MISGUIDED PRECAUTION

– CHEMICALS CONTROL AND THE PRECAUTIONARY PRINCIPLE IN SWEDEN

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The Role of Politics in Chemicals Control in Sweden

Over the past few decades, I have been deeply involved in the development of chemicals legislation in Sweden, and have seen how the concepts behind the legislation have been exported throughout the western world. It is the international impact of these chemical controls that compels me to make some general observations about how these concepts were developed.

In Sweden, the main impetus for improved environmental protection, including chemicals control, came originally from the scientific community. For instance, the bioaccumulating and toxic properties of organic mercury compounds used in agriculture were appreciated some time before the Minimata poisonings in Japan became known. In the years 1964–1966 the Swedish chemist, Sören Jensen, was the first to describe the bioaccumulating properties of PCBs. Initially, the fight for a better environment was an uphill struggle, where industry and government alike showed great reluctance to adopt a more progressive and responsible attitude. Although media coverage certainly played an important role, arguments presented during this early phase were mostly technical, and many respected scientists were closely allied with, the founders of the Swedish environmental movement.

In 1969, the Swedish producer of Thalidomide accepted responsibility for compensating the damage caused. This was a turning point and for more than a decade a balanced and gradual progress was made in various fields of products control, largely based on scientific principles. A notable exception was the dioxin hysteria, which provoked direct intervention at ministerial level in the 1970s to restrict, and later ban, many of the chlorinated phenoxy herbicides.

Regrettably, in spite of significant scientific progress in toxicology and risk assessment, the role of high quality science has gradually become less important in shaping our national policy priorities 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. Instead of focusing on the conservation of wildlife, where much good has been achieved, many respected naturalists started to busy themselves with complex toxicological problems, an area in which they had 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, while showing little understanding of the economic laws of a society that provides them with all the basic conveniences and luxuries that they actively consume.

By controlling a block of MPs that can swing the votes in favour either of the socialist block or the liberal/conservatives, the Swedish Green party, like the German Greens, exert a substantial political influence. In addition, Swedes have been nurtured on a distrust of 'experts', so it is perhaps not surprising that Greenpeace often seems to have more influence on the Swedish Ministry of Environment than does the Royal Swedish National Academy of Sciences. Naturally, such tendencies have disproportionately affected government agency policies, because of the inclination of many politicians to play the environment card to secure support of marginal voters. This has, unfortunately, boosted the influence of environmental groups to an extent that bears little relation to the number of actual members.

In 1979, the Swedish Government commissioned a special group, including some of Sweden's most prominent scientists, led by the Nobel laureate in medicine, Sune Bergström, to assess the reasons for cancer among the Swedish population, as well as to suggest preventive measures. I participated in this work, and in 1984 an extensive report of the Swedish cancer committee (SCC) was presented to the Government. The report's conclusions were not what the politicians had expected and they were apparently disgusted: this stuff could not give the socialists marginal votes in the upcoming elections. What activist politician wants to hear that in comparison with sunbathing, for example, industrial chemicals, pesticides, and air pollution are not significant causes of cancer? They could, of course, accept that smoking was bad, but obviously did not want to convey the message that diet was considered an important factor in avoiding cancer, and not to mention that bad genes also play a role. The SCC conclusions were practically identical with those presented by the famous epidemiologists Doll and Peto to the Office of Technology Assessment of the US Congress in 1981.

Politicians wanted to avoid such political mishaps in the future, so in 1996 when the Swedish Ministry of Environment was looking for specialists on chemical hazards to assist in drafting documentary support for new legislation, did they ask the Royal Swedish Academy of Sciences, or perhaps the famous Karolinska Institute which selects nominees for the Nobel Prize in Medicine? Forget it! The job was conducted mainly by bureaucrats and politicians associated with the Ministry, assisted by some junior consulting firm employees with little knowledge of toxicology. A few true scientific experts, diluted by a majority of laymen, were engaged to serve as hostages with little possibility of influencing the work. Whereas the report of the Swedish Cancer Committee was translated into English and published by a major international scientific publishing company, (Cancer – Causes and Prevention, Report to the Ministry of Social Affairs from the Cancer Committee. Taylor and Francis, London, 1992), the 1997 report from this 'Chemical Committee' called 'A Sustainable Policy for Chemicals', was a major disaster and received scathing criticism from, amongst others, the Swedish Royal Academy of Sciences and the Royal Academy of Engineering Sciences. To a Minister of Environment (now Minister of Foreign Affairs), Anna Lindh, who declared that she has more confidence in Greenpeace than in the Academy of Sciences, expert criticism was to no avail, and the recommendations from this committee now form the ideological basis for one of the most extreme chemical laws in the world.

The Swedish Regulatory Process

The role of Swedish government agencies is to implement the laws enacted by parliament. Traditionally, these agencies have been relatively autonomous. However, in recent years ministers have increasingly interfered with the daily work of the agencies, acting mainly through politically appointed managers on several levels.

The central agency for chemicals control, the National Swedish Chemicals Inspectorate (KEMI) has become a powerful instrument for the promotion of the green ideology favoured by the present socialist government.

Tendencies as those described above are, no doubt, more or less common to most developed nations, but what distinguishes Sweden from most other countries is the effect of environmental extremism on society. Why so? There are several reasons:

A high level of public concern for environmental protection, especially with regard to 'environmental poisons'.

An omnipresent, centralised and highly politicised regulatory bureaucracy combined with a lack of balance of power between regulators, industry, and private interests.

Lack of coherent national strategies for risk assessment and risk management, where the negative consequences are accentuated by the absence of risk–risk comparisons in the regulatory context.

A mistaken belief that efficiency in chemicals control is proportional to the number of bans and restrictions imposed.

A firm conviction of the unmatched excellence of the Swedish model, combined with a pioneering spirit when attempting to convert an ignorant and callous world. Sweden has a strong tradition of cherishing unspoiled nature. It is based on a romanticism of the past, and is held not only among Swedish intellectuals, but also prominent industrialists. In a positive sense, this has probably promoted the progress of traditional environmental protection as well as encouraging the introduction of stringent emission controls to benefit the quality of life. It is true that in comparison with most other industrialised nations, Sweden has relatively few serious environmental problems today. However, when I am confronted with media reports about the state of the environment in this country, it is often difficult to recognise the descriptions, since they seem to be more appropriate to México City, Calcutta, or to certain devastated areas in industrialised Eastern Europe.

It has also been claimed, that the level of risk acceptance in Sweden is particularly low. This over-sensitivity may be true for a nation that has not experienced war since Napoleonic times, and where other national disasters have been scarce. In addition, the 'worry box' concept of the US American humorist Patrick F. McManus (1992) seems to be eminently fitting with respect to many of its citizens:

> 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!

Even when the level of worry among the public (news media) may appear to be more or less constant, the issues of concern may change, and sometimes this happens from one day to the next.

In the past, belief in witches and witchcraft was widespread in our society, including the Church. However, some powerful enlightened rulers in the 17th and 18th centuries, including King Gustavus III (1771–1792), had both the determination and courage to combat ignorance and superstition. Today, Swedish politicians more or less openly admit that, rather than basing their policies on real risk, they are mostly guided by 'risk perception', a concept heavily tainted by a new kind of superstition. Instead of making an attempt to distinguish between what are significant and insignificant risks, our regulators tend to yield to media blackmail that will only accentuate the trend towards an increasing lack of rationality in risk management to the detriment of progress in modern society. Each time regulatory action is taken that is based solely, or mostly, on public 'concern', and where the actual risk is negligible, the mere fact that regulatory action is taken will strengthen the belief in its absolute justification. The layman critical of experts will exclaim: 'You see, it was dangerous – we were right after all!'

The EU Perspective

Will Swedish membership of the EU strengthen the role of science in domestic regulatory affairs? With a past experience in independent expert groups convened by such bodies as the OECD Chemicals Division, the Joint FAO/WHO Meeting on Pesticide Residues, and the International Programme of Chemical Safety (IPCS) in Geneva, I had high expectations of similar groups working under the EU. The Commission has the powers to appoint expert groups to deal with general topics, such as guidelines for risk assessment, classification, and labelling, where the members as a rule act relatively independently and, above all, have adequate scientific qualifications. When such guidelines are issued as EU Council Directives, they become legally binding for all member states. As a consequence, one can already note a sobering influence of EU membership on Sweden's regulatory policies in general.

However, I have been somewhat disappointed when working within the so-called Existing Chemicals Programme. This programme generates comprehensive documents for individual high volume chemicals and contains, for example, recommendations for classification and risk reduction that have far reaching consequences for the European chemical industry. For this reason they deserve a better fate than the kind of political toxicology displayed by the participants from the various national government agency bureaucracies. The historic domination of the Union by left wing governments is here clearly discernible.

Securing Grants at All Costs – the Responsibility of the Scientist

However, it would be unfair to blame biased policies entirely on ill-educated laymen, or opportunistic bureaucrats and politicians. The scientific community itself shares part of the responsibility for this unfortunate development. In many cases, researchers with little knowledge of toxicology have acted far outside their own field of competence and provided fallacious interpretations of their results, while shamelessly exploiting the news media to promote their own interests. Even when discounting such excesses, in order to secure continued funding with respect to certain 'grant-dense' areas like health risks from chemicals, professionals in medicine and epidemiology often tend to overextend interpretation of their own data. In a commentary in the famous US journal *Science* (Taubes, G. (1995) 'Epidemiology faces its limits'. *Science* **269**, 164–169), one scientist affiliated with the prestigious US National Institute Environmental Health Sciences bluntly stated that:

> 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.

It is sometimes realised that a rational policy for chemicals control would demand extensive inter-agency cooperation, but concerted action is hampered by the tendency for bureaucrats to expand their own empire. Each agency tries hard not only to defend it own turf, but to make an attempt to expand its area of competence as much as possible. The public may not realise that the main threat to human health from chemicals in food today is not the presence of minute levels of pesticide residues, or of other industrial chemicals, but rather, the overeating of unhealthy foods including, in particular, a high intake of saturated fat, insufficient intake of fruits and vegetables, and the presence of natural toxins in food. However, if generally known, this could imply a diversion of financial resources from the competent agency for chemicals control to the agency for food control. This situation provides a potential for some unholy alliances between scientists and regulators:

> If, for example, the dioxin question was defused, several laboratories that for decades have specialised in dioxin-related research, and successfully milked agency and other funds for support, could lose its cash cow. After all, it may not be so surprising that no attention was paid to the call from the Swedish Cancer Committee in 1984. This committee emphasised the role of life-style as the main factor in causing cancer, and

> stressed the urgent need for a uniform regulatory policy for risk management based on quantification of risk that involved effective inter-agency cooperation (Swedish Cancer Committee Cancer – Causes and Prevention, Report to the Ministry of Social Affairs from the Cancer Committee. SOU 1984:67, Stockholm. English translation: Taylor and Francis, London, 1992).

Society's implementation of a double standard is particularly obvious in the regulation of pesticides. If the natural substances, solanine and chaconine found in potatoes, were pesticide residues, potatoes would not be permitted on the market because of their high content of these toxic alkaloids (20–100 mg/kg), and also because these substances have not been adequately tested for long-term effects (IPCS, (1993) Toxicological evaluation of certain food additives and naturally occurring toxicants; Solanine and chaconine. WHO Food Additives Series Assessment No. 30, WHO, Geneva, 339–372). The same would be true for the common mushroom, which contains the potent genotoxic carcinogenic hydrazine derivatives (agaritine) that induce a high incidence of malignant tumours at multiple sites in the mouse, in particular in the forestomach, bone, and lungs (B. Toth and J. Erickson. (1986) Cancer induction in mice by feeding of the uncooked cultivated mushroom of commerce, Agaricus bisporus. *Cancer Res*. **46**, 4007–4011). Recently, the 'endocrine disrupter' scare has provided another striking example where exposures to such compounds of industrial origin are dwarfed by the extensive use of oral contraceptives and other 'natural' chemicals, and is also virtually insignificant in comparison with the intake of natural phytoestrogens with food (Table 1). Although exposures to man-made and natural chemicals occur by identical routes of administration and contribute to the same toxicological effects, they are, regrettably, being judged by completely different standards.

Table 1 – Mass balance in terms of oestrogen/anti-oestrogen equivalents of human exposures to natural as well as synthetic compounds that mimic the effects of sexual hormones.

Oestrogens/Anti-oestrogens	Estrogens/Anti-oestrogen equivalents (µg/day)
Oral contraceptive[a]	16,675
Post-menopausal therapy[a]	3,350
Flavonoids in foods (1 g/day)[a]	102
Genestein and genistin (15.6 mg) in 100 g tofu (soybean curd)[b]	16
Zearalenone in 0.5 L Zambian beer	20–50
Zearalenone, daily average[e] intake from Canadian food (3.5–7.0 µg)[e]	0.1-0.7
Di-n-butyl phthalate[c] in UK food (250 µg/day[d])	0.02
TCDD and related compounds (80-120 pg/day)[a]	0.00008-0.0001
Organochlorine insecticides[a]	0.0000025

a) ref. 66;

b) ref. 48, based on in vivo potency relative to ß-estradiol in the neonatal rat;

c) ref. 21;

d) ref. 67, assuming all intake to be dibutyl phthalate;

e) ref. 50, based on in vivo potency relative to ß-estradiol in the neonatal rat. (From R. Nilsson. (2000) Endocrine modulators in the food chain and the environment. *Toxicol. Pathol*. **28**, 420–431).

Big Government – How Sweden's Regulators Triumph over Democratic Principles

Commenting on the Swedish nation, Charles de Gaulle is once supposed to have exclaimed 'What a wonderful people to rule!' From his perspective I totally agree. Sweden's regulators employ the latest technologies and they are generally very efficient in their operations – much more so than US regulators. The agencies' servants are also dutiful in the extreme and probably among the least corrupt (in the classical sense) in the whole world. When French politicians introduce legislation that is generally considered stupid by the pragmatic and cynical French, even the bureaucrats ignore it, or at least find 'the resources insufficient' to give its implementation priority. Not so in Sweden. The faithful Swedish bureaucrat will do his best to implement any decree or regulation to the letter, with complete disregard not only of common sense but sometimes also of the nation's constitution.

In most democracies, those who reasonably believe themselves to be adversely affected by Government regulations have a constitutional right to an impartial hearing of their objections before an independent court. Such rights constitute an important safeguard against arbitrary execution of power. No such rights exist in Sweden. In the case of *Sporrong and Lönnroth v The Government of Sweden*, the European Court of Human Rights noted that

> 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. Judicial review of the administration's acts is, therefore, primarily a matter for administrative courts.

The administrative courts in Sweden are not independent of the government, which is in many cases the highest court of appeal. In practice, this means that procedures, which from a purely formal point of view have been mishandled, may be challenged and remedied, but assessments never cover the technical basis for regulatory action, nor of the reasons for such regulations. Sweden also seems to be unique among modern democracies in not having even an independent court of appeal to judge the constitutionality of proposed laws and regulations.

Not surprisingly, a strong tendency to disregard the protection of the property rights of its citizens has long been a typical trait of the Swedish regulatory tradition that, *inter alia*, has resulted in 18 indictments by the European Court of Human Rights against the Swedish Socialist Government. 16 of these refer to Article 6, para.1, and two to Article 1 of Protocol 1 of the European Convention of Human Rights. The Human Rights Court has made it a point that many of the Swedish Government's decisions have not been

> open to review as to their lawfulness by either the ordinary courts or the administrative courts, or by any other body which could be considered to be a 'tribunal' for the purposes of Article 6 para 1.

Article 6 relates to the right to a fair trial:

> In the determination of his civil rights and obligations or of any criminal charge against him, everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law.

Article 1 of Protocol No. 1 (P1-1), reads as follows:

> Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.

Together with Italy's disreputable legal system, Sweden shares the dubious honour of being foremost in receiving indictments under these articles of the European Convention of Human Rights. For a country that in most other aspects has a solid and usually well-deserved reputation as a staunch guardian of human rights, this should indeed be embarrassing. More so for our prime minister, Göran Persson, who boasts that he is aiming at making Sweden and 'ethical superpower'.

The recently introduced unified Environment Code Act and associated ordinances contain some important changes, in as much as many cases in the field of environment protection will now be referred to the newly created Environmental Courts, with a separate Environmental Supreme Court as the highest level of appeal. These courts will, for example, judge on felonies with respect to the statutes of the Act, and will review refusals to grant exemptions under several environmental statutes. However, objections dealing with pesticide registrations can only be appealed to the Government, and the justification of an ordinance, or of a regulation issued by a competent agency, can also not be challenged in an independent court of justice.

In Sweden, the Central Office for Government Auditing (Riksrevisionsverket) does perform assessments of government agencies, but these audits are mainly of fiscal character, and the agency's operation is not guaranteed independence from the government. Thus there exists no professional and independent body that is empowered to judge agency policy and performance. Professionally substandard agency performance can, therefore, easily pass unnoticed.

This lack of professional external scrutiny, combined with the small size of the chemicals sector, and strong anti-industry sentiment in important parts of the public sector, has encouraged over-zealous regulation of the chemicals industry in Sweden. This is almost perfectly demonstrated in the following example.

Some years ago, an application for registration was made of a pesticide containing a natural plant growth hormone, used in small quantities to stimulate root formation in cuttings of woody and ornamental plants. It is used for this purpose all over the world. The primary reason for not granting registration in Sweden for this simple amino acid derivative with an extremely low exposure potential, and involving a very small number of applicators was not potential health and environmental hazards, but that head of the Pesticide Division of the competent authority thought that the product was 'unnecessary'. From the point of view of 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. Since no health or environmental risks were at stake, 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.

The implementation of a common registration policy for the EU, which Sweden has been forced to accept, is actually most welcome from many points of view. KEMI clearly wants to avoid direct confrontation with EU, but persists in limiting the availability of pesticides by other means. One trick has been to classify virtually all pesticides that are mostly available to the general public in other European countries as class II products, meaning that they can only be used professionally. Annex VI on uniform principles for evaluation and authorisation of plant protection products concerns the Council Directive the placing of plant protection products on the market (91/414/EEC). Although it requires exposure assessment to be conducted (Section 2.4.) to provide a basis for a proper risk assessment, there are at the present no indications that the Swedish authorities intend to comply with these EU regulations when it comes to pesticide products intended for the consumer. Some pesticides that were banned in Sweden were subsequently subjected to joint EU evaluation and found to be acceptable. The head of the pesticides division of KEMI has publicly declared her intention to combat the reintroduction of such pesticides. Further, in practice, the Swedish general public is barred from using just about all effective pesticides, although a large number of practically safe products do exist for various areas of application. Faithful to its socialist traditions, the investments of billions of crowns by private Swedish homeowners in lawns, flowerbeds, rose-gardens, etc. lack protective value in the eyes of the Swedish State.

The withdrawal of a number of copper-containing anti-fouling paints for pleasure boats and marine vessels in the Baltic area based on alleged environmental hazards has led to a number of appeals to the Government. Our politicians who, no doubt, will uphold rulings – as well as the highly unpopular withdrawal of effective mosquito repellents – will then be appealed to the Commission and then further to the European Court of Justice, which will decide on these appeals.

The precautionary principle

Instead of developing a rational strategy for risk management based on good science, defining what is and what is not a significant risk, widespread 'chemophobia' is now tackled by using the so-called 'precautionary principle'. At first glance, this concept seems appealing. It makes sense to 'look before you leap'; after all it is 'better to be safe than sorry'. But it is important to distinguish justifiable precautionary action – based on sound science and an appropriate assessment of the costs and benefits of taking action – with unjustified precautionary action. The 'precautionary principle' fails to distinguish between the two, by elevating to the status of universal 'principle' a notion that is only narrowly applicable.

An example of justifiable precautionary action is the restrictions that were placed on the use of the sedative thalidomide by the US and East German regulators. Across the world, thalidomide (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. However, both the US FDA and the Drug Registration Authorities of what was then East Germany prevented the introduction of thalidomide. Both based their decisions on similar considerations. (Some have argued that the USA avoided the thalidomide disaster simply because FDA was too slow in processing the application from the manufacturer, Richardson-Merrell. This is not true.) Inadequate toxicological supporting documentation initially aroused doubts and suspicions. These were considerably strengthened by an alert, published December 31, 1960 (14 weeks after the application for regulatory approval was made to the FDA), that the drug induced polyneuritis, a side effect for which the documentation from the producers '..fails to make a frank disclosure…' (letter from FDA of May 5, 1961). Both the US and the East German agencies turned down the application for use of thalidomide during pregnancy. The President's Award for Distinguished Federal Civilian Service, made to Dr Frances Kelsey, the FDA official who played a decisive role in blocking approval of thalidomide, was well deserved.

Another example of justifiable precaution is the restrictions that were imposed in Sweden on emissions of certain cadmium compounds into the environment. These restrictions reversed a progressive build-up of the metal in topsoil, corn and human tissues, where kidney damage constitutes the end-point.

By contrast with these precautionary measures based on sound scientific evidence of genuine harm (and where the benefits arguably outweigh the cost), the broader 'precautionary principle' seems to have as many interpretations as the number of administrators that are now using it Sweden. When I recently asked one of our representatives working with the EU program on classification and labelling of chemical substances why Sweden always has to take the most extreme position towards the harshest possible classification, the answer was, 'the precautionary principle'.

This made me think about what the precautionary principle actually means in the regulatory context. I have not been able to find much of legal reference, and indeed very little that I believe would be of any help to a judge in a modern Court of Justice. In its comment of September 19, 2000 to the European Commission with respect to implementing this principle, the Economic and Social Committee (*Official J. Europ. Comm*., C 268/11)

> …notes that there are as yet few legal bases for a precautionary principle and that case law is still in its infancy. Further, explicit and implicit allusion to this principle does not provide a solid base, and the Economic and Social Committee would ask the Commission to submit a concrete and viable case soon.

The Committee also noted, that the precautionary principle seeks to extend what is known under public law as the 'policing powers' of the authorities, and that the implementation of this concept will have major implications at the international level in as much 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 EC Treaty.

It is no wonder that the Swedish Socialist Government loves the precautionary principle. Conceptually, it was already included in previous legislation and has rushed ahead of the European Community and introduced its own interpretation of this far-reaching principle in the new Swedish unified Environmental Code Act of 1998 (SFS 1998:811) that came into force in January 1999:

> 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.

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. For good reasons, the proposal for the new Swedish legislation was harshly criticised by many legal experts, including the Government's own legal council, and to avoid a complete paralysis of the Swedish society, the new Code does incorporate a clause calling for some kind of proportionality between action and the desired level of protection. Thus the use of the precautionary principle should 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, the main defect of the Swedish code and its accompanying explanations remains, inasmuch as there is no guidance to when 'there are reasons to believe' that damage or inconvenience to the environment will occur, or when 'it does not seem unreasonable to implement' the precautionary principle. In other words, what degree of certainty (or uncertainty) is required to trigger actions based on this vague principle.

A second serious shortcoming of the Swedish legislation is that the precautionary principle should be implemented, not only by the competent government authorities, but also by anyone who undertakes whatever kind of action that may have a potential impact on health or the environment. Obviously, most of these actors do not possess, and will never obtain, the scientific/technical competence required to undertake an adequate assessment to judge if the precautionary principle demands some type of action. When, for example, the purchasing departments of major retailers or the departments of the huge Swedish public sector, decide on product acquisitions, they are supposed to make an assessment of potential health and environmental hazards. In most cases they actually try to do so, but here they more or less completely rely on the so-called 'OBS-listan', a long list of potentially hazardous chemicals published by KEMI. The profile of hazardous agents included on the list differs widely, from decidedly harmful compounds like arsenic salts and benzene, to practically innocuous substances, like many zinc compounds. The latter should, of course, not be dumped in rivers in large quantities, but are perfectly safe in most other contexts. The list carries an explanatory section that encourages the user to make some sort of risk assessment if the substances on the list are to be used.

However, because the purchasing departments lack the competence to do this properly, and also because of the pressure to carry products with 'green labels' (supposedly environmentally 'safe'), they mostly refuse to buy any product that contains a chemical that has been included on the KEMI list. The overall result has been 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. The new Swedish unified Environmental Code Act will surely enhance this undesirable development. The argument promoted by the defenders of this policy is, of course, that the market has to improve its (eco) toxicological competence. Wishful thinking! Firstly, even the responsible government agency has only a handful of adequately trained experts suitable for this purpose. Secondly, in many cases when the producers have indeed been able to present a satisfactory risk assessment that substantially 'proves' their product to be 'safe' in spite of the fact that it contains a substance on the KEMI list, their arguments are rejected because 'industry cannot be trusted in such matters'.

The Precautionary Principle, the Substitution Doctrine and the Mosquito Repellents

Apart from its use as a justification for otherwise baseless bans or severe restrictions on the use of chemical products, the precautionary principle is used to justify the application of the so-called 'substitution doctrine'. Current Swedish legislation explicitly states that if a hazardous chemical product can be replaced by a less hazardous alternative, such a substitution must be carried out: the substitution principle.

Used with common sense this does not seem all that unreasonable. However, in the way the previous – and to some extent also the present – legislation has been implemented, almost any chemical product that fulfils certain criteria can be subjected to a ban or severe restriction, irrespective of the actual or projected level of risk.

Consider the example of the mosquito repellents. A number of excellent such substances were withdrawn on the basis of unsubstantiated claims that they were hazardous to health. They were subsequently replaced by considerably less efficient products, which were no doubt used in larger quantities in order to compensate for their inefficacy (or alternatively resulted in larger numbers of mosquito bites – an irritating thing even in a country without malaria and other mosquito-borne diseases).

Thus, bizarre consequences have resulted from the unfortunate combination of a reliance on the precautionary principle and the intrinsic properties (hazard) of a chemical. As Paracelsus pointed out in his treatise *Septem Defensiones,* written 1537–1538: any substance can elicit a toxicological response provided that the dose is sufficiently high when administered by an adequate route. (This is often paraphrased as 'the dose makes the poison.') To what extreme extent the substitution principle must be applied in Sweden is illustrated by the following excerpt from the Government's commentary to the substitution principle:

> The product substitution principle means, that although a harmful substance or product is permitted *per se*, it must be avoided or – provided that the user can obtain the desired result – replaced by one that is less hazardous or completely harmless. Everyone who uses a chemical product or a biotechnological agent must appraise if the same result can be achieved by using an alternative chemical product or biotechnological agent that is less hazardous or completely harmless.

That there is, of course, no such thing such as a 'completely harmless' chemical product except in the imagination of Swedish legislators and the eco-talibans of the green movement, is a frightening token of an absolute disregard for realities:

> It should be observed, that this rule does not only apply to professional sale and use. When a car owner is going to wash and clean his car and buys a detergent for this purpose 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.

When making this assessment, the poor car owner

> …must apply the precautionary principle in such a way that it takes not only factual risk into account, but also of the (potential) risk.

It is, of course, not even remotely possible that any Swede could be indicted on the grounds of having made the wrong choice when selecting a detergent at a gas station, but the principle as such provides guidance when, for example, issuing regulations based on the Environmental Code. It is also important for the local administrations in the context of regulatory control.

Based on what can be described as a mere pamphlet referring to a possible carcinogenic action based on rodent studies – scandalously meagre documentary support – Sweden introduced a total ban from 1996 for trichloroethylene (TRI). The European Commission, which was notified of the proposed regulation, pointed out to the Swedish Government on several occasions that the Commission considered this ban to be unjustified and in violation of Article 30 of the Treaty of Rome (Mario Monti, CEC, letter of October 9, 1996, to the Swedish Minister of Foreign Affairs). While referring to Article 36 of the EU Treaty, which permits national governments to introduce exemptions from the free movement of products between EU member states based on the necessity to protect human health, the Swedish Government insisted on upholding the ban. But in response to pressure from the Commission certain exemptions were granted. One small enterprise that was refused exemption by KEMI appealed to the first administrative county court ('Länsrätten') which reversed the decision by KEMI citing article 30 of the EU treaty. This Agency then appealed to the higher administrative court ('Kammarrätten'), and this court relegated the case to the European Court of Justice for guidance in the interpretation of the EU Treaty. After conducting hearings where the Government of Sweden was represented on the highest level, the Court pronounced its verdict in July this year (C-473/98; Kemikalieinspektionen and Toolex Alpha AB).

The court found that the Swedish regulations were in agreement with article 36 of the Treaty of Rome, and upheld the Swedish ban, noting that the Commission had not yet made use of its power to propose Community measures specifically relating to trichloroethylene, and that exemptions from the ban could, in principle, be obtained. That being so, the Court held that Community law did not prevent a Member State from regulating the industrial use of trichloroethylene. The fact that recent human epidemiological studies had strengthened the suspicions that TRI probably is carcinogenic for humans, obviously had a major impact on the court's decision, and explicit reference was made to the substitution principle as defined by the relevant Council Directives on occupational health (89/391/EEC of June 12 1989, and 90/394/EEC of June 28 1990).

However, the verdict is extremely unfortunate from many points of view. It is deplorable that industry interests did not seem to have been adequately supported by a competent legal council. Thus, I found no evidence that the lawyer representing the enterprise in question ever brought up the critical issue of the actual level of risk, which is necessary in order to be able to judge if the Swedish regulations were proportionate or not to the risks involved. Only a few cases of kidney cancer were found in Germany[1] as a result of massive exposures to TRI after World War II at a level that does not exist either in Sweden or in Germany nowadays. The Swedish competent authority for occupational health, which has publicly stated that the current threshold limit value of 20ppm for TRI provides adequate worker protection, was not even heard at the trial. At the hearings, the Swedish Government falsely stated, that the hygienic standards issued by the Swedish Occupational Safety and Health Agency, '…primarily dealt with short-term protection against trichloroethylene.' (The trichloroethylene trial; draft for statement at the hearing on February 8, 200; Working paper from the Department of Foreign Affairs, he EU Legal Secretariat). Furthermore, in Sweden as well as in all other EU member states, a number of much more potent carcinogens are regularly used under controlled conditions in the working environment. Of equal concern is the fact that the Court paid no attention to the principles laid down by the European Chemicals Bureau in its Guidance documents in support of the Commission Regulation on Risk Assessment for Existing Substances (EC 1488/94). This detailed document explicitly states that the margin of safety (MOS) shall be established for existing chemicals based on actual or predicted risks. Only if ambient or expected exposures approach the level at which harmful effects can be expected to occur, will there be reasons for regulatory action. Instead, the Court emphasised the difficulties in establishing the threshold above which exposure to TRI poses a serious health risk to humans, and said that

> there was no evidence in the case which would enable the Court to hold that national legislation such as the Swedish legislation goes beyond what is necessary to provide effective protection of the health and life of humans.

Given a competent legal council for industry, it would have been fairly easy to demonstrate that the Swedish regulations were totally disproportionate to the objective of protecting the worker's health.

The severe restrictions posed on the use of certain heavy metals in Sweden provide other examples of the misuse of the precautionary principle. During the last decades, the levels of lead in the blood of Swedish children has been steadily decreasing (Strömberg, U., Schuetz, A., and Skerfving, S. (1995) Substantial decrease of blood lead levels in Swedish children 1978-94, associated with petrol lead. *Occupat. Env. Med*. **52**, 764–769) as a result of the phasing out of leaded gasoline. They are now similar to those found in totally unpolluted regions, like the Himalayas (Piomelli, S., Corash, L., Corash, M.B., Seaman, C., Mushak, P., Glover, B., and Padgett, R. (1980) Blood lead concentration in a remote Himalayan population. *Science* **210**, 1135–1137).

Still, the Swedish regulators are resolutely determined to phase out items made of lead, such as automobile batteries, sinks for fishing, keels for sailing boats, etc. In June 2001, the Swedish Government notified EU and the World Trade Organisation (WTO) of its intent to ban the use of lead in shot and buckshot. Bullet ammunition containing lead may only be permitted on shooting ranges, under the condition that efficient retrieval of the used bullets can be guaranteed. This ban is also intended to include Olympic competitions as well as all military purposes. Similar future intentions have also been publicised with respect to all uses of cadmium, including recyclable accumulators. Now, cadmium is always present in zinc and is obtained as by-product from the purification of zinc. If no sensible use can be found for cadmium, the producers will simply let this heavy metal remain in the zinc, and the result will be an extensive and diffuse emission of cadmium from corroding zinc that will be impossible to control (R. Nilsson. (1989) *Cadmium – an Analysis of Swedish Regulatory Experience, Report to the OECD Chemicals Group and Management Committee*, January).

For reasons such as those presented above, it is my opinion that the precautionary principle as defined by the Swedish legislation is unacceptable. Not only does it open the sluices for capricious regulatory action, but it also introduces a factor of arbitrariness that disrupts the functioning of a free market as well as inevitably inhibiting sound technical development. Delegating use of the precautionary principle down to the lowest level of decision makers in society represents, in my mind, a cowardly and unacceptable behaviour of a government in a modern democracy. Through our elected Parliament, government agencies have been trusted with the duty to regulate product safety and restrict use of those products too hazardous to be permitted on the market – a duty that under normal circumstances should not be forced upon the individual citizen, or even on the purchasing office of a department store chain.

[1] (D. Henschler, S. Vamvakas, M. Lammert, W. Dekant, B. Kraus, B. Thomas, and K. Ulm. *Increase incidences of renal cell tumors in a cohort of cardboard workers exposed to trichloroethylene.* Arch. Toxicol. 69, 1995, pp. 291-299; T. Brüning, A.G.M. Sundberg, G. Birner, M. Lammert, H. Bolt, E.-L. Appelkvist, R. Nilsson, and G. Dallner. *Glutathione transferase α as a marker for tubular damage after trichloroethylene exposure.* Arch. Toxicol. 73, 1999 pp. 246-254)

In the proposal for new Swedish unified Environmental Code Act of 1998 to the Parliament, the Government repeatedly refers to the Rio Declaration of 1992. Now, how well does the Swedish interpretation actually agree with existing international concepts. Principle 15 states that:

> in order to protect the environment, the precautionary approach shall be widely applied by states according to their capability. 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.

Here, due consideration must be taken of the second sentence of Principle 15, 'where there are threats of serious or irreversible damage'. This puts considerable restraints on when the principle should be applied – an important qualifier that the Swedish legislators have completely ignored. This type of restraint is even more clearly spelled out for chemicals. Thus, under 'Management-related activities', Chapter 19 (Environmentally sound management of toxic chemicals including prevention of illegal international traffic in toxic and dangerous products) of Agenda 21, 'banning or phasing out' by regulatory action is reserved for 'toxic chemicals that pose an unreasonable and (emphasis added) otherwise unmanageable risk to the environment or human health and those that are toxic, persistent and (emphasis added) bio-accumulative and (emphasis added) whose use cannot be adequately controlled.' I have no problems whatsoever with such a definition of the precautionary principle with respect to chemicals.

When Swedish administrators are relying on the precautionary principle to motivate far reaching regulatory actions, they obviously rely on an interpretation that also differs from that of the legal experts of the European Community. The Economic and Social Committee described the precautionary principle as

> an approach to risk management applied to cases where there is an unknown and potentially dangerous risk – pending scientific findings at a later stage.

However, when this Committee, and also the Rio Declaration, mentions 'risks', these risks are of an entirely different level than envisaged by the Swedish interpreters of the precautionary principle. The view taken by KEMI has prompted it to withdraw the most effective mosquito repellents from the market and is trying to do the same with lead in ammunition and lead sinks for fishing. The Economic and Social Committee thus writes that: 'the contemporary risk indictor is the notion of disaster', and further that:

> Today, the nature of risks has changed, with a shift from accidents to disaster. These include natural and climate related disasters, technological disasters and, increasingly, disasters with an impact on health.

I do not think that even the most fanatical of my colleagues would consider it a disaster for humanity if we continue to use lead sinks for fishing nets, or that the classical mosquito repellent US 622 with a safe record for use all over the world, to be permitted.

It has been widely realised that acceptance of an extremist interpretation of the precautionary principle such as is used by the Swedish government, could obviously prove to be seriously disruptive for society. As a result, the European Commission intends to establish a common definition and specific guidelines for the application of this principle, 'so that each country is no longer able to prescribe a definition of its own' in the words of the Economic and Social Committee, which also concluded that:

> it is essential for the European Union to reach, if possible, an international consensus on arrangements for applying the precautionary principle.

Instead of delegating the implementation of the precautionary principle to the buyers of household detergents, the Economic and Social Committee of the Commission insists that

> 3.4. The precautionary principle is only the State's responsibility. Under this principle, the State must act in line with certain hypotheses. The precautionary principle also makes the State responsible for abstention of action.

Further

> 3.5. State action will apply to the decision-makers concerned, but it is not up to them to make the first move. That is in any case impossible given the vagueness of the precautionary principle. How can a decision-maker reasonably determine what constitutes a risk of serious damage, an effective and proportional measure or economically viable cost?

The Swedish legislation puts the whole burden of proof on the manufacturer, importer, vendor or even user, to demonstrate that suspicions that their product will cause a risk to man and the environment are without grounds. Although recommended in some situations, the Commission and its Economic and Social Committee both reject the use of a reversal of the burden of proof as a general principle.

To my mind, the precautionary principle should be given a central position in guiding legislation for the protection of man and the environment, but in a much more restricted sense than provided by the Swedish concept. In a manner of speaking, the responsible contemporary chemical industry has for quite some time endorsed, as well as implemented, several aspects of the precautionary principle. Clearly, the precautionary principle should only be applied when there are sufficient grounds to believe that a serious or irreversible damage to health and environment will occur. The first step of its implementation is to conduct a risk assessment, identifying available knowledge, and in case of data gaps, make reasonable assumptions given possible uncertainties. As stated by the Economic and Social Committee, this 'involves stepping up the drive to boost knowledge'. Measures based on the principle must be proportional to the chosen level of protection and therefore include a cost–benefit assessment with the intention of reducing the risk to an acceptable level. Further, the urgency for taking preventive measures must be demonstrated. Given the fact that triggering the principle is based on various degrees of uncertainty, it is also necessary that measures based thereupon are provisional. Last and not the least, measures adopted on the basis of the precautionary principle must be subject to legal redress according to Community law.

Alternative Means to Forward (Future? Develop?) Product Safety

Does my stark opposition to the Swedish interpretation of the precautionary principle mean that I think that those who produce or market a product should not have any responsibility for product safety? On the contrary, but there are other means at our disposal. Although not covering the protection of the ozone layer, in the US and some European countries, the existing legal framework for product damage litigation provides adequate safeguards against negligent marketing of hazardous products, as well as against misuse, where certain verdicts can be based on failure to follow the precautionary principle. In Europe this development has been considerably strengthened by EU-directive 85/374/EEC associated with strict liability. In the verdicts of Colona Laigneier/ Societé Pasteur Vaccins of April 4, 1997 as well as that of Armelle Jeanpert / La Societé SmithKline Beecham SA of June 5, 1995, the French courts applied strict liability with reference to this directive even for pharmaceuticals. Within the rule of law, arbitration by the courts ensures a reasonable measure of protection of legal rights. Unfortunately, Sweden has been very reluctant to implement the EU directive on strict liability, and in addition, the shockingly low levels of damages awarded to the victims do not constitute much of a deterrent. On the other hand, this could easily be amended by a much needed legal reform in this area, possibly including the introduction of punitive damages.

In the US, the US Toxic Substances Control Act (TSCA) of 1976 mainly defines regulatory action for chemicals. Pesticides are regulated separately through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The basis for intervention by the competent agency, USEPA, rests on 'the presence of an unreasonable risk of injury to health or to the environment' (TSCA, Sec. 6[a]).

No definition of the 'unreasonable risk' can be found in TSCA, but the House Report provides that, in general, such a consideration will involve:

> balancing the probability that harm will occur and the magnitude and severity of that harm against the effect of proposed regulatory action and the availability to society of the benefits of the substance and mixture.

USEPA must consider the availability of substitute chemicals and the adverse societal effects of the proposed action, but cannot base its actions on 'mere conjecture or speculation'. Section 6(a) of TSCA also provides that the Administrator must utilise the 'least burdensome' requirement necessary to adequately protect against risk. The Supreme Court's verdict in the case Industrial Union Department, AFL-CIO v. American Petroleum Institute, 444 US 607, 639-642 (1980) (benzene) provides a more concrete example of what constitutes a 'significant risk'. The court wrote:

> Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly cannot be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapours that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it.

Although I have not referred to the precautionary principle in US laws and regulations for chemicals, the restrictions imposed on CFCs for the protection of the ozone layer provide an example that in practice this principle can, and has been, implemented in the US. Further, the USEPA has relied on a number of precautionary assumptions in assessing health risks that have resulted in a highly conservative estimate of potential health risks. Sometimes this has resulted in highly exaggerated risk estimates, as has been the case for cancer risks from arsenic in drinking water

The Future

I sincerely hope that some kind of consensus can be reached at the Community level that could ensure a common interpretation of the precautionary principle that is based on sound principles. Although assessment of hazardous substances in the EU may not always represent the ultimate wisdom, the outcome will at least be competitively neutral with respect to industry and trade inside the community. The question remains, however, to what extent countries like Sweden and Denmark are in practice going to conform to Brussels on this issue.

It has been very discouraging, that since Sweden joined the EU – and in contrast to what is the case, for example, in Finland – an increasing number of people favour Sweden's exit from the Union. With the exception of trade and the export industry, resistance to EU is particularly strong among the lower social classes, especially in the northern part of Sweden, but is also prominent in the bloated Swedish public sector. Fierce EU antagonism is almost universal among the politically organised environmental movement and the previous communist party. Since these two parties at the present command sympathies from a sizeable part of the electorate, and with the dominating Social Democratic Party and the Center Party sharply divided over the membership issue, the future of Sweden as a full member of the Community is full of question marks. This unfortunate situation was reflected by the fact that a large number of prominent enemies of EU were elected as Swedish representatives to the European Parliament. Apart from serious economic consequences, canceling its EU membership will accelerate the ongoing marginalisation of Sweden among Western nations, where an increasing part of Sweden's industry opts to move its production base outside the country. The present socialist governments in the EU are more or less in league with the radical green movement. The recent announcement in the newspapers that the Blair administration will issue health warnings on mobile phones because of risk of radiation damage to children under 15, despite an inquiry which found no adequate evidence that mobile phones are harmful, unfortunately demonstrates that the misuse of the precautionary principle is no longer limited to Sweden. When the EU contemplates the general introduction of a principle that, depending on its manner of implementation, could adversely affect innovation within and the development of European industry, it would be highly appropriate to consider the situation within other large economies of the world, primarily USA and Japan, and in the near future China, while keeping in mind the future competitiveness of the Community.

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