Inger-Johanne Sand, professor, dr.juris, IOR, Univ. of Oslo
(i.j.sand@jus.uio.no)

The legal regulation of the environment and new technologies – in the view of changing relations between law, politics and science. The case of applied genetic technology

(This is an excerpt from an article with the same title published in Zeitschrift für Rechtssoziologie, Bd.22/H2, 2001)

I. The field: New forms of environmental law, regulating on knowledge, risk and future consequences

Environmental law is very much a field in the making. As the ecological changes of the environment of the globe and the man-made manipulations have become increasingly *comprehensive and intensive***, the perspectives of environmental law have been widened from the protection of particular sites and anti-pollution legislation** *to more comprehensive schemes* **with** *an ecological and more general orientation* **including a focus on** *biodiversity***. As for** *comprehensiveness***: it has been realised that all or most parts of the natural environment (air, water, earth, biosphere, biodiversity) are affected by various forms of comprehensive social, technological and economic change (industrialisation, product standards, exploitation of natural resources, the uses of chemicals, energy, cars, airplanes etc.), and that the consequences of these changes on the environment are to some extent comprehensive (forest-deaths, pollution of the air and the high seas, poisoning by chemicals, climate changes etc.). As for** *intensity***: the evolution of biotechnology and particularly of genetic technology may have contributed to the alleviation of certain environmental and social problems, but they have at the same time opened up for much more intensive, potentially long-lasting and also unpredictable interventions into the environment than previously, with the possibility of more comprehensive ecological changes. The application of very specialised knowledge and technologies may continuously create both** *new knowledge and uncertainties***. It may also result in a spiralling effect of** *reflexivity* **in our processes of communication about the same and thus in more uncertainties, contingencies and unintended consequences, on possibly grand scopes, in our decision-making in this field.**[1]

The present problems arise from a complex interaction of various factors, but they are all results of industrial society, that is: the combination of *its intensive exploitation of natural resources and its comprehensive use of specialized knowledge and technologies* in society.[2] Modern societies are to an unprecedented degree based on the exploitation of natural resources in ways which are disembedded from local traditions or everyday meaning processes.[3]

In the following I will analyze and discuss *within a legal and a socio-legal framework* the *conditions* and the *configuration* of legal regulation of environmental law *particularly* in the case of the regulation of the deliberate release of genetically modified organisms (GMOs). I will focus primarily on three types of explanatory factors which should be relevant for any socio-legal analysis, but which here will be adapted to an analysis of the legal regulation of the application of genetic technology (the deliberate release of GMOs) as part of the larger field of environmental regulation. The three types of factors are: - the character of *the field* itself,

which here consists of *several conflictual meaning dimensions*, - *the simultaneous existence of several and differentiated (general) communicative systems/functions* (law, politics, economy, science), and - *the existence of several and parallell institutional levels of governance and regulation* (national, EC/EU, GATT/WTO), cfr. below., and the regulatory context these levels are part of.

The first type of factor is the significance of *the character of the field itself,* as expressed by its various meaning-formations, and I will here focus on the regulation of the application of genetic technology in the specific form of deliberative release of GMOs. This is not a ”simple” field, but rather one, which relates to and consists of *several and conflictual meaning-formations*.[4] It is both a very specialised *scientific* field and a field which has consequences for our *natural environment* and one of our *most basic and daily needs*: how vital foods are produced. It is also a field which has become embedded in *markets and corporate environments*. It is also connected to an *ethical* discourse. Within the general communicative rationalities there may be specific contextual and situational meaning-formations and discourses within specific organizations or regulatory cultures. The larger field of the application and regulation of genetic technology is thus not one, but several and conflictual discourses and meaning formations. There will also be gaps and misunderstandings between these meaning formations. *How these different versions of the field interact*, and *how this effects the legal forms of communication and regulation,* will be discussed in the following.

The field contains both the promise of *positive potentials* and the possibilities of unpredictable and *possibly very negative environmental consequences.* On the one hand there are biological, economic and corporate discourses implying positive potentials of increasing food production and economic growth. Bio- and genetic technology have even been deemed to be the most vital technologies for further economic growth in the next century and for whole regions.[5] On the other hand there are also biological and political discourses communicating the possibilities of various negative and comprehensive, even irreversible, risks concerning the application and the release of GMOs.

The second level of factors I will focus on is the simultaneous existence of and interaction between *the different communicative functions (systems)* at work in this field. – *science, politics, law, economics and mass-media*, cfr. above. The inspiration of this is from the theories of the functional differentiation of communication in modern society and systems theeory which have been evolved and used by several authors, but lately developped most explicitly by Niklas Luhmann. These are theories about society, not about one specific sector. The different systems are autonomous. They create their own communications internally on the basis of a specific (binary) code (legal/non-legal, money/no-money, power, (scientific) truth etc.). Each such system is thus normatively closed in relation to the others, but they are at the same time cognitively open. They share information which they process on the basis of their specific code. They are however environment for and influence each other indirectly. The political system, for example, is thus here seen as one system of communication in society among several such generalized systems.[6] The *boundaries and limitations* of each system

enable a *specialization* which also result in a possible *richness* within each communicative system. Society is then seen to consist of *the communications within* each system and *the interaction between* them. Below the level of the general communicative functions (law, politics, science etc.) there are also communicative sub-systems on the levels of *organisations* and *interactions*. Within any social field there may thus be communications from several communicative systems, as illustrated above for the field of regulation of genetic technology.

The third focus here will be on the relevance of the existence of *several parallell and simultaneous levels of governance and regulation* operating both in environmental law in general and in the field of genetic technology in particular: - national, - European (EC/EU and EEA) (supra-, inter- and transnational forms) and – various international treaties and organisations (here: GATT/WTO). These levels will to some extent be coordinated and combined, but they may also be interacting and competing at times with unclear relations, due to the lack of clear hierarchies. The institutionalised interaction between the political and legal institutions of several constitutional levels may also lead to new and more complex relations between law and politics. Legal and political communications will increasingly have to apply

The following discussions will concern how *the more specific politico-legal regulation* **of these social fields is constructed. Law and politics will select and create their own constructions of the fields to be regulated, and then create legal and political concepts, structures and processes for the specific area. Such fields are socially and communicatively constructed by the combination of factors such as : - knowledgebased discourses, - corporate structures, - consumer, ethical or environmental policies, and - the institutions, concepts and processes of law and politics.**

In section II theories of risk and of the functional differentiation of modern societies will be discussed. In section III there will follow a presentation, discussion and comparison of some of the current regimes of the legal regulation of the deliberate release of GMOs: - on the EC/EU level, and - on the international level (GATT/WTO). In section IV there will be conclusive chapters discussing the theories presented in section II applied on the material in section III.

II. Drawing upon the future: - Risk and the application of specialised knowledge.

Risk and uncertainty

Luhmann has emphasized how we by increasingly and extensively applying specialized knowledge and technologies are in the process of changing our uses of *the social* **and** *the time dimensions* **by extending them significantly.**[7] *We are increasingly drawing upon the future***, creating more uncertain consequences and increasingly complex structures. Our rooms of operation and our social abilities are thus extended, but at the cost of increased risks. Social complexity is enabled, but probably at the cost of institutionalized forms of trust. Basing our social organisation much more predominantly on complex and rapidly changing systems of** *knowledge* **and** *new technologies* **has meant that our existing social institutions and forms of trust have been put under pressure. Unintended consequences are increasingly created***. We allow for more risk and uncertainty, but to some extent without or with less stabilized institutions to handle that***.**

The increasing interest and relevance have been explained in several ways. I will present two different theories which both will give some of the background for risk as a part of modern society. They are different, but share some common features. The first and primary theory to be discussed here is Niklas Luhmann´s sociological theories of risk (”Soziologie des Risikos” (1990)) which contribute risk to modern society, its functional differentiation and specialization and its continuous *decision-making* **and uses of knowledge. Decision-making and its coordination create unintended consequences and contingent situations. Risks are thus an inherent part of decision-making in modern differentiated societies. We cannot escape it and will have to learn to live with it. Risks are not necessarily negative or dangerous. The other theory is Ulrich Beck´s theories on risk society (”Risikogesellschaft” (1986)).[8] His theories are founded on the argumentation of modernity defined as an industrial society founded on the exploitation of natural resources and this to such an extent that it is more or less out of control. Society is fragmented and disembedded. The predominance of unintended consequences and society´s inability to deal with this is close to his definition of risk society. He sees the need to reduce risk and to fight it. He includes a political element in his theories. However, both theories combine an insight into the specific characteristics of modern society as specialised and as differentiated, and that somehow** *these processes of specialisation and differentiation, with an enormous increase in the decisions taken*, **have resulted on the focus on risk and the semantics of risk. Whether risk is produced more often than previously is a more disputed question which is hard to settle.**

Niklas Luhmann defines *risk in opposition to danger*. *Risks are created by conscious decisionmaking.* **By creating new projects and new knowledge we make new selections and decisions and thus also continuously create risks consciously and voluntarily whereas they could have been avoided.** *Dangers just are there* **– by nature or created by others at a far distance. This creates a different context for the definition of risk than** *the old opposition between risk and safety*. **The latter distinction is excluded by Luhmann because modern societies cannot guarantee safety. It is in practice non-existent and can only function as a reflexive standard. There are only degrees of risk, or different forms of risk, never safety.**

Luhmann takes his point of departure in risk as some kind of measurement and in our tendencies of future orientation. We make, and we have always made, decisions which *bind time* **– even if we do not know enough of the foreseeable future. Taking risks, acting without sufficient knowledge was early on conceived of as necessary, unavoidable for the development of society. Modernity is characterised by our increasing tendency to do so.** *Law*, **normative expectations, and** *contracts* **have been used systematically and pervasively by modern society – to organise and coordinate it and to bind time. We institutionally ”agree” on how the future will be with the aid of legal norms and contracts thus constructing normative expectations which may be disappointed and still be essential elements of the social organisation of society, in contrast to cognitive expectations.**

Regulating on non-stabilized knowledge and science

Areas heavily dependent on the dynamics of specialized knowledge and science have special characteristics which *challenge both our conceptions of fact, how it is described*, **and** *the regulatory abilities of the systems of law and politics*. **Parts of the environmental and the health areas are examples of this, particularly the fields of food-production and bio- and genetic technology. Both descriptions of the areas and proposals for regulation**

will depend on specialized knowledge. The vital judgments of what substances are ”hazardous to human health or the environment”, must initially depend on *specialized scientific knowledge***.**

A high degree of specialization **will also mean** *a high degree of complexity* **because of the many selections to be made and thus possible unintended side-effects. This also implies a high degree of contingency. Specialized knowledge may imply** *certainty* **in some things, but it will also mean uncovering new fields and new questions and thus** *new uncertainties* **in a very systematic way.**[9] **Niklas Luhmann has in a criticism of rational theories of knowledge emphasized the element of** *non-knowledge* **– which per definition is undefined and unknown in scope, but always significant and hugely underestimated in all forms of rational analysis. Non-knowledge is also a reminder of the fact that rationality is always bounded.**[10]

Specialized knowledge in general and the field of bio- and genetic technology in particular is also *reflexive***, in continuous change and thus** *non-stabilized***. That is also the case of the knowledge of its application. There is a continuous flow of new information, new knowledge is produced and existing knowledge reviewed and reevaluated in the light of the new.**[11] **State-of-the-art-knowledge in many specialized fields could thus be said to always be in-process, and often offering various, conflicting views rather than one authoritative. This is enhanced by the effects of the many unintended side-effects and also the possibilities of very long-term consequences which are difficult or impossible to predict at all. Areas such as bio- and genetic technology are thus** *future not past oriented***.**

It is also acknowledged that even if science should tend towards truth and objectivity, its processes cannot escape vital *elements of contingency, subjectivity, controversy and pluralism.* **Different research projects may then come up with different results on the same objects of research.** *Scientific controversies* **may be the result simply and contingently of different researchers drawing different boundaries of their research objects, seeing different things, using different criteria, asking different questions.**

III. New forms of environmental regulation. Comparing the European and international forms of regulation of the release of genetically modified organisms.

Regulations of genetically modified organisms on inter-, supra- and national levels of governance. The European level

Environmental law in Europe and on an international basis has evolved along several orientations during the last twenty years. Two such very basic evolutionary lines are: - environmental regulation as part of or as consequences of market regulation (SEA, GATT), and - independent environmental regulations concerning vital and often international issues such as climate change, changes in biodiversity, chemical pollution, the uses of bio- and genetic technology etc. Within these two orientations there are both diverse elements and further orientations and also inter-connections. The EC directive on the deliberate release and the placing on the market of GMOs, dir. 90/220 (old) and dir 2001/18 (new), is an example of a harmonizing directive on an environmental issue given within a framework of market regulation, the SEA. This directive and the contradictory considerations underlying it will be the core of the comparative analysis in this section III.

The contained use of, the release and the placing on the market of genetically modified organisms were only to a very little extent regulated explicitly in the member

state countries before the process and the enactment of the EC Council Directives 90/219 and 220, and later the new directive 2001/18/EC (replacing 90/220), which are all presumed to preempt national regulations in these areas.[12] (Directive 90/219 concerns genetically modified
microorganisms and will not be further discussed here.) Fear of too diverse national regulations were part of the motivation to pass harmonizing regulations in these fields, cfr. above. The directives were enacted on the basis of art. 95 (100a) as part of the single market implementation and not primarily with an environmental goal. Purely environmental competences would also have been lacking at that point. The directives have been amended later.[13]

The directive on the release and placing on the market of GMO´s consists of a system of *notifications and consents* **for each specific GMO to be deliberately released or placed on the market. So far 16 permissions have been given out of 31 notifications whereas over 1.000 experimental releases have been accepted.[14] The goals of the directive are both** *the approximation (harmonization) of laws* **etc. among the member states (in order to avoid disparity between the rules and any barriers to free trade) and** *the protection of human health and the environment***, cfr. art.1 and the preamble, dir. 90/220 and 2001/18 (both emphasizing the "high level of protection"). Consents may be given only when the releases are found to not represent any hazard to human health and the environment. The method by which to evaluate this is by the use of** *risk assessments* **and then the further evaluation of these, cfr. Annex II, and thus clearly in dir. 90/220 implicitly by** *the standard of scientific evidence.* **This standard is not explicitly mentioned in the original directive as the basis for evaluating the level of protection, except for only indirectly and peripherally in art.11 no.1. In the proposals for amendments (COM (98) 85) the standard of scientific evidence for the evaluation of the protection is included directly in art.13a no.2 and clearly emphasized in the introduction of the document.[15] The implementation of the standard is further strengthened in the amendments by the improved demands for and** *criteria of what a risk assessment* **may be in the new proposal for an Annex II and by the new art.20a with the obligation for the Commission to consult the relevant** *Scientific Committee* **on matters concerning effects on human health and the environment.[16] In the later proposals for amendments (of the amendments) there is also included in art.20a no.2 a possibility for the Commission to consult its** *European Group on Ethics in Science and New Technologies* **on any** *ethical* **questions regarding new releases of GMOs (COM (99) 139).[17] In the new directive 2000/18 the main structure of the previous directive is kept, but several vital changes have been made. Some of them are already mentioned in the previous proposals for amendments. First, and principally, the standard of precaution, has been included in art.1 and 4 as a general guideline for the assessments of the notifications and thus for the whole implementation of the directive. It is also specified that GMOs with genes expressing resistance to antibiotics shall be taken into particular consideration, art.4 no.2 with a view to phasing out the use of antibiotic resistance markers in GMOs. Possible gene transfer from from GMOs to other organisms shall also be under observation. Consultation of the relevant Scientific Committee is made obligatory. There is also an obligation to consult relevant committees established by the EC on ethical implications of the GMOs. Transparency and public accessibility to the notifications and the risk assessments are more clearly emphasized in the new directive, cfr. art. 7 no.2 (b), art. 9 and 24.**

The problems and the implications of identifying an ethical problem are not satisfactorily dealt with. There is however a clear line of change in the formulations of both the preambles and the texts of the directive itself from the 90/220 version to the various proposals for amendments and then to the new dir. 2001/18. As examples can

be mentioned an increasing tendency to include demand for scientific evidence, the precautionary principle, regard for delayed effects and also obligatory consultation of Scientific and ethically relevant committees. Apart from the mentioning in the new dir.2001/18 of genes expressing resistance to antibiotics no specific possible problems are mentioned.

In the above mentioned EC directives and regulations, including the amendments, *the uses of risk analysis and assessments are still the main instrument* **for enabling decisions on consents and eventual hazards. The risk analysis include the various modes of: - risk assessments, risk management and risk communication. Risk assessments must be made by both the notifiers and the competent authorities. Scientific evidence is however given a broader and more complex presentation in the EC/EU documents referred to above, including references to delayed effects and incomplete evidence (cfr. footnotes), than in the SPS (Sanitary and phyto-sanitary protection) agreement where it is emphasized in a more narrow way. This will be discussed more fully below.**

In art.16 of directive 90/220 there are measures enabling a member state to postpone (temporarily) the implementation of notifications otherwise accepted if there are scientific indications of possible hazards. This is comparable to the equivalent general clause in art.95 no.(4). The latter article has been extended with the possibility of declaring non-implementation when "new" scientific evidence indicates hazards to human health and the environment, art. 95 no. (5). In both cases the indications must be that there are possible hazards which are specific to the conditions in that member state. In the new directive from 2001 it is a condition that consents can only be given up till ten years, art.15 no.4. Labelling and continuous monitoring is required, art. 19. When new information is available both the notifier and the competent authorities must assess it and indicate whether the conditions of the consent should be amended, or the consent provisionally restricted or terminated, cfr. arts.20 and 23.

The preconditions for giving a directive on the deliberate release of genetically modified organisms and thus enabling the uses of such organisms also in food-stuffs, is that *this is available technology which is presumed to contribute to increasing food-production***. It has been promoted and used in the US and in Canada previous to any use in Europe. In the Commission´s White Paper on "Growth, Technology, Employment. The Challenges and ways forward into the 21st century" (1994)** *the significance of and the positive resources in biotechnology* **for the next century are strongly emphasized.**[18] **Biotechnology is presumed to be the most significant factor of economic growth of the next century. It is openly admitted in the preamble of the amendment to dir. 90/220 (COM (98) 85) that even if safety is important, it is also "essential to ensure that regulation does not unnecessarily hinder the potential for technological innovation. This growth sector has not yet reached its full potential and cruising speed."**[19] **It is also referred to that this new technology will maintain the competitiveness of Europe and make a major contribution to economic growth. At the same time it is however recognized that there are risks, and that the uses of genetically modified organisms may have** *possible long-term effects* **which we do not have sufficient knowledge of, and which may be irreversible cfr. the preamble to the 90/220 directive. The effects may be different when released in open fields than in a laboratory, and the long term effects might be extremely difficult if not impossible to predict.** *Precaution, preventive action* **and the keeping of** *a high level of protection* **concerning health, safety, environment and consumer protection are however also included in the preambles of both the original directive and the amendments.**[20] **The precautionary principle is even further emphasized in the preamble of the latest proposal for amendments to the directive.**

In the Commission Green Paper on "The general principles of food law in the

European Union", COM (97) 176 and the Commission´s communication to that, COM (97) 183, the uses of *scientific research and advice* **as a proactive approach is emphasized as the main policy for improving the safety of consumers` health and food policy, combined with** *control and inspection,* **and all performed according to** *excellence, independence and transparency* **and in order to achieve a high level of protection. Greater transparency in the various processes of decisionmaking and inspection is emphasized, including clear separations between legislation, inspection and scientific consultation. Scientific evidence is then announced as the main guideline for both the general research which is presumed to be carried out in the foods sector, as well as for the regulations and their implementation.** *Risk analysis (including: assessments, management and communication of the risks involved)* **by both the applicants and the competent authorities and a more systematic use of** *the Scientific Committees* **on the EU level are the primary instruments for the implementation of safety based on scientific principles and evidence.**

It is however also emphasized in these documents that scientific advice "has its limits", and that it can not be the only factor in the decision-making processes. Other factors which may be relevant, would be the evaluation of what kind of safety it is possible to attain, with what means and at what cost, an evaluation of the tolerance of risks in society and *the precautionary principle***, including the possible relevance of (temporarily)** *incomplete scientific evidence***.** [21] **In the communication on the Green Paper from the Commission the view is formulated such: "The Commission will be guided in its risk analysis by the precautionary principle in cases where the scientific basis is insufficient or some uncertainty exists."**[22] **In the preceding Green Paper on Food Law it is stated that the precautionary principle should prevail when "…the scientific evidence is incomplete or unconvincing one way or the other which makes a full risk assessment impossible."**[23] **Even ethical considerations are mentioned as possibly relevant in the Communication from the Commission. This is definitely a more open orientation towards the conflict between scientific evidence (in a more narrow conception) and the precautionary principle than in the regulations of the GATT/WTO and the SPS treaty where the questions arising from situations of incomplete scientific evidence are not explicitly dealt with.**

The policy-statements in the Green Paper from 1997 and in the following communication from the Commission seem to be quite closely continued in the proposals for amendments to dir. 90/220 from 1998 and 1999 mentioned above, and there are significant changes over time from the original directive and throughout the various proposals for amendments in 1998/99. In the first amendment (COM (98) 85) there is on the one hand a strong emphasis on the need for *technological innovation* and the positive resources of biotechnology. On the other hand *the precautionary principle* and the need to build public confidence in this area are also more clearly emphasized than in the preamble of the original directive.[24] *Scientific evidence* as the standard for the evaluation of the need of protection is included in the proposals for directive amendments, and the relevance of *ethical* concerns is mentioned in the introduction to the text.[25] The criteria of risk assessments are improved, and there is an obligation for the Commission to consult the Scientific Committees. One could say that the texts for this proposal for amendments strengthen diverse and conflictual elements of the relevant argumentation: - the positive rhetorics on biotechnology, risk assessments and scientific evidence as the main instruments and also the precautionary arguments, but without expressing any clear preferences. In the preamble of the proposals for amendments

there is also included the argument of ”delayed effects” as parts of what must be taken into consideration.[26] In the Parliament´s opinion and further proposals for change concerning the above mentioned amendments the precautionary element is more clearly emphasized in several ways. One proposal is to include the obligations of the precautionary principle in the text of the directive, art.4 no.1. In the discussions on scientific evidence it is remarked that ”in relation to the deliberate release of GMOs….science is not able to give clear-cut answers”, and that these problems should be cleared up ”through close co-operation between scientists and policy-makers”.[27] In one of the proposals for amendments to the text of the directive ”secondary and long term effects” are included in the evaluations, art.2 no.6. There is also a proposal for en explicit mentioning of an ensuring ”that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are not released into the environment”, proposal for a new art.4 no.1b. There are thus several traces of the increasing concern which has been expressed among consumers about the uncertainties of GMOs in the proposals from the Parliament. After this a new amended proposal for the directive from the Commission has been issued.[28] The inclusion of the precautionary principle in the preamble of the directive is repeated here, and so is the relevance of not only ”direct and indirect”, but also of ”delayed” risks. The most important novelty here is however the inclusion of the possibility for the Commission to consult its European Group on Ethics in Science and New Technologies in questions which may give arise to ethical concerns, cfr. art.20a no.2, proposal for amended text. This should be a significant change in the treatment of ethical questions from the previous proposal for referring these to the more general Scientific Committees. Still, however, there is no clear discussion on the implications (procedures, sanctions etc.) of the identification of an ethical problem.

In the new directive 2001/18 it must be fair to say that there is a clear change compared to the dir. 90/220 in so far as *the precautionary principle* **is underlined as a basic guideline both in art.1 and 4. Throughout the preamble precaution and protection are emphasized as considerations and constitutes its overall “paradigm”. The economic optimism on behalf of the use of biotechnology is no longer included in the preamble. The consultation of Scientific and ethical committees which are relevant (such as the European Group on Ethics in Science and New Technologies), are made obligatory, arts.28 and 29. Some of the specific problems of previous GMOs such as the use of antibiotic resistant markers, are more directly addressed with a view to phasing them out, art.4. Monitoring of information, labeling, openness and public access to the notifications and the risk assessments are also significant parts of the new directive, in contrast to the old, thus enabling a much wider circle to participate in or influence the decision-making processes, arts.20 - 24. Consents can not be given for longer than ten years and must then be renewed. There are however no comments as to how the precautionary principle is to be practiced: - what the levels for precaution are to be etc., or what would be relevant ethical problems which might hinder a notification from being given a consent. The complex questions of what constitutes a scientific evidense, are also not further discussed in the preamble of the new directive.**

The directive, theold and the new one, and the policies upon which they have been and still are based, are however still *ambiguous* in their communication: On the one hand they emphasize the risks involved, and that they are recognized and attended to, including

the considerations of safety and precaution. On the other hand it is presumed, the risks notwithstanding, that it is vital to support such technological innovation, and that it should be possible to consent to the deliberate release of some GMOs, after risk assessments having been carried out.

The regulation of GMOs and multi-level governance

During 1998/1999 there have been comprehensive discussions, both among politicians and in a wider civil society, concerning both the amendments of the directive and the more material discussions on risks and how to secure the safety of human health and environment in this area. The news coverage has also at times been comprehensive. Following long discussions and strong internal disagreements it was agreed in June 1999, in addition to new amendments to the directive (the final discussions and enactments of which were postponed, at this point until March 2000), to have an informal moratorium on any new notifications under the directive for the next three years.[29] It was presumed, by some of the members, that the EU under the directive, and probably also under the WTO agreement, would be barred on legal grounds from enacting a formal moratorium. It was also feared that the US could oppose it under the GATT/WTO agreement. France, Denmark, Italy, Greece and Luxembourg did support a more formal temporary agreement. The UK resisted this. The British position was to improve the procedures and to continue research. An informal temporary break while proceeding with further resarch has been the resulting compromise.

An important part of the background for the more hesitant mood in the EU on GMOs has been the increasing consumer protests against GMO foods. The symbolic and the ethical aspects of the GMOs and the inherent uncertainties to which it would be impossible to give full reassurance, due to the still insufficient research, have resulted in quite strong consumer demands of GMO free foods and of labellings assuring this. Several food producers in Europe (Unilever, Cadbury, Nestlé) and food chains in the UK (Tesco, Co-op) have followed up on such demands and claim not to retail any foods consisting of GMOs. As the relative share of GM production of both soya and maize in the US (and among Monsanto´s producers) has increased rapidly, the consumer protests in Europe have led to reactions within Monsanto, the world´s largest food producer, as their share prices started falling.[30] Monsanto has reacted both by asking American farmers to produce more non-GMO foods and by going into dialogues with various British environmentalist and consumer groups.

The consumer reactions have thus significantly affected both corporate and governmental strategies and ”inspired” unorthodox reactions from the authorities vis-a-vis existing legislation and procedures. Both the informal three year moratorium on further deliberate releases of GMOs and the avoidance of taking Austria and Luxembourg to court on their position on the maize b-t GMO illustrate this. *In a clearly legally regulated area, the EU athorities have chosen to act strategically and with precaution rather than legalistically and according to the rules.* This might illustrate that this is recognized also by the authorities as an area still in change and unstable both factually and legally/politically.

A new white paper on ”Food safety” (COM (1999) 719) has also just been published along with a communication from the Commission on the precautionary principle (COM (2000) 1). In both papers it is signalled that the use of risk analysis based on scientific evaluations must be the primary strategy in matters such as food safety or others where precaution might be relevant. If a scientific evaluation, as complete as possible, uncovers indications for reasonable grounds for concern for potentially dangerous effects, but at the same time is unable to produce sufficient scientific certainty, then the use of the precautionary principle might come into question. Any use of the precautionary principle. must thus be preceded by scientific analysis. Distinction should be made between the element of precaution which may be an element of the assessment of the scientific data, and the use of the precautionary principle as an independent part of a risk analysis.[31] Any measures taken should also take into consideration : - proportionality, non-discrimination and consistency, so as to avoid unwarranted use of the precautionary principle.

The international level – GATT/WTO and the Convention on Biological Diversity

The GATT/WTO agreement does not have any explicit regulation of GMOs specifically. It is basically a general regime of trade regulation promoting free trade and with prohibitions against any quantitative restrictions on imports other than duties, taxes and other charges, art.XI. Exceptions to this in art.XX are relatively similar to those included in TEC art.30 cfr. 28, and among these are measures which are deemed necessary to protect ”human, animal or plant life or health”, art.XX (b). The level of protection may in principle be decided on at the national levels, but they are also subject to certain criteria. Such protective measures must thus not be used in manners which could constitute arbitrary or unjustifiable discrimination between countries having similar conditions, or act as disguised restrictions to international trade, art.XX. The additional agreement, under the GATT/WTO, on Technical Barriers to Trade (TBT) has similar measures.

The SPS (Application of Sanitary and Phyto-Sanitary) agreement, also under the GATT/WTO agreement, contains further regulations on how the protection of human, animal or plant life and health may be secured while minimizing the negative effects on the goals of a free trade regime, cfr. the preamble of the agreement. The two main elements which are emphasized as the basis for such measures, are: - first: the recognition of international standards, guidelines and recommendations, particularly in the form of the Codex Alimentarius Commission, art.3, - and secondly: the uses of scientific principles, arts.2 no.2, and 5 no.2. It is also specified that such measures cannot be maintained without sufficient scientific evidence. Higher levels of protection than those achieved through the international standards may be maintained if this can be justified on a scientific basis, cfr. art.3 no.3 and 5 no.1-8. The method for evaluating the appropriate or necessary levels of protection is by risk assessments based on scientific evidence, art.5. Arbitrary and unjustifiable distinctions if these result in discrimination or any disguised barrier to trade, are not allowed. The relative cost-effectiveness of various measures may also be taken into consideration. In cases of insufficient, but relevant scientific evidence protective measures may be adopted provisionally awaiting further research and information ”within a reasonable period of time”, art.5 no.7.

Unlike the EC/EU regime the WTO/GATT does not have any system or practice for

the production of harmonizing social or protective regulations other than the general recommendation in art.3 to base the measures on international standards, guidelines or recommmendations.

Protective measures concerning GMOs have not been dealt with directly by the WTO. The US has however made it clear that it would not consider a more restrictive practice by the EU than that which so far has been established under the 90/220 and 2001/18 directives, necessary or consistent with the criteria of scientific evidence. It has thus warned against the moratorium mentioned above and threatened with sanctions (traderelated). The case concerning the uses of hormones in the production of ”meat and meat products” brought on as a complaint by the US and Canada against the EU does however offer many similarities to and contain many of the same legal points as a case on GMOs would have and will thus be discussed in the following.[32]

One vital point in the interpretation of the SPS treaty is the relevance and the status of *the precautionary principle*. The EU considered it ”a general customary rule of international law” or at least ” a general principle of law” whereas both Canada and the US could not accept it as more than an approach.[33] The appelate body´s conclusion was that it was not necessary to take a final position on this in the case in question, and referred to the preceding panel´s report that the principle still awaited authoritative formulation.[34] In relation to the SPS treaty it is argued that the precautionary principle is included in art.5.7, where ”insufficient” scientific evidence allows for more information and renewed assessments ”within a reasonable period of time”, and that the principle otherwise cannot override art.5.1 and 5.2. This illustrates a clear disagreement among the various actors concerning the status of this principle in international law. The appelate body then goes on to emphasize the requirements in art.2.2 and 5.1 in the SPS treaty as the vital criteria against which to evaluate the necessity of all protective measures, that is: the use of risk assessment and sufficient scientific evidence.[35] It is further emphasized that a risk assessment implies the uses of scientific evidence and not policy-oriented judgements (”systematic, disciplined and objective inquiry”), and that it is a requirement ”that there be a rational relationship between the measure and the risk assessment”.[36] The appelate body does not find that there is any requirement that the prevailing views (of protective measures) are shared by a majority in the relevant scientific community or identifies a certain minimum quantifiable magnitude of risk. Elements not susceptible to quantifiable analysis may also be included. It is however deemed to be a requirement that the relevant reports must conclude with the existence of an identifiable risk for human health on a scientific basis, under the combination of art.5.1 and 2.2. A general fear of such risks is clearly insufficient, according the the appelate body.[37] There must be a clear documentation on a scientific basis. ”Insufficient” scientific evidence may only postpone decisions for ”a reasonable period of time”, art.5.7. The conclusion of the report from the Appelate Body was then that the EU had not produced sufficient scientific proof for hormone-injected meat to be considered hazardous to human health and thus to legitimize any ban or restrictions on imports.[38] The protective measures were then seen as a violation of SPS art.5.1. The practice

under the WTO/GATT regime does thus so far indicate a more strict view on when there is a relevant ”scientific evidence” than in the EC/EU regulatory regime and practice.

The WTO/GATT regime differs significantly from the EC/EU in several ways: - it is primarily a trade treaty and will then, in principle, only contain negative forms of regulation, - its member states are much more heterogeneous, - there is a very small administration and control system, - it is international law not supranational and thus much more removed from the citizens both concerning procedural access in specific cases and the lack of any electoral contact. All these factors would mean that there probably is a much greater distance between the organisation and the treaty on the one hand and the relevant citizens on the other hand than in the case of the EU. Public reactions would then generally be conceived of as less urgent or relevant for the WTO than for the EU.

Another international treaty which might be relevant for this area is the Convention on Biological Diversity (CBD), under the UN (June 5th 1992), and the annexed protocol on Biosafety. The latter agreed on in Montreal January 28th 2000. It remains to be seen whether it will be ratified and implemented by the parties to the CBD. These treaties are not part of the GATT/WTO regime, but parallell and partly signed by the same countries.

IV. Conclusions: The legal regulation of scientific constructions analysed by theories of multi-level governance, risk and the differentiation of law, politics and science

A. Comparing the three levels of governance and their use of regulatory standards

The presentation above illustrates *how differently the same field may be regulated by different levels of governance* **which are, as in this case, both autonomous and interrelated. Norway, as an example, is obliged legally on all three levels: - by EU directives and regulations as far as they have been incorporated by the EEA, - the international treaties as far as Norway specifically and formally has signed and ratified them, and - the national.**

The EU/EEA approach started with *a comprehensive market regulation combined with the ”necessary” or traditional exemptions such as protection of human health and the environment***, cfr. TEC art. 28 and 30. Its ambitious approach to an efficiently functioning market and to the censuring of any breaches of it consequentially has meant defining both the market and its exemptions legally quite closely. One of the results of that strategy has been** *harmonizing legislation* **in the EU/EEA within the field of human health and the environment where the directive on the deliberate release of genetically modified organisms has been one of several. Harmonizing legislation is enacted by TEC art.95 and is thus part of the single market regulation. Exemptions to the principle of free competition has, in this area, been limited to** *the protection of human health and the environment***. Sustainability and ethical considerations have not been included explicitly so far. Protective measures must however also meet the standards of** *objectivity, non-discrimination, necessity and proportionality.* **Within environmental legislation these principles have been the basis for the evolving argumentation and practice of using**

scientific evidence **as a main criteria for judging whether a certain substance or process is hazardous for human health and/or the environment.**

By accepting legislation in the form of a system of notifications for the release of GMOs, while also having the knowledge of possibly significant risks, the legislators can be said *to have accepted the positive possibilities at the cost of the risks,* **but with the use of risk assessments for reviewing in each case. The EU is now increasingly recognizing the problem of** *incomplete or insufficient scientific evidence***, on the legislative, the judicial and the political-argumentative levels. This also consequentially opens the door for applying the** *precautionary* **principle, but so far this has been kept primarily on the political-argumentative and not on the legal level.**

Within the Norwegian act on GMOs the considerations primarily concern *the protection against hazards to human health and the environment***. Arguments such as** *sustainability, social utility and ethics* **are however included in the act, and this underlines the fact that consents to the deliberate release of GMOs will not only be considered in relation to scientific evidence in risk assessments. The free competition principle has no overriding or censuring status. The mentioned arguments will also open the door to protective measures in situations of incomplete scientific evidence.**

The WTO/GATT level has so far not explicitly regulated this area as this treaty is explicitly and only trade related. Its consequences for this field are related to the fact that the treaty establishes *free trade* **as an overriding principle which cannot be excepted at any cost. Exemptions are granted, and they are relatively parallell to those of the EU, but here there is no harmonizing legislation in this particular (or in any) field. The GATT treaty has however been supplemented by the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) concerning the inclusion of considerations of human, animal or plant life or health under the GATT treaty, formulated as "***protection of human, amimal or plant life or health***". The criteria for protection are scientific principles and evidence and the use of internationally recognised standards.** *Scientific evidence* **as well as standards of** *objectivity, non-discrimination and proportionality* **have been demanded in any cases of applying such exemptions. Incomplete scientific evidence has so far not been accepted as part of the legal semantics.**

Neither of the two mentioned international levels have thus so far included vague concepts such as sustainability or ethical considerations in their legislative texts. In both cases the framework of the regulation is primarily competition law. The significant changes are *the clearer acknowledgement of the relevance of incomplete scientific evidence* and *the obligatory uses* of *Scientific Committees* as well as *the possible use* of the *European Group on Ethics*.

It does then seem that *the more international and heterogeneous the level of regulation and governance the more stabilized and "efficient" standards of evaluation are asked for* **: -** *free competition* **and** *scientific evidence***. In both cases the standards are vital and focal concepts within either the economic or the scientific systems of communication. The two standards refer essentially to the two vital symbolically and generalized media of communication: - money/markets and science/truth. They are thus what we can call relatively robust concepts, in so far as they refer to a vast and authoritative literature and to common and comprehensive practices as to their definitions and practical interpretations. The literature and practices of applying these concepts are also very much international and so technological that they to some extent may cut across cultural differences. Such standardised concepts do have comparative advantages in the regulation of large and heterogeneous areas. The principles or concepts of** *ethics,*

precaution and sustainability **do not seem to have the same stabilized and to some extent cross-cultural or technological reference background. Neither do they have the same status of expressing functional or social codes. They are more culturally dependent and thus more contingent and difficult to apply across cultural differences.**

B. How legal and political regulation is constructed and meaning shaped in fields of scientific constructions and risks

The meaning formations of this field does then include conflicting and even incompatible discourses. Through the processes of legislation, which will be both *political and legal,* such conflicts are not necessarily solved. It is more to the point to say that decisions have to be made, and in order to do that social complexities have to be reduced and selections made. These processes are not always ”rational”, objective and transparent. The various communicative systems and the conflicting and incompatible discourses cannot fully understand each other. They present *different parts of the construction of the field*, and there are *misunderstandings and gaps between the different meaning formations*. Complex combinations of arguments are unavoidable parts of the process.

Risk analysis and assessments are *reflexive* instruments in the evaluation of the technologies. The reflexive processes of law and politics cannot elaborate further on what is considered *scientific* evidence within the system of science. They may however apply *political* or *legal* criteria to elaborate on and “translate” the scientific material, within these systems and decide on the legal and political consequences of various situations. One could say that the *political and the legal* processes may pressure the *scientific* processes into creating *more authoritative concepts on forms of incomplete scientific evidence or indications of hazards* which are sufficiently *robust* for use in political and legal regulation. Or: the political and legal systems may create their own concepts or standards to evaluate or proceduralize the scientific information. The *legal* system may contribute to an increased reflexivity by the use of various *procedural* arrangements: - more varieties into who are included in hearings, decisionmaking etc., - increased acceptance for ecological and ethical arguments and standards, and – how to deal with the burden of proof. *The precautionary principle* may be used as a *political* or *legal standard* in order to supplement the scientific arguments. The advantages of scientific analysis and evidence are that they are generally accepted as more or less objective and neutral vis-a-vis partial interests. Political criteria are much easier labelled subjective and contingent, and they are more vulnerable.

The works of science imply in themselves an endless amount of selections being made and decisions taken in order to know *what is ”scientific”***. Contingencies and the systematic limits of knowledge may however also play a role here.**[39] **The more we know, the more we should also be aware of that we do not know. There are thus systematic uncertainties as to what can be labeled as scientific knowledge.**

Scientific knowledge or evidence as they are used in risk assessments, for policy processes and in judicial decision-making will thus always in a certain way be *negotiated results of communicative processes***, with inherent limitations and imbalances. ”Science” used in such contexts is however different from many other criteria because it is part of a particular communicative and coded system and thus also part of an**

authorized framework of references to which it can be compared. It is an attempt of tendential objectivity.

This has enabled the use of the criteria of ”scientific knowledge or evidence” in a systematic way in complex processes of decision-making where (1) specific elements of communication from different situations or cases within one generalised communicative system (here: science), can be *compared* **across differences in time, space and culture, and where (2) communicative elements from different generalised systems of communication (law, politics, science etc.), representing different types of rationalities, have to be** *coordinated***. The use of systemic codes enable a thematic definition and an ordering and a reduction of the complexity within specific areas of society. At the same time a richness of details is also enabled internally. Such generalised codes may enable the coordination between different systems of communication.**

The international practices concerning the uses of scientific knowledge and evidence in the context referred to above have been created within a framework where the overriding goal has been market regulation, not initially environmental regulation. The emphasis here has been on the creation of efficient markets and in order to achieve that it has seemed necessary to apply rationalized and (relatively) easily compatible concepts. One could argue that the evolved rationality and efficiency of the practices concerning the standards of ”free competition” or a ”free market” have *paradoxically contributed to a pressure on creating equivalently ”rational” and standardized concepts defining their exceptions* **(of protection). The demand for “scientific evidence” of environmental hazards has become the rationalized version of the protective exception.**

The standard of ”scientific evidence” may be lacking in distinguishing qualities regarding the handling of more complex situations of scientific uncertainties and controversies and the various degrees and nuances of incomplete scientific evidence. The more robust standards may thus in their present state not always be best equipped to handle new and more complex situations of risk, qualified uncertainty or unresolved social problems. We may need more nuanced scientific and legal concepts and arguments to describe these in order to decide when and how precautionary measures should be applied.

Outside the processes of legal regulation there are more general and all-encompassing debates on the possible long term risks and harmfull effects of the uses of GMOs as well as on the ethical questions related to such use. The questions are asked more openly as to *the role, the qualities and the limits of science* in areas concerning such possibly long term and thus unpredictable consequences which also may be of some significance. If science does not want to label scientifically indicated, but very uncertain risks with long term and possibly significant consequences, then there may be a problem with the vital and almost exclusive role of science and its methods in deciding on what may be hazardous to human health and the environment. There may then still be work to do with creating more robust concepts which can be used in legal situations. This can partly be done by developping more detailed scientific concepts being able to *express scientific doubt* and *scientific indications* of hazard, and partly by creating *new concepts with an ethical basis*, but which are accepted as more robust. Precaution is of course a vital concept, but its ultimately contingent character makes it difficult and unpredictable to apply in many situations.

The use of *institutional couplings or forms of co-evolution* in the form of *cross-disciplinary boards or other common arenas* where it may be possible to gather representatives of scientific,

legal, corporate, administrative and other private organisational institutions, may be one way of dealing with the problems of the gaps between the different codes of communication and meaning formations in this field. It could among other things serve to explore the way we communicate about this field in a more open way than that which is possible within specialised scientific or institutionalised legal and political processes, which more easily will focus on the characteristics and the limits of the existing communicative codes of science, money, legality etc. *In a cross-disciplinary setting it may be more legitimate to identify uncertainties and risks which can not yet be fully scientifically proved or specifically placed in one of the other systems*, but which may be unintended consequences of their interaction. New problems or consequences may then be more easily identifiable.

In fields which we know are scientifically complex, and which may have long term and unpredictable consequences, there should be an increased acceptance of applying precautionary measures when the consequences may be significant. More constructively: it is also necessary to work on how to make more operational and specifiable concepts for the expression of the precautionary principle as a crossroad between forms of qualified, but incomplete scientific evidence of hazard and legitimate and ethical worries among citizens in legal decisionmaking. In this way the reality descriptions coming from the scientific field could be supplemented by more diversified descriptions of the field and the possibilities of using precautionary measures when the possible consequences may be significant.

(Footnotes)

[1] Anthony Giddens, ”The Reflexivity of Modernity” in ”Consequences of Modernity”, Stanford University Press, 1990. Olivier Godard, ”Social Decision-Making under Conditions of Scientific Controversy”, in ”Integrating Scientific Expertise into Regulatory Decision-Making”, ed. Joerges, Ladeur, Vos, 1997.

[2] Cfr. the current climate changes, the widespread pollution of the high seas etc. Ulrich Beck, ”Risk Society”, Sage, London, 1992, part I, ch.1, and ibid., 1996; Gunther Teubner, ”The Invisble Cupola: From Causal to Collective Attribution in Ecological Liability”, in ”Environmental Law and Ecological Responsibility”, eds. Gunther Teubner, Lindsay Farmer and Declan Murphy, Chichester, 1994.

[3] Niklas Luhmann, ”Ökologische Kommunikation”, Westdeutscher Verlag, Opladen, 1986, ch..11; and ”Risk: A Sociological Theory”, de Gruyter, Berlin, 1992, ch.8.

[4] Niklas Luhmann, ”Risiko und Gefahr”, in ”Soziologische Aufklärung 5”, 1990; Ulrich Beck. ”Risk Society and the Provident State” in ”Risk, Environment and Modernity”, eds. Lash, Szerszynski and Wynne, Sage, London, 1996.

[5] Cfr. European Commission White Paper ”Growth, Competitiveness and Employment”, 1994, p.115 flw.

[6] Niklas Luhmann, ”The Differentiation of Society”, Columbia University Press, 1981, and ”Soziale Systeme”, Suhrkamp, Frankfurt, 1984.

[7] Niklas Luhmann, ibid., 1984, ch.8 and 11, and ibid., 1990.

[8] Ulrich Beck, „Risikogesellschaft“, 1986 („Risk Society“, 1992, p.183 flw.).

[9] Cfr. as an example the documented, but still uncertain effects of GMO plants on the endangered monarch butterflies, Independent May 20th 1999.

[10] Niklas Luhmann, “Gesellschaft der Gesellschaft“, band I, Suhrkamp, Frankfurt, 1997.

[11] Anthony Giddens, ibid. 1990.

[12] OJ L 117/1 and 117/15 (1990)

[13] Cfr. proposals COM (1998) 85 and 479.

[14] This information is as of December 1999.

[15] COM (98) 85, p.4, 58 and 63; cfr. Green Paper on Food, COM (97) 176, p.2 and 10, and Communication from the Commission (COM) 183, p.3, 6, 16 and 19.

[16] COM (98) 85, p.36 and 63.

[17] COM (OJ) (99) 139 – amended proposal for a European Parliament and Council directive amending directibe 90/220, cfr. also the official proposal for amendments (COM (98) 85) OJ C 139 (1998) and the opinion of the Parliament on the same proposals OJ C 150 (1999).

[18] European Commission White Paper on ”Growth, Competitiveness and Employment”, 1994, p.115.
[19] COM (1998) 85, preamble p.2.
[20] Ibid.
[21] COM (97) 183, p.10 and 16.
[22] Ibid., p.20.
[23] Green Paper ”The general principles of food law in the European Union”, COM (97) 176, p.10.
[24] COM (98) 85, p.2-4.
[25] Ibid. p.4.
[26] OJ C 139 (98),p.1.
[27] OJ C 150 (99), Legislative resolution embodying Parliament´s opinion on the proposal for an amending directive to dir. 90/220, amendment in recital 5c.
[28] COM (99) 139.
[29] The Independent and Information (Danish) June 25th 1999. COM (98) 85.
[30] Independent on Sunday October 3rd 1999, see also Independent May 21.-23.rd 1999.
[31] COM (2000) 1, p.4-5.
[32] WTO Appelate Body AB 1997 – 4 (WT/DS 26 and 48/AB/R).
[33] Cfr. COM (97) 176 and 183.
[34] WTO Appelate Body 1997 – 4, p.45-46.
[35] Ibid., p.68-72.
[36] Ibid., p.75.
[37] Ibid. P.76-80.
[38] WTO Appelate Body – 1997 – 4.
[39] Niklas Luhmann, ibid., 1997, vol.I, ch.1.1.