the strictest regulations of chemicals in the world. Sweden's membership in the European Union (EU) (since 1995) has caused some changes, which may point to a more realistic assessment of chemical risks, but attempts by Swedish regulatory agencies to undercut EU regulations and directives, as well as political pressures to withdraw from the EU, threaten many of these improvements.

Many overly stringent Swedish regulations impose burdens on the country's citizens and harm the economy, while providing no or little improvement in health, safety, or the environment. Other countries, considering the possible effects of tying their policies to the PP, should study its effects in Sweden.

Science in the Emergence of Swedish Environmental Policy

The scientific community provided much of the original impetus for improved environmental protection in Sweden. Swedish scientists, for instance, focused attention on the health hazards from organic mercury compounds used in agriculture several years before the Minimata poisonings in Japan brought those problems to the attention of the rest of the world.[1] The Swedish chemist Sören Jensen was the first to describe the bioaccumulation properties of PCBs, and the pioneering radiation and biochemical re-

1. C.-G. Rosén, H. Ackefors, and R. Nilsson, "Seed Dressing Compounds Based on Organic Mercury—Economic Aspects and Health Hazards," *Svensk Kemisk Tidskrift* 78, no. 8 (1966): 8–19.

search of Lars Ehrenberg in the early 1970s opened up new approaches for quantitative determination of risk for mutations and cancer.[2]

Indeed, many scientists were closely allied with the founders of the Swedish environmental movement, and, along with the media, were instrumental in overcoming industry and government reluctance to adopt a more progressive and responsible attitude toward environmental protection. More basically, many respected scientists furnished the technical arguments that provided the foundations for improved protection of the environment.

A decade of balanced and gradual progress in reducing and regulating exposures to chemical hazards that began in the 1960s, which was largely based on scientific principles, was given additional stimulus after the Swedish producer of the sedative thalidomide (Neurosedyn), Astra, accepted responsibility for compensating for the malformations in children caused by their mothers' intake of its product.[3] The decade was not without some notable exceptions to the wise use of science, including the dioxin hysteria in the 1970s that provoked the Swedish Parliament to directly intervene, restrict, and later ban many of the chlorinated phenoxy herbicides in 1977.

In the late 1970s, there was a noticeable change in the policymakers' general attitude as questions arose about environmental causes of cancer, and the Swedish government commissioned a group of Sweden's most prominent scientists, led by the Nobel

2. S. Jensen, "Report of a New Chemical Hazard," *New Scientist* 32 (1966): 612; L. Ehrenberg et al., "Evaluation of Genetic Risks of Alkylating Agents; Tissue Doses in the Mouse from Air Contaminated with Ethylene Oxide," *Mutation Research* 24 (1974): 83–103. See also Anon., "Cover Legend on Lars Ehrenberg," *Cancer Research* 47 (September 15, 1987).

3. H. Sjöström and R. Nilsson, *Thalidomide and the Power of the Drug Companies* (London: Penguin Books, 1971).

Prize laureate in medicine, Sune Bergström, to assess the causes of cancer among the Swedish population and to suggest preventive measures. The conclusions of the Swedish Cancer Committee,[4] in which I participated as a member of the Committee staff, were not what the politicians had expected, and some were apparently disappointed, even dismayed by the scientists' conclusions. What activist politician could expect to win votes by revealing that sunbathing, for example, is a more significant cause of cancer than industrial chemicals, pesticides, and air pollution? They could publicize, of course, that smoking was bad, but they were not eager to convey the message that diet is one of the most important factors in developing or avoiding cancer, and that genetic susceptibility is also a major determinant of cancer risks.

Politics Takes Over

Regrettably, in spite of significant progress in toxicology and risk assessment, science has gradually become less important in shaping Swedish national policy for chemicals control. Worse still, good science plays an ever smaller role in influencing the environmental movement, which to a large extent has been hijacked by extremists. Many respected naturalists, instead of concentrating on the conservation of wildlife and other aspects of the natural environment where they made major contributions, have elected to busy themselves with complex toxicological problems for which they have little or no training. With respect to chemical risks, environmental pressure groups nowadays mostly preach a primitive "eco-fundamentalism" based on ignorance of the scientific issues involved, with little understanding of the economics

4. Swedish Cancer Committee (SCC), *Cancer—Causes and Prevention, Report to the Ministry of Social Affairs from the Cancer Committee* (Stockholm: SOU, 1984), p. 67. English translation.

of a society that provides them with all the basic conveniences and luxuries that they actively consume.

By tradition, Swedish government agencies are to act autonomously to implement the laws enacted by parliament. In recent years, however, ministers have increasingly interfered with the daily work of the agencies directly or indirectly through political appointments of managers on several levels. As a result, the central agency for chemicals control, the National Swedish Chemicals Inspectorate (KEMI), has become a powerful instrument for the promotion of the extremist green ideology favored by the Social Democrats who have been in power almost continually since World War II.

Politicians learned a lesson from the SCC report,[5] and twelve years later, in 1996, the Swedish Ministry of Environment appointed a "Chemicals Committee" chaired by the Social Democrat Kerstin Svensson to develop the basis for Sweden's chemical regulation policies. All of the committee's five delegates were politicians. Why should they bother to ask the Royal Swedish Academy of Sciences, or the world-famous Karolinska Institute, which selects nominees for the Nobel Prize in Medicine, to recommend scientists to assist in their work? Forget it! The task of assessing the *Panorama of Risks from Chemicals* was given to a consulting firm with little knowledge of toxicology.[6] Although the jumbled group of "experts" assisting the committee included some scientists, with few exceptions the scientists appeared to have been little more than hostages with limited possibilities to influence the main focus of the committee's work. Among other recommendations, the committee proposed that PVC (polyvinylchlo-

5. Ibid.

6. Statens Offentiga Utredningar (SOU), *Towards a Sustainable Chemicals Policy*, Swedish Government Public Reports Series (1997): 84, plus Annex I (in Swedish).

ride, one of the most commonly used plastics) as well as all so-called "endocrine disruptors" should be totally eliminated. The report paid no attention to the fact that oral contraceptives are the most powerful "endocrine disruptors" ever produced by industry for general use.

The Swedish Royal Academy of Sciences, the Royal Academy of Engineering Sciences, and other professional organizations scathingly criticized the committee's 1997 report *Towards a Sustainable Chemicals Policy*.[7] Expert criticism meant little to the Minister of Environment at that time (now Minister of Foreign Affairs), Anna Lindh, who, in the case of the alleged dangerous properties of PVC, declared that she had more confidence in Greenpeace than in the Academy of Sciences.

Her predecessor on the chair as Minister of Environment and Energy, Birgitta Dahl (now speaker for the Parliament), had shown the way almost a decade earlier. In April 1989, in front of an audience from the Stockholm Worker's Commune, Mrs. Dahl claimed that automobile emissions had passed cigarette smoking as the main cause of lung cancer in Sweden! The SCC appointed by Mrs. Dahl's own party comrades had found that air pollution accounted for not more than about one percent of all cancers in the Swedish population. But why should a Minister of Environment bother about checking scientific information?

The Chemical Committee's recommendations became the ideological basis for some of the most extreme chemical regulation laws in the world that culminated in the bizarre left-wing slogan "An Environment Free of Poisons" ("*En Giftfri Miljö*"). In 1999, the red-green majority of the Swedish Parliament transferred this misnomer,[8] which brings back concepts from the Mid-

7. Ibid.

8. Swedish Ministry of Environment, *An Environment Free of Poisons* (Government Report MJU6, 1998–99).

dle Ages, into a general political goal for the Swedish society. As pointed out centuries ago by Paracelsus in his treatise *Septem Defensiones* (written 1537–38), any chemical substance can be a poison when the dose is sufficiently high. According to the parliamentary decision of 1999, the levels of *all* anthropogenic substances in the environment "should be close to zero."

Naturally, such follies have a political background. At the level of the Swedish Parliament, the "green" block, consisting of the Environmental Party and the likewise environmentalist Center Party, exerts a substantial political influence. The Swedish "Greens" control a sufficient number of members of parliament that they can swing votes in favor either of the Social Democrats or the liberal/conservatives, endowing the Greens with clout out of all proportion to their numbers.

Reasons for Environmental Extremism in Sweden

Political influence on agency actions are part and parcel of policies in all developed nations, but the effect of environmental extremism on policy is more pronounced in Sweden than in most other countries. Why so?

Sweden has a strong tradition of cherishing unspoiled nature, based on a romanticism of the past that holds sway among prominent Swedish industrialists as well as among intellectuals, and it has promoted traditional environmental protection as well as the introduction of stringent emission controls to benefit the quality of life. However, these basically benign tendencies have been pushed to extremity by the following additional elements:

1. The high level of public concern about environmental protection, especially with regard to "environmental poisons"
2. An omnipresent, centralized, and highly politicized regula-

tory bureaucracy combined with an imbalance of power among regulators, industry, and private interests

3. Lack of coherent national technically based strategies for risk assessment coupled with regulatory emphasis on inherent properties (hazard), regardless of the probability that adverse effects will actually occur (risk level)
4. A mistaken belief that efficiency in chemicals control is proportional to the number of bans and restrictions imposed
5. A firm conviction about the unmatched excellence of the Swedish model for environmental protection, combined with a crusading spirit directed at convincing an ignorant and callous world to adopt it

In comparison with most other industrialized nations, Sweden has relatively few serious environmental problems, but I believe, as do many others,[9] that the level of risk acceptance is particularly low in large sectors of the Swedish population. Indeed, many pampered Swedish citizens, who have not experienced major natural disasters or war since Napoleonic times, appear to carry around their own personal "worry box" described by the American humorist Patrick F. McManus: "It's as though a person has a little psychic box that he feels compelled to keep filled with worries. When one worry disappears from the box, he immediately replaces it with another worry, so the box is always full. He is never short of worries."[10]

Swedish politicians more or less openly admit that the concerns of the most risk-adverse people, rather than objective measures of risk, guide their policies directed at chemicals. Such pol-

9. V. Bernson, "The Swedish Experience," *Regul. Toxicol. Pharmacol.* 17 (1993): 249–61.

10. P. F. McManus, *The Good Samaritan Strikes Again* (New York: Henry Holt, 1992), p. 1.

icy-guiding concerns are not limited to Sweden, of course. The chapters by Bruce Ames and Lois Gold and by Stephen Safe in this volume document the misguided attention focused on synthetic as opposed to natural carcinogens and on synthetic "endocrine disruptors" as opposed to natural ones in the United States.

Only a limited fraction of the total national budget is available for risk prevention, and regulatory efforts should obviously be conducted in the most cost-effective manner. However, instead of making an attempt to distinguish between significant and insignificant risks, Swedish regulators too often yield to pressures from environmental organizations, accentuating the trend toward an increasing lack of rationality in risk management to the detriment of progress in modern society. In the context of a different risk (radiation), Chauncey Starr recently aptly portrayed the possible impacts of such decisions: ". . . this example illustrates that the moral high ground assumed by well-meaning activists for single health causes may well be socially immoral, when evaluated by the welfare of the total population."[11]

Each regulatory action, based solely, or mostly, on public "concern" and ignoring actual levels of risk, strengthens the public's belief in its risk perceptions as absolute justification for political and regulatory actions. The layman critical of experts will exclaim, "You see, it was dangerous—we were right after all!"

Scientists' Responsibilities

It would be unfair to blame biased environmental policies entirely on ill-educated laymen, opportunistic bureaucrats, and politi-

11. C. Starr, "Hypothetical Fears and Quantitative Risk Analysis," *Risk Analysis* 21 (2001): 803–6.

cians. The scientific community shares in the responsibility, in particular when researchers with little knowledge of toxicology act far outside their own field of competence and provide fallacious interpretations of their results, while shamelessly exploiting the news media to promote their own interests. In the September 3, 2001, issue of Sweden's largest daily newspaper, *Dagens Nyheter*, four well-known scientists from the Karolinska Institute and one from the University of Lund blasted "scientists who talk rubbish" in the media so that "the legitimacy of science is abused and the general public misled."

Scientists who stop well short of talking rubbish may overextend interpretation of their own data in order to secure continued funding in certain "grant-dense" areas like health risks from chemicals. In a commentary in the U.S. journal *Science*, one scientist affiliated with the prestigious U.S. National Institute of Environmental Health Sciences bluntly stated: "Investigators who find an effect get support, and investigators who don't find an effect don't get support. When times are tough it becomes extremely difficult for investigators to be objective."[12]

The quest for funding can lead to some unholy alliances between scientists and regulators and the creation of "cash cows" for researchers. If, for example, the dioxin or the PCB issues were defused, several laboratories that for decades have specialized in dioxin and PCB-related research, successfully milking agency and other sources for support, could lose their cash cows.

An Example of Swedish Overregulation

In some important respects, the Swedish legal system differs from that found in almost all democracies. Swedish citizens do not have

12. G. Taubes, "Epidemiology Faces Its Limits," *Science* 269 (1995): 164–69.

the right to go before an independent court if they believe a new law or regulation does not conform with the provisions of the Swedish Constitution. Further, in some types of civil cases there is no possibility for private citizens or regulated industry to ask for judicial review of a government agency decision by an impartial tribunal that is independent of the government.

The absence of judicial review and of independent, external scrutiny of regulatory agencies, combined with the small size and relative political impotence of Sweden's chemical industry and the strong anti-industry sentiment in important parts of the public sector, have produced overzealous regulation of chemicals. This state of affairs is almost perfectly demonstrated in the following example.

Several years ago, Vibeke Bernson, in charge of pesticide registrations in Sweden, rejected an application for registration of a pesticide that contained a natural plant growth hormone. The hormone, marketed worldwide, is used in small quantities to stimulate root formation in cuttings of woody and ornamental plants. Mrs. Bernson rejected the application, not because of potential health and environmental hazards, but because she thought that the product was "unnecessary." From the point of view of the national economy this was certainly true. However, for a handful of farmers who had invested much of their own money in greenhouse cultivation of ornamental plants, the availability of these growth promoters was important. The sole consequence of turning down the Swedish growers' application for registration was to give the growers in other countries, especially the Netherlands, a significant competitive advantage.

Swedish Law and Civil Rights

Commenting on the Swedish nation, Charles de Gaulle is once supposed to have exclaimed, "What a wonderful people to rule!"

Looking at Sweden's state bureaucracy from his perspective, as the head of a government, I would totally agree. Housed in spacious modern offices and supported by the latest advances in information technology, Sweden's civil servants are generally efficient, much more so than in most other countries, including the United States; they are dutiful in the extreme and probably among the least corrupt (in the classical sense) in the whole world. However, there is a downside to the efficiency of the Swedish state machinery.

In most democracies, the right of citizens and industry to appeal regulatory decisions before an independent court is an important safeguard against arbitrary execution of government power. In Sweden, these rights are very much restricted. Although the Central Office for Government Auditing ("*Riksrevisionsverket*") assesses the performance of government agencies, the audits are mainly fiscal in nature, and the auditing agency's operation is not guaranteed independent from the government. Thus, there exists no professional and independent body empowered to judge agency policy or performance.

Overall, Sweden has an excellent record for most civil liberties, and the prime minister, Göran Persson, boasts of his aim to make Sweden an "ethical superpower." Sadly, however, Sweden's exemplary performance in most areas of civil rights does not extend to all aspects of the Convention on Human Rights. In particular, Sweden does not guarantee its citizens the right to a hearing of appeals to certain types of government actions.

According to Article 6 Sec.1 of *The Convention for the Protection of Human Rights and Fundamental Freedoms*, ratified by Sweden in 1950, ". . . everyone is entitled to a fair and public hearing within reasonable time by an independent and impartial tribunal established by law."

In this context, the European Court of Human Rights, which has jurisdiction over the Convention, has noted:

> 47. Generally speaking, the Swedish administration is not subject to supervision by the ordinary courts. Those courts hear appeals against the State only in contractual matters, on questions of extra-contractual liability and, under some statutes, in respect of administrative decisions.
>
> 48. Judicial review of the administration's acts is, therefore, primarily a matter for administrative courts. (*Sporrong and Lönnroth v. The Government of Sweden*—Case no. 1/1981/40/58-59).

Sweden's failure to have citizens' complaints judged "by an independent and impartial tribunal" has contributed to the European Court of Human Rights handing down eighteen indictments under Sec. 6-1 of the Convention against the Swedish Government. Although Austria (another European nation that has been dominated by Social Democrats since World War II) is burdened by thirty-five and Italy by twenty-seven indictments, Sweden's place as the number three offender in Europe against these basic articles of the Convention on Human Rights is not flattering for a would-be "ethical superpower."

General Legislation on Environment Protection

The fundamental goal of Sweden's *Unified Environment Code* enacted in 1999 is "to establish the prerequisites for sustainable development in society,"[13] and it applies to all human activities that have *potential* negative consequences with respect to health or the environment. The Code introduced several novel features, integrated a number of previous acts dealing with various aspects of environmental protection, including chemicals control, and calls for the Swedish Environmental Protection Agency, which is

13. *S*tatens *F*orfattningss*s*amlingar (SFS), *The Unified Environment Code* (SFS 1988:808, 1998).

responsible for implementation of the Code, to use the best available techniques for environmental protection.

The Code created separate regional Environmental Courts, and an independent Environmental Appellate Court, which can hear appeals from the Environmental Courts. The Code also allows for appeals from the Environmental Appellate Court to the Supreme Environmental Court.

For certain types of regulatory decisions—licensing emissions from industries, waste-treatment facilities, road constructions, water protection, and so on—the Code represents a marked improvement of private rights in Sweden as defined by Article 6, Sec.1 of the Convention. On the other hand, the Environmental Courts will not hear objections to restrictions issued by KEMI concerning, for instance, pesticide use, household chemicals, or other chemical products in trade. In the area of chemicals regulation, there remains no provision for taking challenges to an independent court of justice in Sweden, leaving appeals to the Court of Justice of the European Union in Luxembourg as the only option.

Swedish Precaution-Based Regulation of Chemicals

I recently asked an employee of KEMI working with the EU program charged with classifying and labeling chemical substances why Sweden always takes the most extreme position toward the harshest possible classification. The answer, "Because of the precautionary principle (PP)," made me think about the meaning of the PP. At first glance, this concept seems appealing. It makes sense to "look before you leap"; it is "better to be safe than sorry."

The prevention of the introduction of thalidomide by the U.S. Food and Drug Administration (FDA) as well as by regulators of what was then East Germany (DDR) provides an example of jus-

tifiable precautionary action. Across the world, thalidomide (trade names, Contergan, Kevadon, Distaval, Neurosedyn, etc.) caused more than 10,000 severely malformed children to be born to mothers who had used the drug during pregnancy. In both the United States and the DDR, inadequate documentation about the results of toxicological testing raised government scientists' suspicions about the safety of the drug, and on December 31, 1960, the *British Medical Journal* published an alert that thalidomide induced polyneuritis. The producers of the drug had earlier failed to make a frank disclosure about the side effect,[14] and both the U.S. and the DDR agencies had raised questions about the safety of use of thalidomide during pregnancy.[15] The U.S. and DDR decisions, based on precaution, saved thousands of babies from being born with malformations.

Sweden's restrictions on cadmium provide another example of justifiable precaution. Elevated cadmium levels in crops become a human health risk because ingested cadmium causes a progressive accumulation of the metal in the kidney cortex, eventually causing tissue damage. The success of the Swedish restrictions was measured as reversals in the progressive build-up of the metal in the environment.[16]

Well before the PP became a political slogan, government agencies and the chemical industry built precaution into risk management decisions. A decision by a chemical company not to market a potentially hazardous product is seldom if ever publicized, but the world would certainly have experienced a large number of additional severe accidents from chemicals if precaution had not prevailed among responsible industry decision mak-

14. Food and Drug Administration (FDA), letter, May 5, 1961.
15. Sjöström and Nilsson, *Thalidomide*.
16. R. Nilsson, *Cadmium—An Analysis of Swedish Regulatory Experience, Report to the OECD Chemicals Group and Management Committee* (Paris: January 1989).

ers. Swedish regulators rarely acknowledge such contributions to public health and safety from the chemical industry. Quite the contrary! On July 12, 2000, one of KEMI's top-ranking Social Democratic managers gave the following revealing message about his opinion of scientists associated with industry:

> It is my opinion that scientists (not scientists in general) during previous years have, to a strikingly high degree contributed to chemical uses with an impact that has completely justified many citizens' concerns. I am speaking about "scientists" who, like other lackeys, have done what their master, industry, told them to do without devoting one single thought to health and environment. I suppose that money is the driving force. I am not at all convinced that we can expect any significant initiatives from that quarter to achieve improved health and environment, rather to the contrary.[17]

According to J. Morris, German civil servants coined the term "precautionary principle" ("das Vorsorgeprinzip") in the 1970s,[18] but I have been unable to find much of a useful legal reference or definition that would be of any help to a judge in attempting to apply the PP. Indeed, the EU Commission's Economic and Social Committee noted that there are as yet few legal bases for a precautionary principle and that case law is still in its infancy.[19] Further, explicit and implicit allusion to this principle does not provide a solid base, and the Committee asked that the Commission submit a concrete and viable case soon.[20]

17. KEMI, Letter by e-mail from B. Lindwall to R. Nilsson, July 12, 2000. (In KEMI public record.)

18. J. Morris, *Rethinking Risk and the Precautionary Principle* (Oxford: Butterworth-Heinemann, 2000), pp. 1–21.

19. The Economic and Social Committee of the EU Commission (ESC), "Comments to the European Commission with Respect to Implementing the Precautionary Principle," *Official Journal of the European Community C 268*, 11 (September 19, 2000).

20. Ibid.

The Committee drew attention to the fact that the PP allows authorities to extend their "policing powers," and that the implementation of this concept will have major implications at the international level inasmuch as: "It enables countries to temporarily suspend their free trade commitments. The precautionary principle gives countries a sovereign right—and makes them the sole arbiter—on matters affecting the safety of their nationals. There is thus a stark contradiction with the EU Treaty."[21]

The Swedish Ministry of Environment's commentaries to the Swedish *Act on Chemical Products* of 1985 (SFS, 1985) incorporated the basic concepts of the PP into Swedish legal doctrine,[22] but it was first put forward as a legally binding doctrine in the Swedish *Unified Environmental Code* of 1998:

> 3 § Anyone who carries out, or intends to carry out, an activity or action of whatever nature shall undertake protective measures, follow restrictions and undertake such precautions in general to prevent or counteract that the activity or action in question results in damage or inconvenience with respect to human health or environment. With the same aim, any professional activity shall use the best available technique. These precautionary measures must be undertaken as soon as there is reason to believe that an activity or measure can cause harm or *inconvenience* with respect to human health or to the environment. [Emphasis added][23]

The legal text actually uses the term "inconvenience" ("*olägenhet*"), because the unified code covers everything from protecting the ozone layer to the manufacture and marketing of chemicals, the recycling of beer cans, or the building of a golf course. Recognizing that unfettered application of the law could

21. Ibid.
22. *S*tatens *F*orfattningss*s*amlingar (SFS), *Act on Chemical Products* (SFS 1985: 426, 1985b).
23. SFS, 1998.

result in a complete paralysis of Swedish society, many legal experts, including the government's own legal council, harshly criticized the original proposal for the new proposed Swedish legislation. As a result of the criticisms, the code that was adopted incorporates a clause calling for some kind of proportionality between action and the desired level of protection. Thus the use of the PP is to be reserved for situations "where it does not seem unreasonable to implement the same. When conducting this assessment, the benefits of the protective measures and other precautionary measures should be related to the costs for implementing the same."

However, a main defect of the Unified Environmental Code of 1998 and its accompanying explanations remains. Left unanswered is what degree of certainty (or uncertainty) is required to trigger actions based on the vague PP. Another serious shortcoming of the Swedish legislation is that it makes *anyone* who undertakes *any* action that may have a potential impact on health or the environment responsible for implementation of the PP.

The defenders of such a policy, of course, promote the argument that the "market" has to improve its (eco) toxicological competence. Wishful thinking! Even KEMI has only a handful of trained experts to perform adequate risk assessments. Delegating responsibility for implementing a poorly defined PP down to individual consumers represents a cowardly and unacceptable behavior of the Swedish state, especially in a situation when KEMI employees themselves lack clear guidelines on how to interpret and implement the PP.

The Substitution Principle

The "Substitution Principle" is a fundamental provision of the *Ordinance on Chemical Products* issued pursuant to the *Act on Chemical Products* of 1985.[24]

> If anyone uses a chemical product (or preparation as defined by 2 § of the Ordinance on Chemical Products), and in case such product (or preparation) can be replaced by a product (or preparation) that is less hazardous, but accomplishes the same or similar purpose, and does not entail an unreasonable additional cost, the more hazardous product must be avoided, i.e., it should not be used.[25]

In essence, the product substitution principle, restated in the Unified Environmental Code of 1998, means that although the use of a harmful substance or product is permitted *per se*, it must be avoided or "replaced by one that is less hazardous or completely harmless. Everyone who uses or imports a chemical product must take initiative to appraise if the same result can be achieved by using an alternative chemical product that is less hazardous or completely harmless, or in some other way."[26]

There is, of course, no such thing such as a "completely harmless" chemical product except in the imagination of politicians and the Greens. In a frightening disregard for realities, the Comments to the Unified Environmental Code extends responsibility for adhering to the substitution doctrine to everyone:

> It should be observed, that this paragraph does not only apply to professional use, but the use concept also includes the

24. *S*tatens *F*orfattningss*s*amlingar (SFS), *Ordinance on Chemical Products*, issued in pursuant to the *Act on Chemical Products* (SFS 1985:835, 1985b).

25. Ibid.

26. "Comments to the Unified Code," *SOU 103, Part 2* (1996), p. 29.

> situation when a private person, who in his role as consumer, undertakes any kind of action . . . the purchase of a detergent may be cited as an example. When, for instance, a car owner is going to wash and clean his car and buys a detergent for this purpose, such as a degreasing agent, in a gasoline station, he must select a product that causes as little harm to the environment as possible, provided that it cleans his car.[27]

Failure to follow the substitution principle to prevent damages to humans or to the environment may carry stiff penalties. In cases of severe negligence, large fines can be levied, and violators can be subject to up to two years' imprisonment.[28]

Applying the Substitution Doctrine

Used with common sense, the substitution doctrine does not seem unreasonable. If a less hazardous chemical can do the job, why not use it? However, in practice, substitution can be required for almost any chemical product marketed in Sweden that fails to satisfy certain hazard criteria, irrespective of the actual level of risk its use carries.

Children's Sand Piles

Because very high exposures to crystalline silica can induce lung tumors in laboratory animals, the World Health Organization's (WHO) International Agency for Research on Cancer (IARC) classified it as a carcinogen.[29] Applying the Swedish interpretation of the PP, and under the criteria established by the Swedish Government's program for *An Environment Free of Poisons*, crystalline

27. Ibid.
28. SFS, 1998, 3§.
29. International Agency for Research on Cancer (IARC), "Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans," *Silica and Some Silicates* (Lyon, France: WHO, 1987), pp. 39–143.

silica should therefore be totally eliminated from all consumer products.[30] Natural sand usually contains appreciable amounts of crystalline silica and should thus be banned for use in, for instance, sand piles for children. The lung cancer risk from silica for children playing with sand is negligible because of limited exposures, and for obvious reasons, products containing sand are, of course, not banned in Sweden. Nevertheless, the example illuminates the bizarre consequences that may result from a substitution policy that does not take actual risk into consideration.

Department Store Risk Assessment

Swedish law requires that major retailers make an assessment of potential health and environmental hazards when deciding on which products to stock and sell. As a guide to which chemicals should be avoided, KEMI has published a list of "especially hazardous chemicals" ("*OBS-listan*"). The hazard profiles of the KEMI-listed substances differ widely, from decidedly toxic compounds, like arsenic salts and benzene, to practically innocuous substances, such as metallic zinc and many zinc compounds. (Like any other chemical, including table salt, zinc and its compounds should, of course, not be dumped in rivers in large quantities, but they are perfectly safe in most other contexts.)

KEMI's list of toxics is one of the most important sources of information for retailers in deciding on their purchases. Recent versions of the KEMI list carry an explanatory section that encourages the user to make some sort of risk assessment of the listed substances rather than automatically deciding against a product because it contains one or more of the listed chemicals. However, according to information from the Swedish Chemicals Manufacturers Association, retailers' purchasing departments

30. Swedish Ministry of Environment, 1998–99.

can seldom undertake one.[31] Lacking the competence to do this properly, and under pressure to carry products with "green labels" (supposedly environmentally "safe"), they often refuse to buy any product that contains a chemical that is present on the KEMI list. The overall result is the promotion of a number of consumer products of inferior quality in the name of an imaginary or negligible improvement in safety. Alternatively, products are marketed that contain substances not on the list, which are less well investigated and could even be more harmful.

Reasonable and Prudent Precautionary Principle in an International Perspective

I agree that the "precautionary principle" should be given a central position in guiding legislation for the protection of man and the environment, but in a more restricted sense than it is now used in Sweden to tackle widespread "chemophobia." Not only does the Swedish interpretation of the PP open the sluices for capricious regulatory action, it also introduces a factor of arbitrariness that disrupts the functioning of a free market, inevitably inhibits sound technical development, and shifts too much responsibility for technical decisions to citizens and small businesses that are not trained to make them.

Today, reference to the PP can be found in several international agreements and declarations. However, the description of the PP that has had the greatest impact can be found in the *Rio Declaration* from the 1992 United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, and the Swedish government repeatedly referred to it when it proposed the Unified Environmental Code of 1998 to the Parliament. How-

31. J. Bäckström, Kemikontoret, the Swedish Chemicals Manufacturers Association (personal communication, 2002).

ever, the Swedish interpretation agrees poorly with the Declaration, where Principle 15 states that:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[32]

PP in the European Union

In 1995 Sweden became a member of EU, which, at least in some ways, has had a sobering influence on national regulatory policies. With a total population of 365 million citizens, the EU has an economy equal to that of U.S. It is a highly complex organization, and the interested reader is referred to EU (2002) for information about it.

For this discussion of the PP and regulatory policy, it is important to know that the EU Commission, the "driving force and executive body" of the EU,[33] is composed of a president and twenty independent members appointed by the Member States after approval by the European Parliament. Based in Brussels, the Commission, aided by its very large staff, proposes legislation, monitors compliance with legislation and with the treaties that govern the EU, administers common policies, and provides substantial economic support for research and development. The European Court of Justice in Luxembourg ensures that the law is observed in the process of Community integration. The EU Commission has the power to appoint expert groups to deal with general topics,

32. United Nations (UN), *Agenda 21: The UN Programme of Action from Rio* (New York: United Nations, 1992).

33. European Union (EU), "Europa. The European Union at a Glance" (http://europa.eu.int/abc-en.htm, 2002).

such as guidelines for risk assessment, classification, and labeling. The members of the expert groups, as a rule, act relatively independently of the Commission, and, above all, most have adequate scientific qualifications. The Economic and Social Committee, a source of technical analyses and opinions for the EU, is a consultative body that includes representative trade unions and social and professional groups as appropriate to the tasks assigned to it, and it has issued several documents concerning risk assessment, the PP, and regulatory policies. At the beginning of 2000, the EU Commission issued general guidelines on the use of the PP with the stated goal to "avoid unwarranted recourse to the principle as a disguised form of protectionism" and to "build a common understanding of how to assess, appraise, manage, and communicate risks that science is not yet able to fully evaluate."[34] The EU Commission makes the very important point that "the precautionary principle, which is essentially used by decision-makers in the management of risk, should not be confused with the element of caution that scientists apply in their assessment of scientific data."[35]

While the Swedish Government sees the PP as an instrument to restrict the overall use of manmade chemicals in society, the EU Commission reserves its implementation of the PP to risks that "in the event of non-action may have serious consequences." The EU Commission's statement is similar to the second sentence of Principle 15 in the Rio Declaration, which reserves the use of the PP to "threats of serious or irreversible damage." The words of the EU Commission and the Rio Declaration impose considerable restraints on when the PP should be applied, and the EU Economic

34. The Commission of the European Communities (CEC), *Communications from the Commission on the Precautionary Principle* (Brussels: COM, February 2, 2000).

35. Ibid.

and Social Committee underlined that the PP is to be used only for serious situations when it wrote "The contemporary risk indictor is the notion of disaster."[36]

Regulatory restraint is even more clearly spelled out for chemicals in *Agenda 21*, the program of action adopted by the UNCED Conference.[37] Under Chapter 19 of the Agenda, "banning or phasing out" by regulatory action is reserved for "toxic chemicals that pose an unreasonable *and* otherwise unmanageable risk to the environment or human health *and* those that are toxic, persistent *and* bio-accumulative *and* whose use cannot be adequately controlled."[38] [Emphases added]. In accord with industry,[39] I have no problems whatsoever with such a definition of the PP with respect to regulation of chemicals.

In summary, "risks" in the EU Commission and the Rio Declaration are on a totally different level from the risks addressed by the Swedish regulators. Swedish regulators have, for instance, banned the dry cleaning solvent trichloroethylene, barred the Swedish public from using practically all efficient pesticides, withdrawn a number of effective mosquito repellants, banned copper-based antifouling paints, and are moving to do the same with lead in ammunition, sailing boat keels, accumulators in cars, and sinkers for fishing, and to ban cadmium in recyclable accumulators, and so on. I think that Sweden has gone far beyond anything that the EU Commission had in mind for requiring application of the PP.

Unfortunately, the EU Commission is disconcertingly vague on when to act or not to act under the principle. It states that the "political decision" to rely on the principle is "a function of the

36. ESC, 2000.
37. UN, 1992.
38. Ibid.
39. The European Chemical Industry Council (CEFIC), *Position Paper: Precautionary Principle* (Brussels, Feburary 15, 1995).

risk level that is 'acceptable' to the society on which the risk is imposed." On the other hand, the EU Commission states:

> Recourse to the precautionary principle does not necessarily mean adopting final instruments designed to produce legal effects that are open to judicial review: The decision to fund a research programme or even a decision to inform the public about possible adverse effects of a product or a procedure may themselves be inspired by the precautionary principle.[40]

The EU Commission underlined that actions under the PP should be

1. proportional to the chosen level of protection
2. nondiscriminatory in their application
3. based on an examination of potential benefits and costs
4. subject to review, in the light of new data

I see little evidence that Swedish regulators consider these guidelines in their rushes to regulate.

Sweden's Application of the PP

Sweden's crusade against the use of certain heavy metals provides a recent example of a blatant failure to observe the EU Commission's first requirement of *proportionality* of measures to achieve the appropriate level of protection. Many of the proposed restrictions cannot be expected to improve human health at all, or to have significant beneficial effects on the environment. During the last decades, lead levels in the blood in the Swedish population, including children, have steadily decreased, mainly as a result of the phasing out of leaded gasoline,[41] and they are now similar to

40. CEC, 2000.

41. U. Strömberg, A. Schuetz, and S. Skerfving, "Substantial Decrease of Blood Lead Levels in Swedish Children 1978–94, Associated with Petrol Lead," *Occupat. Environ. Med.* 52 (1995): 764–69.

those found in totally unpolluted regions, like the Himalayas.[42] Still, Swedish regulators are resolutely determined to phase out virtually all items made of lead. In June 2001, the Swedish Government notified the EU and the World Trade Organization (WTO) of its intent to ban the use of lead in shot and buckshot, and to allow lead only in bullets that will be used on shooting ranges, and only under conditions of retrieval of the used bullets. This ban is to include Olympic competitions as well as all military purposes. Lead, when ingested, may cause severe lead poisoning in waterfowl, and existing Swedish legislation has already banned the use of lead buckshot for certain purposes. The proposed general ban on lead in other types of ammunition makes little sense.

The Swedish government's announced intentions to ban all uses of cadmium, including in recyclable accumulators, may, in fact, increase health and environmental risks. Cadmium is always present in zinc, and it is obtained from the purification of that metal. If no sensible use can be found for cadmium, the producers will simply leave it in the zinc, resulting in extensive and diffuse emission of cadmium from corroding zinc that will be impossible to control. The regulators' answers to the problems presented by cadmium-laden zinc are attempts to curb uses of zinc as well, in spite of the fact that deficiency of the essential element zinc is a public health problem.

Who Is Responsible for Application of the PP to Risk Decisions in Sweden?

The EU Economic and Social Committee underlines that the PP is the state's responsibility. Under normal circumstances, the regulators should not force the individual citizen, or even the purchasing office of a department store chain, to take on their re-

42. S. Piomelli et al., "Blood Lead Concentration in a Remote Himalayan Population," *Science* 210 (1980): 1135–39.

sponsibilities. The Swedish legislation observes no such restraint. It places responsibility for applying the PP on industry, businesses of all sizes, and private citizens, and it also puts the burden of proof on the manufacturer, importer, vendor, or user to demonstrate that suspicions that their product will cause a risk to man or the environment are without grounds. In other words, Sweden reverses the burden of proof, putting the burden on the organization or person wanting to sell or use the product to prove it is without risk, rather than on the government or some agent of the government to prove that it is risky. Both the EU Commission and its Economic and Social Committee reject such reversals of the burden of proof as a general principle, although reserving it for some situations.

Given the fact that the PP can be triggered under great uncertainty, the EU Commission has emphasized that measures based upon it are to be *provisional*. Not unexpectedly, Sweden has opposed this limitation.

Exporting the Precautionary Principle

Roger Bate (see his chapter in this volume) has described the usefulness of DDT in the control of malaria-bearing mosquitoes, and the resurgence of malaria in many countries after DDT use was restricted or banned. Sweden, along with several other countries, has been active in lobbying for a total ban on DDT.

I. M. Goklany, in his recent excellent monograph, discusses implementation of the PP with respect to DDT use in different countries.[43] Prudent use of the PP can justify a ban on DDT in Sweden or the U.S., where problems with malaria are limited and affordable alternatives are available. Consideration of conditions

43. I. M. Goklany, *The Precautionary Principle. A Critical Appraisal of Environmental Risk Assessment* (Washington, D.C.: Cato Institute, 2001).

in a country like India, where malaria is a major disease problem and alternatives to DDT are not affordable, should lead to a totally different outcome. The much more severe immediate effects of *not* using DDT should outweigh the far smaller risks that would accompany a ban. To insist that the PP should be applied the same in both kinds of countries, as Sweden has done, is unscientific as well as highly unethical.

Sweden Evades EU Legislation

The ruling Swedish political establishment is, of course, well aware that issuing restrictions based on its own extremist version of the PP may cause serious international complications. In particular, the EU Commission as well as the WTO can be expected to raise objections about Sweden introducing non-tariff barriers to trade. To head off complaints appearing before the European Court of Justice and WTO, Sweden has devised various subtle means to circumvent its international obligations under, for instance, the articles on the *Free Movement of Goods* as stipulated by the 1957 Treaty of Rome.

Defining Hazardous Substances

Pursuant to the legally binding EU Directive 67/548/EEG on *Classification, Packaging, and Labelling of Hazardous Substances,* and as a result of concerted effort, the Member Countries have classified and labeled a large number of chemicals based on degree of hazard. For certain substances, Swedish regulators have been reluctant to accept the EU evaluations, and KEMI publishes its own "particularly hazardous substances" list (*OBS-listan*) mentioned above. Referring to alleged risks to the environment based on KEMI criteria that differ from the EU regulations, Sweden promotes its own alarmist concepts about metallic copper, chro-

mium, cobalt, nickel, and zinc and its compounds. Taking KEMI's approach to its logical ends, Swedish citizens had better get rid of all stainless steel kitchen sinks, nickel-plated faucets, zinc-plated nails, copper roof linings and gutters, and send their copper pots to a recycler of hazardous waste. Turpentine, and most kinds of commonly and widely used distilled petroleum products, should also be avoided. Other commonly used products will probably face the same fate as KEMI extends its lists.

The EU classification and labeling of a chemical as a hazard, by itself, does not translate into any regulatory action. Instead, any regulatory action is to be based on a determination of the *level* of risk associated with the particular uses of a substance. Both the EU *Directive 93/67/EEC on Risk Assessment for New Notified Substances* and the *Commission Regulation (EC) 1488/94 on Risk Assessment for Existing Chemicals* state that quantitative risk assessments are the basis for rational risk management, and that the goal of risk management is to set exposure levels sufficiently low *not* to cause harmful effects. The Swedish Ministry of Environment prefers to forget these directives, and a major part of Sweden's recent policy for chemicals regulation, based entirely on hazard with little or no consideration of exposure, is totally at odds with the basic concepts underlying risk management in the EU as well as in the U.S.

Sweden's Pesticide Regulations

Pesticide regulation is another area where Sweden wants to avoid direct confrontation with the EU Commission, while trying to evade EU regulations. Annex VI to the EU's uniform principles for evaluation and authorization of plant protection products (*Council Directive on the Placing of Plant Protection Products on the Market*, (91/414/EEC) requires that exposure assessments be

conducted (Section 2.4.) as a basis for risk assessment. There are at the present no indications that the KEMI intends to comply with this aspect of the EU directive, especially when it comes to pesticide products intended for the general public.

Sweden's trick to avoid following the intentions of the directive is to classify virtually all pesticides that have previously been permitted for use by the general public as "Class II products," meaning that they can be used only by professionals. As a result, the Swedish citizen is barred from using practically all effective pesticides, including a large number of virtually safe products used by consumers worldwide.

For example, the EU recently cleared the herbicide glyphosate (Roundup), which is practically nontoxic to humans, for consumer use. Nevertheless, KEMI has notified importers and distributors that sales of glyphosate to the public will be severely restricted in the future. Faithful to its socialist traditions, the almighty Swedish State attaches no value to the billions of Swedish crowns invested by private homeowners in lawns, flowerbeds, rose gardens, and so on. An appeal to KEMI's decision will most likely be directed to the European Court of Justice.

The withdrawal of a number of copper-containing antifouling paints for pleasure boats and marine vessels in the Baltic, based on alleged minor environmental effects localized to marinas, led to a number of protests to the Swedish government. Although the government upheld the mandated withdrawals, these restrictions will likely also be appealed to the EU Commission and then further to the European Court of Justice.

Try as it will, Sweden probably cannot avoid direct confrontation with the EU Commission in some cases. Even before the EU had set up a common registration process for all active ingredients in pesticides (Council Directive 91/414/EEC), it was clear that Sweden would not be able to convince the EU of the scientific

justification for its previous bans of a number of pesticides.[44] The Ministry of Environment has officially characterized this development as more or less a catastrophe for environment protection in Sweden.

This response is absolute nonsense. Sweden had banned the herbicide amitrole and several bis-dithiocarbamate fungicides because of flawed scientific evaluations that misinterpreted thyroid tumors in rodents, known to lack relevance for humans, as indicators of a human risk associated with normal usage. In contrast to Sweden's action, IARC and the U.S. Environmental Protection Agency cleared all of them of suspicions of causing cancer at current exposure levels,[45] and the EU has approved amitrole for general use. Sweden's Minister of the Environment, Kjell Larsson, has declared that Sweden will fight all the way to the European Court of Justice to stop reintroduction of these horribly dangerous pesticides.

Future Developments

My past experience in independent expert groups convened by such bodies as the Chemicals Division of the Organization for Economic Cooperation and Development (OECD), the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Meeting on Pesticide Residues, and the International Program of Chemical Safety (IPCS) in Geneva led to high expectations for similar EU groups charged with the task of evaluating chemical risks. Although assessment of hazardous substances in EU

44. R. Nilsson, "Integrating Sweden into the European Union: Problems Concerning Chemicals Control," *The Politics of Chemical Risk—Scenarios for a Regulatory Future 9*, ed. R. Bal and Halffman (Dordrecht, Netherlands: Kluwer, 1998), pp. 159–71.

45. IARC, "Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans," *Some Thyreotropic Agents* (Lyon, France: WHO, 2001), pp. 381–410.

may not always represent the ultimate wisdom, I expected the outcomes to be at least competitively neutral with respect to industry and trade inside the community.

However, I have been somewhat disappointed when working within the framework of the EU Existing Substances Program. Under the program, committee members from EU Member States, regulatory agencies generate comprehensive documents for individual high volume chemicals that include recommendations for classification and measures for risk reduction with far-reaching consequences for the European chemical industry. With several notable exceptions, most participants in the committees do not act as independent experts, but rather as advocates for their respective national administrations while practicing various degrees of "political toxicology." In my opinion, it seems quite clear that Sweden has had some success in exporting some of its extremist concepts to other countries in this context.

However, in 2002, as I write this, the recent swing of public opinion to the right that has toppled most of the European Social Democratic governments may herald some important changes to the EU's environmental agenda. Those changes, if they take place, may unfortunately strengthen the left-wing EU-skeptics in Sweden, and eventually result in the country's leaving the Union.

Such a move would have serious economic consequences and accelerate the ongoing marginalization of Sweden among Western nations, where an increasing part of Sweden's industry opts to move its production base outside the country. Any nation that considers incorporating the Swedish variant of the precautionary principle into major parts of its legislative framework should also consider the future competitiveness of their nation in relation to the other large economies outside the EU, primarily the U.S.A., as well as Japan, and, increasingly, China.