



Science and norms in policies for sustainable development: Assessing and managing risks of chemical substances and genetically modified organisms in the European Union

Mikael Karlsson *

Department of Environmental and Energy Systems, Karlstad University, SE-651 88 Karlstad, Sweden

Received 12 October 2004

Abstract

Use of chemical substances and genetically modified organisms cause complex problems characterised by scientific uncertainty and controversies. Aiming at sustainable development, policies for assessment, and management of risks in the two areas are under development in the European Union. The article points out that both science and norms play a central role in risk assessment as well as risk management and suggests that the precautionary principle, the principle of public participation, and the polluter pays principle, all adopted in the European Union, offer a way to operationalise the concept of sustainable development. It is shown, however, that a number of steps ought to be taken to better implement the principles through different policy measures. In doing so, and by recognising the role of both science and norms, the decision-making on risks related to the use of chemicals or genetically modified organisms can be improved to better promote sustainable development.

© 2005 Elsevier Inc. All rights reserved.

Keywords: Science; Norms; Sustainable development; Risk management; Risk assessment; GMO; REACH; Precautionary principle; Public participation; Polluter pays principle

1. Introduction

Science describes the world; politics govern it. Scientific knowledge is just one of two fundamental components of policy making. What is right and wrong, desired or undesired, cannot be judged on the basis of science alone. In politics, norms based on values are also central. When scientific facts are clear and norms are homogenous, political decision-making is a rather easy task. With plural values, decisions are harder to make, but still manageable through ordinary processes in democratic political systems. However, when diverging values cause controversy or conflict, and when key facts simultaneously are under dispute,

or even completely missing, the complicated situation arisen requires special attention and management.

Such complex situations are not seldom a starting point in contemporary environmental policy-making. As will be shown, this is true for the management, aiming at sustainable development, of chemical substances and genetically modified organisms (GMOs) in the European Union, where a number of complex problems, related to scientific uncertainty and diverging values, can be identified.

In the following, the two problem domains of chemical substances and GMOs will be described and characterised. The meaning of the objective of sustainable development will be analysed, framing a background against which present, and emerging EU policies for risk assessment and risk management of chemical substances and GMOs will be analysed. The paper ends with a comparison of the two areas, and a discussion on norms and science in policies for sustainable development.

* Fax: +46 8 702 08 55.

E-mail address: Mikael.Karlsson@snf.se.

2. Chemical substances, genetically modified organisms, and complex risks

The experiences following more than half a century of use of man-made chemicals are divided. On the one hand, the benefits for society at large have been enormous. Production and use of chemicals play an indispensable role in, e.g., agriculture, medicine, industry, and for the daily welfare of citizens. On the other hand, the use of many chemicals has caused severe problems due to their toxic or otherwise ‘hazardous’ properties, such as persistence and liability to bioaccumulate.

Adverse effects of already regulated hazardous substances prevail. For example, the levels of chlorinated hydrocarbons in oceans and marine biota are still high enough for authorities in the European Union to recommend or issue food restrictions for pregnant women (SNFA, 2004) and for the population at large (EC, 2001a). In the USA, PCB-levels in fishes in the Great Lakes are high enough to cause adverse health effects, such as impaired memory, among consumers with high fish consumption (Schantz et al., 2001). Remediation costs for hazardous substances are often high. The total remediation and waste management costs for PCB in Sweden during the period 1971–2018 has been estimated to 380–480 million euro, health and environmental costs uncounted; the corresponding figure for the whole EU is 15–75 billion euro (NCM, 2004).

In addition to this, new problems are recognised. This is partly due to re-evaluations of earlier risk assessments, such as when the US National Research Council in 2001 considered arsenic in water five to ten times as carcinogenic as earlier thought (NRC, 2001), but also follows from completely new assessments of existing and new chemicals. In the European Union, for example, the use and the effects of single phthalates (such as DEHP) and brominated flame retardants (such as deca-BDE) are under scrutiny, and new regulations are being developed or imposed (ECB, 2004). Nevertheless, most substances in the European Union have not been assessed at all for their health and environmental risks (Allanou et al., 1999). As a result, a proposal for a new regulatory framework for registration, evaluation, authorisation and restrictions of chemicals (REACH) has been presented in the European Union (European Commission, 2003). This proposal is at present the most disputed element of EU chemicals policy and has given rise to an infected debate in more or less all relevant political fora (European Commission, 2001a, 2002, 2003; Scott and Franz, 2002; US House of Representatives, 2004).

Compared with the use of man-made chemicals, releases of GMOs is a relatively recent activity, even though the global area planted with genetically modified (GM) plants is increasing fast (James, 2003). Just as for chemicals, the risks are difficult to assess, and the debate on how to manage them is contested. On the one hand, proponents claim limited risks and large benefits for, e.g., agriculture, environmental protection, and global food security (Heap,

2003; Persley, 2000). On the other hand, and in contrast to the debate on chemicals, critics point not only at risks, but also question the benefits (Murray, 2003; Nestle, 2003). EU consumers in general seldom claim any benefits and feel on the contrary exposed to different risks (Bucchi and Neresini, 2004; Gaskell et al., 2003). The health and environmental risks of GMOs can be structured in three groups.

First, adverse effects can be caused by toxic or otherwise hazardous properties of a GMO, if humans or other organisms eat or in other ways are exposed to the GMO, or products released or derived from it. For instance, GM food may cause human allergies (Nestle, 2003), and insect resistant plants may affect non-target organisms and thereby decrease biodiversity (Groot and Dicke, 2002). Second, GMOs with a relatively high fitness can spread in the environment, or their genes can be transferred to other organisms, which may cause unwanted environmental changes. An escaping GM fish with strengthened growth capacity could illustrate this potential problem (Howard et al., 2004). Third, the use of GMOs can cause adverse environmental effects through altered practises in agriculture. One example is that cultivation of herbicide tolerant GM crops, through altered use of herbicides, has been shown to decrease weed to such an extent that, e.g., non-target organisms, such as birds dependent on weed seeds, may be negatively affected (Firbank et al., 2003).

In addition to effects on health and the environment, wider socio-economic harm may follow use of GMOs. One obvious example is the millions of US dollars in liabilities that a company had to pay when its so called ‘Starlink corn,’ permitted by US EPA for feed but not for food, unintentionally was spread in the food chain in the USA and other countries (Nestle, 2003).

The debate whether GMOs cause benefits or costs (or both) is contested. Against this background, and due to health and environment concerns, EU decision-makers upheld a moratorium for commercial releases of GMOs for some years and still block some decisions. As a result, the legislation on GMOs has been reformed (Karlsson, 2003a). Comprehensive risk assessments are nowadays required by law but still their validity is subject to debate (Smith, 2004), not least concerning how to interpret uncertainties, which is a partly normative, partly scientific question. Science and values are integrated in the argumentation regarding uncertainties.

As shown, use of both chemicals and GMOs cause highly complex risks, characterised by scientific uncertainty and controversies. Policy regimes for assessing and managing risks in the two areas are in place or under development in the European Union. The new legislation aims at promoting sustainable development. In the following, the meaning of this objective will be analysed and operationalised.

3. Operational principles for sustainable development

The concept of sustainable development is a cornerstone in international politics, something that was manifested at

the United Nations World Summit for Sustainable Development in Johannesburg 2002 (United Nations, 2002). In the European Union, sustainable development is stated in primary law as an objective for the union (EU, 1997), and a strategy for achieving the objective has been elaborated (European Commission, 2001b). In EU and elsewhere, the concept is often interpreted with reference to the World Commission on Environment and Development, meaning that ‘the needs of the present’ should be met ‘without compromising the ability of future generations to meet their own needs’ from environmental, economic, and social perspectives (WCED, 1987). This implies a moral duty to develop the society with a much stronger emphasis on improving the state of the environment, as well as socio-economic and environmental living conditions for present and future generations. For the sake of clarity, scientific findings are naturally of highest importance when elaborating and implementing policies for sustainable development, but nevertheless sustainable development is a wide-reaching normative concept, not a scientific one.

Many attempts to operationalise the concept take a restricted view and focus on ‘nature as such’ or ‘relationships between man and nature,’ such as preservation of certain environmental components (e.g., biodiversity), a specified state of the environment (e.g., limit values for pollutants), or preferable use of resources (e.g., maximum sustainable yield) (Karlsson and Ljung, 2001). Science is a given cornerstone in such estimations, but when finally deciding on what is to consider desirable or acceptable, norms always play the central role. To some extent of course, values influence the scientific work, and vice versa, but still, science has no decisive role in policy issues.

Compared with the full meaning of sustainable development, the just mentioned interpretations ignore important aspects. In cases of high scientific uncertainty, estimating, and deciding, for instance, which limit values that are suitable for humans and other species is difficult and in many cases even impossible. The number of miscalculations during the last century, resulting in severe environmental risks and problems, has been quite high, for example, when it comes to hazardous chemicals (Harremoës et al., 2001). Further, such interpretations of sustainable development tend to overlook the fact that management of environmental risks often is very controversial, as is the case for, e.g., genetically modified organisms.

Recognising uncertainty and controversy, which follow use of chemicals or GMOs, sustainable development might better be operationalised in terms of relationships *within* social systems, rather than as relations *between* humans and nature. Without neglecting the high value of science, such a perspective emphasises the normative character of the objective of sustainable development, and underlines that it has high relevance for structures and processes in social systems. When managing risks under uncertainty and controversy, aiming at sustainable development, three important questions arise: how should the uncertainty be interpreted and managed? Who should do the interpreta-

tion and decide on management strategies? How should the responsibility for the management be distributed?

Answers are offered by three commonly accepted principles in environmental policy, namely the precautionary principle, the principle of public participation, and the polluter pays principle, all adopted by the international community as well as in the European Union (EC, 1997; UNCED, 1993). These normative principles offer a way to further operationalise the significance of the environmental, social and economic dimensions of sustainable development, and will be further elaborated in the following.

First, precautionary decisions have been taken in environmental policy since long (Karlsson, *in press*). An often-referred formulation of the precautionary principle is found in principle 15 of the *Rio Declaration* (UNCED, 1993). This version is relatively weak though, since it merely discredits lack of scientific proof as an argument for stalling prevention. Most binding environmental agreements stipulate a more strict interpretation, namely that ‘if there is a threat, which is uncertain, then some kind of action is mandatory’ (Sandin, 1999). Even though several detailed questions follow from this formulation, it is evident from the background above, that use of GMOs as well as chemical substances invokes.

A number of aspects regarding the interpretation of uncertainty in risk assessment and management follow from the principle (Karlsson, *in press*). To decrease uncertainty, strengthened research is important regarding direct as well as indirect and long-term effects. Under uncertainty, one question concerns what degree of “proof” that is required for decision-making. In science, an adequate bias often says that it is better to miss one true cause–effect relationship, than to interpret a false phenomenon as true. In precautionary decision-making, however, the probability of failing to conclude a true phenomenon should be minimised. In doing so, the burden of proof ought to rest with the operator concerned, and not with the regulator. Further, the principle triggers substitution when less uncertain and less hazardous ways of reaching an objective are at hand. Other measures, such as prohibitions, may also come in question. When deciding on a specific management measure, the principle challenges the ambition to maximise expected utility, and gives preference to rather choose alternatives that, based on estimations and not only quantified probabilities, causes least possible loss if realised (the so-called ‘maximin-rule’), an idea advocated by, e.g., Rawls (1971), and elaborated by, e.g., Hansson (1997).

The second principle, regarding public participation, implies that citizens and the civil society have a right to take part in both risk and uncertainty assessment processes as well as decision-making on risk management. The principle is underlined in the *Rio Declaration* and *Agenda 21* (UNCED, 1993), and is a central pillar in the so-called Aarhus Convention (UN ECE, 1998), the latter presently step by step being incorporated in EU law (see e.g., EC, 2003a).

Public participation provides a mean for risk assessment and risk management processes to better encapsulate all three dimensions of sustainable development. It also enables decision-makers to better understand both diverging interpretations of uncertainty and the underlying values held by different stakeholders, thereby providing them with means to make better informed decisions (Karlsson, 2003b). Further, a participatory process empowers citizens to influence the development, gives legitimacy to the values they hold, and stimulates activity and involvement. It may thereby reduce controversies and contribute to restore trust in science among the public. Several methods for public participation have been developed and applied, such as public hearings and laymen participation in different forum (SBC, 2002; UN ECE, 2000).

The third principle for sustainable development, the polluter pays principle, concerns the distribution of costs and the ultimate polluter's responsibility to 'pay' for, e.g., environmental costs. The principle has for decades been a cornerstone in OECD policy (OECD, 1972) and can be found in the *Rio Declaration* (UNCED, 1993). In the EC treaty, the principle is laid down as an obligation for the polluter to cover costs for mitigating measures, as well as costs encountered by people facing remaining pollution, once mitigation has taken place (EC, 1997). According to neo-classic economic theory, the implementation of the principle internalises external costs and directs development towards increased socio-economic efficiency (Pigou, 1920).

The polluter pays principle can be operationalised by setting technical standards, such as requiring best available technology, through charging environmental taxes and fees for pollution or preventive work (such as supervision and risk-related research), or by implementing liability and insurance systems.

Since use of chemicals as well as GMOs causes complex risks, the principles, and operational tools just described might give guidance for policies in the area. In the following, the present regulatory regimes for each problem domain will be described and analysed in relation to the three principles of sustainable development.

4. Present and emerging risk policies for chemical substances in the European Union

When it comes to assessing the effects on man and nature of chemical substances, uncertainty is a key obstacle, and unexpected effects have, therefore, been rather common during the last decades (Harremoës et al., 2001). In the European Union, the so-called existing substances, i.e., those reported to be on the market before September 18 in 1981, which largely have unknown inherent properties (Allanou et al., 1999), have been target for a risk assessment process for some years (EEC, 1993). Out of more than 100,000 existing substances, however, less than 100 have been completely assessed (ECB, 2004). Evidently, the process is very slow. Regarding risk assessment of so-called new substances, the regulation in place functions better,

even though critique has been raised about, e.g., lack of flexibility regarding assessment of exposure differences (European Commission, 2001c).

With some exceptions, such as accidents with chemicals, risk assessments are limited to cases where chemicals are handled under normal use. The assessment of new and existing chemical substances consists of several steps, mainly (a) hazard identification, (b) dose–response assessment, (c) exposure assessment, and (d) risk characterisation. Risk is characterised as the ratio of estimated ordinary (or worst-case) exposure levels, and levels estimated to be harmful. An assessment thus compares “predicted environmental concentrations” with the “predicted no effect concentration,” as well as the “no observed effect level” or the “lowest observed effect level” with ordinary exposure levels (European Commission, 1993, 1994).

The assessments are carried out by experts in authorities through relatively standardised methods without always considering specific environmental circumstances. In the process, science delivers fundamental knowledge, but questions regarding, e.g., what endpoints to study, and what degree of evidence to consider conclusive are ultimately given normative (but scientifically based) answers. It has been shown that the so-called objective risk assessments are all but objective (Rudén, 2002), but the factual subjectivity of experts is seldom officially admitted.

In the presently applicable directives and regulations that govern the risk assessment, the precautionary principle is not acknowledged at all, and the public is not generally able to participate, even though some Competent Authorities have formal or informal reference groups for risk assessments, in which different stakeholders occasionally may participate. Neither is the polluter pays principle implemented, since authorities (i.e., the taxpayers and not the polluters) in general must cover large costs for assessing substances.

Turning to the management of chemical substances, the general stipulation to show unacceptable risks in formalised assessments based on comprehensive scientific findings before regulatory decisions on, e.g., restrictions of a chemical may be taken (European Commission, 2001c), hampers precautionary risk management. Substances not scientifically proven to have toxic properties, i.e., are causing cancer, mutations or reproductive effects in, e.g., animal experiments, are normally not considered a case for restrictions, not even when there is scientifically based suspicion of problems (such as when substances are persistent and bioaccumulative). This is particularly problematic since risk assessments hardly consider, e.g., interactions between different stress factors, such as synergetic effects. Persistent and bioaccumulative substances are generally not considered a problem under present chemicals law, in spite of strong scientific support that chemicals having those properties often cause severe problems (CNC, 2000). By in this way ignoring that uncertainty about inherent properties and exposure routes is rather a rule than an exception, risk management is attributed with inefficiencies and ineffective-

ness. Thus, the legislative norms set by politicians may actually hinder them to protect public health and the environment, except in rare cases of high scientific certainty.

In addition, the public is not able to participate in decision-making on management regimes, and has a low trust, when it comes to environmental problems, for business and political institutions (EORG, 2002). The polluter pays principle is not implemented, since most environmental costs are not at all internalised.

These and other problems are the underlying rationale for the present and contested attempts in the EU to develop a new chemicals policy. In what follows, these new approaches will be analysed through the lens of the three principles of sustainable development.

The emerging REACH policy explicitly states that the precautionary principle should be applied and places the burden of proof with operators. However, stringent requirements will continue to apply for restricting the use of a chemical, thus contradicting the precautionary principle. In the REACH proposal (European Commission, 2003), besides carcinogenic, mutagenic, and reproduction-toxic substances, ‘very’ persistent and ‘very’ bioaccumulating substances will be targets for authorisation. On the one hand, this increases the number of hazardous substances that are considered a target for further management. On the other hand though, these substances are supposed to be granted a permit through an authorisation process if a producer can show that each substance in question is “adequately controlled” or beneficial from a socio-economic point of view (European Commission, 2003). However, any socio-economic analysis on chemicals meets the problem on how to weigh regulatory costs in the short run against health and environmental benefits in the long run something being impossible in cases of high uncertainty and not in line with the ‘maximin-rule.’ The authorisation concept in REACH is, therefore, hardly compatible with the precautionary principle. Further, substitution is not a mandatory element of the proposal (even though the idea is vaguely acknowledged), which means that a hazardous substance might be permitted, even though there are better alternatives at hand.

To better cope with the complexity, a number of legislative amendments could be made to implement the precautionary principle (Karlsson, *in press*). Regulators should be free to base decisions on findings less conclusive than full scientific evidence. Unknown substances in a specific group of chemicals could be classified in the same manner as the most hazardous chemical in that group. Inherent properties should be given a stronger weight in such classifications. Once a classified substance has been considered hazardous and subject to further management, the question arises how and to what extent to manage it. Here, potentially toxic, or persistent and bioaccumulative substances should be considered a target for substitution or phase-out. Legislative proposals along these lines have been presented elsewhere (CNC, 2000).

Looking at participatory management, the on-going (October, 2004) so-called Extended Impact Assessment of REACH has been set up by the European Commission, with a strong role for of the chemicals industry, but without enabling the civil society organisations to really participate in the process (WWF and EEB, 2004). This is just one example showing that the principle of public participation hardly can be said to have been satisfactorily implemented.

Concerning the polluter pays principle, environmental taxes, and liability regimes are neither in place at present nor proposed for the near future. The new EU directive on environmental liability (EC, 2004) gives exceptions for authorised activities. In the same manner, as soon as a producer has fulfilled his obligations under REACH, e.g., once a substance has been authorised, the so-called duty of care is considered fulfilled and liability claims can never be raised, regardless of the magnitude of any negative consequences in case of unexpected harm. The proposed system does thereby not implement the polluter pays principle.

5. Risk policies for genetically modified organisms in the European Union

The EU policy on genetically modified organisms has undergone a reform during the last years. A new directive on deliberate release of GMOs has entered into force (EC, 2001b), and regulations on, e.g., labelling and traceability have been developed and implemented (EC, 2003b,c). In what follows, the new GMO regime will be analysed in relation to the three principles of sustainable development.

As for chemicals, risks of GMOs are often difficult to assess. While a GM potato for industrial use, grown in an area with few wild or cultivated relatives, would be relatively easy to assess, such circumstances are exceptional. Often, genes are spread by pollen or in other ways, and quite many of the modified properties are potentially problematic. Uncertainty is high. When it comes to formal risk assessments of GMOs, an operator is required to establish the assessments on a case by case basis. Of particular importance are (1) the characteristics of a GMO that may cause a number of different adverse effects, (2) the magnitude of each such effect if realised, and (3) the likelihood of the realisation of each effect. A key question is the probability itself of an adverse effect. Nowadays, the required scope of the risk assessment is rather wide, where direct and indirect effects on health and environment that might follow, e.g., of deliberate release should be considered. Unlike the situation when assessing chemical substances, risk is here understood as the product of the magnitude of adverse effects, and the probability of those effects happening at all (Steinhäuser, 2001).

The deliberate release directive (EC, 2001b) states explicitly that the precautionary principle must be taken into account, but does not specify any clear implication of the principle (Karlsson, 2003a). The burden of proof rests with an operator when applying for the required permit for a release and the operator must always submit a notifi-

cation including a risk assessment. However, if a Member State demands a stricter management of an already authorised GMO, it must scientifically prove that unacceptable risks are at hand, a stipulation not compatible with the precautionary principle. Further, no reference is made to substitution at all. Concerning hazardous inherent properties though, the directive sets final dates when genes coding for resistance to antibiotics should be phased-out from market and other kinds of release, but only as long as they may have adverse effects. Scientifically based guidelines with a much wider focus on inherent properties of GM crops have been presented (ACRE, 2000) and could serve as a guide for further development of the EU legislation in line with the precautionary principle.

Concerning public participation, the understanding of environmental and socio-economic consequences following use of GMOs is of course subject to not only laymen's, but also experts' values. By acting as if assessments were completely objective, the values of experts will often be given too much weight, and the values held by the public might be neglected. A complementary approach to traditional risk assessments dressed in scientific and quantifiable terms would be for authorities to actively invite people to express their value-laden views on GMOs and risk policies. Such an effort could reduce the tendency to overlook wider ethical issues related to the three dimensions of sustainable development, and could also help to restore trust in science and scientific expertise. The new directive opens for consultation of the public to some extent, but the implementation is up to each Member State to manage. Nothing of course restricts Member States from applying extensive participatory decision-making on releases of GMOs, but so far the record is not very impressive, even though some improvements can be seen, such as the Farm-Scale Evaluations in the UK (SBC, 2002). Nevertheless, public participation seems, in general, to stop at information on websites and labelling of GMOs, which is hardly to consider adequate.

Finally, when it comes to the polluter pays principle, the directive on environmental liability (EC, 2004) will not have any meaning when it comes to ordinary use of GMOs, since it gives exceptions for authorised activities, among them permits for deliberate releases of GM crops. No other tools have been applied to implement the polluter pays principle in general.

6. Concluding remarks

Use of chemical substances as well as genetically modified organisms gives rise to similar kinds of complex problems characterised by uncertainty and controversies. That said, however, a number of differences can be pointed out. While the debate on GMOs is partly focused on whether or not there are any benefits or costs at all, the dispute over the REACH proposal seems to be concentrated on how large costs and benefits are. In all these deliberations, both scien-

tific knowledge and values held by different stakeholder play a role.

Concerning risk assessment, the key principles underlying the processes set up for chemicals and GMOs, respectively, differ. This might be explained by unjustified traditional, as well as substantial technical reasons; an example of the latter is that the number of chemicals on the market is about a thousand times higher than the number of marketed GMOs. Notice though in both cases, that even though risk assessments build on scientific methods, the endpoints considered relevant to study, and the way to interpret findings and uncertainty, follow from normative decisions, i.e., from a specific policy regime. As shown above, however, neither assessment regime is designed to fully implement the three principles of sustainable development.

As regards the management of risks, there are also similarities and differences. In chemicals policy, the idea to increasingly base management on inherent properties (such as persistence and capacity to bioaccumulate) and less on proven risk is gradually receiving increased attention, something that can be seen in the REACH proposal. For GMOs, however, inherent properties are in general not targets as such in the present regulations. Here, a lesson might be learned from decades of problematic use of chemicals: inherent properties matter and may well form a basis for amendments of the directive on deliberate release of GMOs. On the other hand, the management of GMOs seems to offer better possibilities for the public to participate. When it comes to the idea that the polluter should pay, neither management regime implements the principle. As for risk assessment, it can be concluded that the three principles are far from fully implemented in the risk management systems.

To conclude, there are substantial shortcomings in both policy areas in relation to the objective of sustainable development. In coping with the complexities in each problem domain, implementation of the proposed principles of sustainable development could increase the chances that use of chemicals and GMOs increase environmental and socio-economic gains, and simultaneously decrease risks for health and the environment.

These proposals are of course normative. But so are all ideas on policy. There is no such thing as scientific policies or scientific legislation. Science (not sound science, which is tautological) is good, and getting better and better, in describing the world, including the risks and problems of GMOs and chemicals. Nevertheless, decisions in society are made in democratic processes, in which stakeholders interpret uncertainty and scientific information in relation to norms that reflect values, altogether hopefully for the benefit of man and nature.

Policies that recognise complexity and the importance of both norms and science, by implementing risk assessment and risk management regimes that are based on the principles discussed, will more likely than present risk policies promote sustainable development.

Acknowledgment

The author thank Hanna Karlsson for valuable comments on earlier drafts of this article.

References

- ACRE, 2000. Best Practice in GM Crops Design. Advisory Committee on Releases to the Environment, Department for Environment, Food and Rural Affairs, London.
- Allanou, R., Hanse, B.G., van der Bilt, Y., 1999. Public availability of data on EU high production volume chemicals. European Chemicals Bureau, Institute of Health and Consumer Protection, Joint Research Centre, European Commission, Ispra.
- Bucchi, M., Neresini, F., 2004. Why are people hostile to biotechnologies. *Science* 304, 1749.
- CNC, 2000. Non-Hazardous Products—Proposals for Implementation of New Guidelines on Chemicals Policy, Committee on New Guidelines on Chemicals Policy (CNC), SOU 2000:53. Fritzes, Stockholm.
- EC, 2004. Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on Environmental Liability with Regard to the Prevention and Remedying of Environmental Damage. *Official Journal of the European Communities L* 143, 56–75.
- EC, 2003a. Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 Providing for Public Participation in Respect of the Drawing up of Certain Plans and Programmes Relating to the Environment and Amending with Regard to Public Participation and Access to Justice Council Directives 85/337/EEC and 96/61/EC. *Official Journal of the European Communities L* 156, 17.
- EC, 2003b. Regulation (EC) 1830/2003 of the European Parliament and of the Council of 22 September 2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC. *Official Journal of the European Communities L* 268, 24.
- EC, 2003c. Regulation 1829/2003/EC of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed. *Official Journal of the European Communities L* 268, 1.
- EC, 2001a. Council Regulation 2375/2001/EC of 29 November 2001 Amending Commission Regulation 466/2001/EC Setting Maximum Levels for Certain Contaminants in Foodstuffs. *Official Journal of the European Communities L* 321, 1.
- EC, 2001b. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC. *Official Journal of the European Communities L* 106, 1.
- EC, 1997. Treaty Establishing the European Community. *Official Journal C* 340, 173–308.
- ECB, 2004. ECB Newsletter 2:04, 6 July, 2004. European Chemicals Bureau, Institute of Health and Consumer Protection, Joint Research Centre, European Commission, Ispra.
- EEC, 1993. Council Regulation 793/93/EEC of 23 March 1993 on the Evaluation and Control of the Risks of Existing Substances. *Official Journal of the European Communities L* 84, 1.
- EORG, 2002. Eurobarometer 58.0. The attitudes of Europeans towards the Environment. The European Opinion Research Group (EORG), for the Directorate General Environment, Brussels.
- EU, 1997. The Consolidated Version of the Treaty on European Union, Article 2. *Official Journal C* 340, 173–308.
- European Commission, 2003. Proposal for a Regulation of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), Establishing the European Chemicals Agency and Amending Directive 1999/45/EC and Regulation (EC) on Persistent Organic Pollutants. COM (2003) 644.
- European Commission, 2002. Minutes of the Conference on the Business Impact of New Chemicals Policy, 21 May 2002, ENTR/E3/Se. European Commission, Brussels.
- European Commission, 2001a. Stakeholders' Conference on the Commission's White Paper on the Strategy for a Future Chemicals Policy, Brussels, April 2, 2001. European Commission, Brussels.
- European Commission, 2001b. Communication from the Commission. A Sustainable Europe for a Better World: A European Union Strategy for Sustainable Development. The Commission's proposal to the Gothenburg European Council. COM (2001) 264.
- European Commission, 2001c. White Paper on a Strategy for a Future Chemicals Policy. COM (2001) 88.
- European Commission, 1994. Regulation 1488/94/EC of 28 June 1994 Laying Down the Principles for the Assessment of Risks to Man and the Environment of Existing Substances in Accordance with Council Regulation 793/93/EEC. *Official Journal of the European Communities L* 161, 3.
- European Commission, 1993. Directive 93/67/EEC of 20 July 1993 Laying Down the Principles for Assessment of Risks to Man and the Environment of Substances Notified in Accordance with Council Directive 67/548/EEC. *Official Journal of the European Communities L* 259, 10.
- Firbank, L.G., Perry, J.N., Squire, G.R., Bohan, D.A., Brooks, D.R., Champion, G.T., Clark, S.J., Daniels, R.E., Dewar, A.M., Haughton, A.J., Hawes, C., Heard, M.S., Hill, M.O., May, M.J., Osborne, J.L., Rothery, P., Roy, D.B., Scott, R.J., Woiwod, I.P., 2003. The Implications of Spring-Sown Genetically Modified Herbicide-Tolerant Crops for Farmland Biodiversity: A Commentary on the Farm Scale Evaluations of Spring Sown Crops. Department for Environment Food and Rural Affairs, London.
- Gaskell, G., Allum, N., Stares, S., Bauer, M.W., Lindsay, N., Brocklehurst, M., Wagner, W., Torgersen, H., Kronberger, N., Grabner, P., Jelsøe, E., Mortensen, A., Lassen, J., Kamara, M.W., Rusanen, T., Rusanen, M., Boy, D., de Cheveigne, S., Bardes, J., Chervin, J., Hampel, J., Kohring, M., Matthes, J., Sakellaris, G., Chatjouli, A., Allansdottir, A., Matteuci, F., Midden, C., Meijnders, A., Gutteling, J., Nielsen, T.H., Berg, S.F., Twardowski, T., Przystalski, A., Jesuino, J., Diego, C., Fjæstad, B., Ohman, S., Olofsson, A., Bonfadelli, H., Dahinden, U., Leonarz, M., Einsiedel, E., Downey, D., Eyck, T.T., Priest, S., 2003. Europeans and Biotechnology in 2002. Eurobarometer 58.0, second ed. A Report to the EC Directorate General for Research from the Project Life, Sciences in European Society.
- Groot, A.T., Dicke, M., 2002. Transgenic Crops in an Agro-Ecological Context: Multitrophic Effects of Insect-Resistant Plants. Laboratory of Entology, Wageningen University.
- Hansson, S.O., 1997. The limits of precaution. *Found. Sci.* 2, 293–306.
- Harremoës, R., Gee, D., MacGarvin, M., Stirling, A., Keys, J., Wynne, B., Guedes Vaz, S., 2001. Late Lessons from Early Warnings: The Precautionary Principle 1896–2000. Environmental issue report No. 22. European Environment Agency, Copenhagen.
- Heap, B., 2003. GM crops and the third world, In: Ford, B.J. (Ed.), *GM Crops. The Scientists Speak. Proceedings of the 2002 Cambridge Conference on Genetically Modified Crops and Food* organised by the Cambridge Society for the Application of Research. Rothay House, Cambridge.
- Howard, R.D., DeWoody, J.A., Muir, W.M., 2004. Transgenic male mating advantage provides opportunity for Trojan gene effect in a fish. *Proc. Natl. Acad. Sci. USA* 101, 2934–2938.
- James, C., 2003. Preview: Global Status of Commercialized Transgenic Crops, 2003. ISAAA Briefs No. 30. ISAAA: Ithaca, NY.
- Karlsson, M., in press. The precautionary principle, Swedish chemicals policy and sustainable development. Accepted for publication in the *J. Risk Res.*
- Karlsson, M., 2003a. Biosafety principles for GMOs in the context of sustainable development. *Int. J. Sust. Dev. World* 10, 15–27.
- Karlsson, M., 2003b. Ethics of sustainable development—a study of Swedish regulations for genetically modified organisms. *J. Agric. Environ. Ethics* 16, 51–62.
- Karlsson, M., Ljung, M., 2001. Understanding Conditions for Sustainable Development: A Complementary View for Successful Realisation. In: *Proceedings from the 2001 International Sustainable Development Research Conference*, 5–6th April 2001 at University of Manchester, UK. ERP Environment, Shipley, pp. 126–133.

- Murray, D.R., 2003. *Seeds of Concern. The Genetic Manipulation of Plants*. University of New South Wales Press Ltd., Sydney.
- NCM, 2004. Cost of Late Action—The Case of PCB. *TemaNord* 2004:556. Nordic Council of Ministers (NCM), Copenhagen.
- Nestle, M., 2003. *Safe Food. Bacteria, Biotechnology and Bioterrorism*. University of California Press, Berkely.
- NRC, 2001. *Arsenic in Drinking Water: 2001 Update*. Subcommittee to Update the 1999 Arsenic in Drinking Water Report, Committee on Toxicology, Board on Environmental Studies and Toxicology, National Research Council (NRC). National Academy Press, Washington.
- OECD, 1972. *Recommendation of the Council on Guiding Principles Concerning the International Economic Aspects of Environmental Policies*. C(72)128.
- Persley, G.J., 2000. Agricultural biotechnology and the poor: promethian Science. In: Persley, G.J., Lantin, M.M. (Eds.), *Agricultural Biotechnology and the Poor*. US National Academy of Sciences and CGIAR, Washington, pp. 3–21.
- Pigou, A.W., 1920. *Economics of Welfare*. Macmillan and Co, London.
- Rawls, J., 1971. *A Theory of Justice*. Oxford University Press, London.
- Rudén, C., 2002. *From Data to Decision*. Doctoral Thesis. The Institute of Environmental Medicine, Karolinska Institutet, Stockholm, Sweden.
- Sandin, P., 1999. Dimensions of the precautionary principle. *Hum. Ecol. Risk Assess.* 5, 889–907.
- SBC, 2002. *Report of a European Workshop. Public Information and Public Participation in the Context of EU Directives 90/220 AND 2001/18*, Leiden, the Netherlands, 30–31 May, 2002. Schenkelaars Biotechnology Consultancy (SBC) on behalf of the European Federation of Biotechnology Task Group on Public Perceptions of Biotechnology.
- Schantz, S.L., Gasior, D.M., Polverejan, E., McCaffrey, R.J., Sweeney, A.M., Humphrey, H.E.B., Gardiner, J.C., 2001. Impairments of memory and learning in older adults exposed to polychlorinated biphenyls via consumption of great lakes fish. *Environ. Health Persp.* 109, 605–611.
- Scott, A., Franz, N., 2002. Industry Sees Red on EU White Paper. *Chemical Week*, July 17, 2002.
- Smith, J., 2004. EU experts fail to agree on GMO maize imports. Reuters, Monday September 20, 2004.
- SNFA, 2004. *Food for two. Cost Recommendations for Pregnant*. Department of Information and Nutrition, Swedish National Food Administration (SNFA), Uppsala. Available at www.slv.se on September 28, 2004.
- Steinhäuser, K.G., 2001. Environmental risks of chemicals and genetically modified organisms: a comparison. *Environ. Sci. Pollut. Res.* 8, 120–126.
- UNCED, 1993. *Report of the Conference of the United Nations on Environment and Development (UNCED)*, Rio de Janeiro, 3–14 June 1992., vol. 1–3. United Nations, New York.
- UN ECE, 2000. *The Aarhus Convention: An Implementation Guide*. United Nations, New York and Geneva.
- UN ECE, 1998. *Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters*. Done at Aarhus, Denmark, on June 25, 1998.
- United Nations, 2002. *Report of the World Summit on Sustainable Development*, Johannesburg, South Africa, 26 August–4 September, 2002. A/CONF.199/20*.
- US House of Representatives, 2004. *A Special Interest Case Study: The Chemical Industry, the Bush Administration, and European Efforts to Regulate Chemicals*. US House of Representatives, Committee on Government Reform, Minority Staff Special Investigations Division, Washington.
- WCED, 1987. *Our Common Future*. Report by the World Commission on Environment and Development (WCED). Oxford University Press, Oxford.
- WWF, EEB, 2004. WWF and EEB withhold support for additional REACH impact assessment being carried out by KPMG for UNICE and CEFIC. Press Release 16th July 2004. WWF and EEB, Brussels.