The Application of the Precautionary Principle in the European Union

Stuttgart, April 2003

Executive Summary

EU-project:

"Regulatory Strategies and Research Needs to Compose and Specify a European Policy on the Application of the Precautionary Principle" (PrecauPri)*

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Brief Overview

The executive summary at hand presents the results of our interdisciplinary project on the application of the precautionary principle in the European Union. It is divided into seven sections.

The *first* section outlines the major ***objectives*** which the project pursued, sets out the ***milestones*** during the two years of project duration, and sketches the ***main project product*** which is a policy framework for precautionary risk regulation in Europe – in short the 'general model'.

The *second* section presents the ***basic conceptual considerations*** underlying the general model of precautionary risk regulation. It first sets out the project team's comprehension of the concept of precaution. It then expounds what the team has identified as the four key challenges of characterising, evaluating and managing risks: these are seriousness, uncertainty, complexity and socio-political ambiguity. Finally, this section sketches different types of discourse and participation which the general model provides for in the risk analysis process.

The *third* section sets out the architecture of the ***general model of precautionary risk regulation***. The model is characterised by the following three key stages: screening, appraisal, and management. In addition, it includes a design, development and oversight function which ensures that the overall process is robust to changes in circumstances and to the perspective of all interested and affected parties. The general model presents the 'heart' of the project.

The *fourth* section exposes the five ***approaches to risk analysis*** which the general model distinguishes. These approaches are integrated in the formal decision analytic concept. They provide tools for assessing, evaluating, and managing serious, uncertain, complex and/or ambiguous risks and include different methods for selecting objectives, assessing and handling data, and finding the most appropriate procedure for balancing pros and cons.

One key objective that the project pursued was the legal compatibility and adaptation of the general model with respect to EU jurisdictions and negotiations. The *fifth* section exemplifies the most significant ***legal issues*** associated with the general model and sets out how crucial legal principles are integrated into the model.

The *sixth* section presents the results of the empirical work. The general model was tested using ***new organic chemicals*** as a case study. The results demonstrate the theoretical and practical feasibility of the model.

Finally, section seven describes some schematic ***examples*** from the ***food safety area*** to address certain possible complexities in the practical application of the General Model and so warrant more detailed discussion. The purpose of these examples is simply illustrating the 'sense' of the General Model.

1. Objectives, Milestones and Results of the Project

A range of closely related versions of the precautionary principle has been adopted in legal instruments developed at national, European Union and international level in a variety of sectors. The 2000 Communication on Precaution of the European Commission (COM (2000) 1 final) highlights the general relevance of the Precautionary Principle for the policy of the European Union in areas such as environmental protection, consumer protection and health protection. This key policy document specifies some of the major requirements for applying the principle. The concept of precaution itself, however, and its implementation in the expanding and increasingly important field of risk regulation are highly debated and controversial.

In the face of this situation, the thematic network PrecauPri aimed at devising a policy framework for the application of the Precautionary Principle which provides guidance to European policy makers with respect to European and international risk governance. In a fruitful co-operation of social scientists specialised in risk and uncertainty issues, natural scientists specialised in chemical risks, and a legal scholar with special expertise in risk regulation the project team[1] developed a ***general model for the implementation of precaution in European risk regulation***. The model is understood as a strategic response to the most prominent challenge of risk reduction and management for the protection of human health and the environment which accompanies the European integration process.

The project pursued the ***overall aim*** to develop a model for precautionary risk regulation which is scientifically sound, politically feasible, legally compatible and democratically legitimated.

The more ***specific objectives*** which the project pursued included:

- to specify the procedure for applying the EU-philosophy of the precautionary principle
- to develop and test the framework using new organic chemicals as a case study
- to test the social and political viability of the framework through a series of expert workshops with major stakeholders in Europe following the group Delphi method
- to establish a European network among researchers, political decision makers and different stakeholders

These objectives were met by passing the following ***milestones***:

- Initial workshop with research experts, policy makers and key stakeholders in Stuttgart/Herrenberg, May 2001 as a starting point for the development of a general model of precautionary risk regulation
- Development of the general model of precautionary risk regulation and empirical testing using new organic chemicals as a case study
- Refinement of the general model in response to the input gained by a series of four workshops with major stakeholders in key risk areas following the group Delphi procedure:
  - January 2002, Stuttgart/Haigerloch: workshop with industry experts
  - March 2002, London: workshop with environmental and consumer groups

[1] Research and policy specialists from two member countries of the European Union (Prof Ortwin Renn and his team in Germany, Dr Andrew Stirling and his colleague in the United Kingdom) and from Switzerland (Prof Ulrich Mueller-Herold and his team at the Swiss Federal Institute of Technology) were involved in the project. In addition, Dr Elizabeth Fisher from the UK contributed to the project as a legal scholar. The project ran from April 2001 to March 2003. The results were presented at a project dissemination conference in Brussels on February 27, 2003.

- May 2002, Munich: workshop with regulatory agencies and administration
- September 2002, Strasbourg: workshop with legal scholars and practitioners

- Further refinement in response to an internal meeting with members of the European Commission's Directorates-General and Services to get feedback on the draft general model (Brussels, December 2002)
- Final dissemination workshop with EU-officials and network members in Brussels, February 2003.

Results

The ***general model*** presents the core project result and may be used as a boilerplate for precautionary risk regulation within and beyond the EU-context (in more detail and illustrated by a schematic representation under point 3). It is characteristic of it that it:

- honours and carries forward the ***EU-philosophy of precautionary policies and good governance***
- defines the ***Precautionary Principle*** as a general principle employed in the screening of threats for properties of seriousness or uncertainty in order to determine their subsequent treatment in regulatory appraisal and management
- identifies ***Precautionary Appraisal*** as a specific approach to appraisal adopted in cases where screening has identified a lack of scientific certainty
- defines and concretises ***scientific uncertainty*** as one of four key challenges dealing with contemporary threats; the other major issues are identified as ***seriousness, complexity, and socio-political ambiguity***
- provides a basic architecture for responding to these key features of a threat which builds on the three pillars of ***screening, appraisal, and management***
- understands ***screening*** as the process whereby the key features are identified in order to select the most appropriate efficient and proportionate approach to more detailed regulatory appraisal and to help prioritise attention to different threats
- promotes ***good governance*** through the transparent, accountable and inclusive nature of the regulatory design and in particular the incorporation of deliberative and participatory processes
- is principally ***legally compatible*** with respect to EU jurisdictions and provides rationales for applying the Precautionary Principle and implementing it in national contexts; the proposed procedure assures that application is bound to certain measurable conditions and thereby prevents arbitrary judgments.

The second major project product are the results of the ***case study*** (see point 6 for more detail). In order to evaluate theoretical and practical feasibility the general model was tested empirically using ***new organic chemicals*** as a case study. Exemplification in the chemicals field shows that the general model can deliver quantitative results without compromising scientific reasoning and regulatory feasibility: After appropriate calibration (using data of historical chemicals) the developed sequence of filters tailored to precautionary screening of global chemical threats completely separates economically important high production volume chemicals from precarious chemicals mentioned in the protocols of Montreal, Kyoto, and Stockholm. The case study provides a method to reproduce in a shortcut important results of a long and cumbersome historical development in dealing with organic chemicals.

2. Conceptual Considerations for a General Model of Precautionary Risk Regulation (Section A)

This section presents basic conceptual considerations underlying the general model of precautionary risk regulation. They refer to the idea of precaution, the key challenges of contemporary risks, and the incorporation of transparency and participation into risk regulation.

2.1. The Concept of Precaution

The concept of precaution has been framed in many different ways in the literature and in regulatory documents. In our attempt to construct a comprehensive concept, we defined precaution as a ***prudent and sound choice of response in the face of uncertainty***. With uncertainty we refer to a situation in which well-founded hypotheses of potential negative impacts are available, yet final empirical evidence of harm is missing. Prudent and sound choices are characterized by using ***substantive and procedural steps to evaluate potentials for harm***. Such an appraisal aims at identifying ***specific characteristics of threats*** (including inherent hazards or social mobilization potential) and does not focus merely on the likelihood of consequences and damage potential.

2.2 Major Challenges of Characterizing and Evaluating Risks

The thematic network PrecauPri aimed at developing a general model of precautionary risk regulation which allows to cope with what the project team has identified as ***four central challenges*** of contemporary risks. These are seriousness, uncertainty, complexity, and ambiguity. For this purpose the team developed a *sequential procedure for screening, appraising, and managing risks* (see point 3 for a detailed description). ***Screening*** is the process whereby the four key challenges that might be associated (to different degrees) with a certain threat are identified in order to select the most appropriate efficient and proportionate approach to more detailed regulatory appraisal and to help prioritize attention to different threats.

The *first step* of this, so to speak, 'preliminary risk assessment', is to screen the risk candidates for their seriousness by using risk- or hazard-related criteria. The *second step* is to screen the risk candidates for the level of uncertainty, complexity, and socio-political ambiguity.

- ***Seriousness*** describes in particular the inherent potential of a risk agent to cause harm to the environment or to human health, e.g. exposure-based hazard criteria such as ubiquity, persistency, bio-accumulation or cause-effect related criteria such as carcinogenicity, mutagenicity and reprotoxicity. Criteria of seriousness may be an excellent *guide for setting up an early warning system*, if effects are still unknown or ignorance about potential impacts prevails. Alternatively, in areas where there exist robust applicable data, seriousness may refer to risk-based thresholds, such as mortality rates from rail accidents or injury rates in the construction sector.
- ***Uncertainty*** comprises different and distinct components and reduces the strength of confidence in the estimated cause and effect chain due to:
  - *variability* of individual responses to an identical stimulus
  - *measurement errors* caused by e.g. measurements imprecision, modelling or extrapolations (from animals to humans or large to small doses)
  - *indeterminacy* resulting from a genuine stochastic relationship between cause and effect(s)
  - *lack of knowledge and ignorance*

When scientific uncertainty is high, it is no longer possible to apply probabilistic risk assessment techniques.

- ***Complexity*** refers to the difficulty of identifying and quantifying causal links between a multitude of potential candidates and specific adverse effects. The nature of this difficulty may be traced back to interactive effects among these candidates (synergisms and antagonisms, positive and negative feedback loops), long delay periods between cause and effect, inter-individual variation, intervening variables, and others. With complex risk candidates sophisticated models of probabilistic inferences are required.
- ***Ambiguity*** denotes the variability of (legitimate) interpretations based on identical observations or data assessments. This do not refer to differences in methodology, measurements or dose-response functions, but to the question of what all this means for human health, environmental protection, and management requirements. Moreover, in contemporary pluralist societies diversity of risk perspectives within and between social groups is generally fostered by divergent value preferences, variations in interests and very few if any universally applicable moral principles. High complexity and uncertainty favor the emergence of ambiguity, but there are also quite a few simple and almost certain risks that can cause controversy and thus ambiguity.

It is important to note, that the considerations concerning seriousness, lack of scientific certainty, complexity, and socio-political ambiguity can hardly be organized as a clearly separated step by step screening procedure. Instead, the screening elements must be conceived of as being interrelated. Accordingly, the screening procedure must allow for interactions.

2.3 Participatory and Discursive Procedures

The PrecauPri-project targeted to develop a general model of precautionary risk regulation which promotes good governance and accountability through the transparent and inclusive nature of the regulatory design and in particular through the incorporation of deliberative and participatory processes. Participation serves the purpose of including the knowledge, values and interpretations of all relevant actors and to honour the principles of democratic governance. One should be aware, however, that including additional actors in the decision making process implies longer time frames, less transparency of the decision making process with respect to outsiders, and often compromises of consistency and coherence. The project team hence developed a ***gradual model of involvement*** that includes different actors only if such an involvement is likely to improve the regulatory process or seems fair and appropriate from a normative democratic viewpoint.
The first principal opportunity for different actors to become involved is the ***screening procedure***. This process rests on a ***set of assumptions and normative conditions***. Among them are the reference to the respective ***protective goal***, the choice of ***endpoints*** for the risk appraisal and the choice of ***significance levels***.

As a result of the screening process, the following five different appraisal models may be pursued (sequentially or exclusively; see point 3 for a detailed description). Each of the five models demands ***different levels of involvement***:
Case 1: *Standard risk assessment*: No need to involve additional actors.
Case 2: *Extended risk assessment*: High degree of seriousness and/or complexity of a specific risk requires additional involvement of external experts to provide an appropriate risk reduction option. Such an exercise is called ***epistemological discourse***.
Case 3: *Precautionary appraisal*: Characterising and balancing threats under high uncertainty requires an ***evaluative-reflective discourse*** including other experts from universities and stakeholder groups. The aim of such a reflective discourse is to find regulatory measures that help to assure adequate protection against potential hazards, but support innovations in

technologies and products. Instruments such as stakeholder hearings, mediation, negotiated rule making and others may serve this purpose.
Case 4: *Discursive process*: Coping with a situation of high ambiguity demands an ***overall participatory discourse*** involving major stakeholders and affected citizens. The main objective is to search solutions which resolve conflicts among actors. Established procedures of parliamentary decision making, but also novel procedures, such as citizen action committees, citizen advisory panels and citizen juries, are potential instruments to deal with ambiguities.
Case 5: *Presumption of Prevention*: Should the discourse come to the result that a proposed activity or substance is intolerable due to its hazardous characteristics or its potential risks, the activity is banned or at least restricted. In some cases, however, the threats in question may be assigned to precautionary or discursive approaches for further appraisal, if stakeholders claim that mitigating factors in the form of countervailing risks, over-riding benefits or unavoidable constraints on control might justify conditional relaxation of restrictive regulatory instruments.

3. A General Model for Precautionary Risk Regulation (Section B)

3.1. Introduction

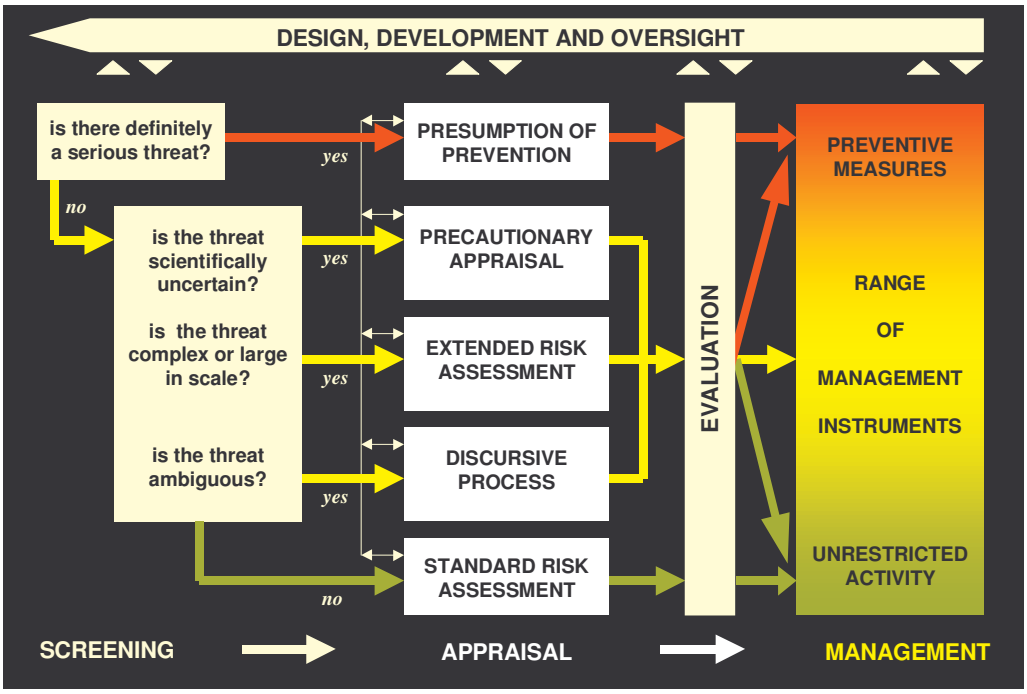
This general model for the precautionary regulation of risk aims to:

1. Ensure consistency with key elements in: EU policy on the precautionary principle (e.g.: 2000 CEC Communication and the Nice EU Ministerial Resolution); overarching principles of good governance (e.g.: 2001 CEC White Paper on Governance); and international trade regulation frameworks (e.g.: WTO, TBT, SPS and Codex).
2. Establish a basis for a coherent positive understanding of precaution among different interest groups, allowing effective communication and promoting consistency, predictability and non-arbitrariness.
3. Provide for practical applicability to the full range of different types of risk to which precaution is relevant under a variety of contrasting institutional contexts and compatible in principle with the different national jurisdictions of EU member states.

3.2. Overview

Figure 1 presents a schematic representation of the general model. There are three major steps to the process envisaged: *screening*, *appraisal,* and *management*. These correspond to the three key stages in conventional risk regulation: hazard characterisation, risk assessment and risk management, but with differences as set out below. Throughout, a general distinction is drawn between the ‘precautionary principle’, ‘precautionary appraisal’ and ‘prevention’. The precautionary principle is employed in ‘screening’ threats to determine their subsequent regulatory treatment. Precautionary appraisal is a specific approach to regulation adopted in cases where screening has identified a lack of scientific certainty. Prevention refers to the approach that is taken when a threat is identified as being both serious and certain.

Figure 1: A General Model of Precautionary Risk Regulation



3.3. Screening

In the screening stage, key features of the ***threat*** in question are identified in advance. These attributes are then used to select the best approach to more detailed regulatory appraisal, bearing in mind the particular kinds of information required for effective and efficient regulation. Screening also helps in prioritising attention to different threats. This essential activity relates to established notions of 'risk assessment' in discussions under the auspices of the WTO and elsewhere, which can be either quantitative or qualitative in form.

The term 'threat' is important here, because it admits interpretation either in terms of probabilistic risk or intrinsic hazard properties, depending on the context. Such intrinsic properties bearing on the '***seriousness***' of the threat may relate to endpoint effects (such as carcinogenicity, mutagenicity or reprotoxicity) or to exposure potentials (like bioaccumulation, persistence and ubiquity). Each of these offers a criterion of 'seriousness'. Where any threat is held under these criteria definitely to be serious, then subsequent regulatory appraisal involves a 'presumption of prevention'.

There are a number of reasons why a threat may be considered not to be definitely serious. One important reasons is where the threat is subject to '***scientific uncertainty***'. Screening here involves examining the applicability of probabilistic risk assessment techniques in any given case. Specific criteria include various questions about the status of the relevant theoretical frameworks, the presence of substantive novelty or unprecedented characteristics in the products or production processes and the sufficiency and applicability of the relevant models and data sources. Where any of these criteria are triggered then risk assessment techniques are ruled out and regulation instead takes the form of 'precautionary appraisal'.

Where a threat is judged neither definitely to be 'serious' nor 'scientifically uncertain', then the question remains as to whether it is nonetheless significant in scale or whether there exist complexities which, whilst not scientifically uncertain, do warrant treatment using extended risk assessment techniques. Criteria of '***complexity and scale***' that may be employed to screen for such cases include the presence of cumulative or additive causal mechanisms and whether

the threats involve exposed populations, potential scales of damage or likely time delays which exceed certain critical thresholds. Where any one of these filters is activated, then the threat in question is assigned to 'extended risk assessment' in subsequent regulatory appraisal.

Where threats are identified not to be definitely serious, and not to present scientific uncertainty or issues of scale and complexity under the criteria described above, then there still remain questions over the '***socio-political ambiguity***' of the threat. Does it involve perceptions of catastrophic potential harm? Is it associated with significant institutional conflict or political mobilisation? Are there issues of 'distributional equity' or signs of 'social amplification' in the news media? If these criteria are activated, then the threat in question is assigned to a ***discursive process*** in subsequent regulatory appraisal.

Where a threat is found not to be serious, uncertain, complex, large in scale or socio-politically ambiguous in any of the senses described above, then it may be subject to a 'standard risk assessment' process. As is conventionally the case at present, this is the approach that is adopted in the case of a very large number of cases of routine risks.

3.4. Appraisal

As described above and in Figure 1, the screening process may allocate threats to treatment by one or more of five different approaches to regulatory appraisal. Each is designed to gather the information necessary for regulatory decision making in different contexts in the most effective and efficient fashion. Where a given threat displays a number of different attributes, these different aspects may be allocated to parallel treatment by different types of appraisal.

If the threats in question are definitely (that is, certainly and unambiguously) serious then – as at present – subsequent regulatory appraisal adopts a ***presumption of prevention.*** This is shown with the colour red in Figure 1. Rather than aiming at further elaborate characterisation of the threat, this involves simply examining for countervailing justifications or over-riding social need which would dictate a precautionary approach. Otherwise, regulation results in the implementation of preventive measures.

On the other hand, if the threats in question are found under the screening criteria to be certainly and unambiguously not serious, not complex and not large in scale, then they are assigned directly to routine administration by ***standard risk assessment***. Here, appraisal takes a straightforward form, based simply on probabilities and magnitudes, and is performed by in-house staff. In such routine cases, there is a presumption, subject to management considerations, in favour of approval. This is shown with the colour green in Figure 1.

If screening is unable to allocate to straightforward preventive (red) or standard (green) management measures, then more elaborate regulatory appraisal procedures are undertaken. If a lack of scientific certainty has been identified in screening, then the subsequent regulatory process takes the form of ***precautionary appraisal***. This involves a broad-based approach, with the full engagement of different interested and affected parties and which does not rely on probabilistic techniques. Key characteristics of this approach include unconstrained scope, involving consideration of benefits and justifications (as well as all direct and indirect effects) of a full range of technology and policy options, looking at the entire associated product and life cycles. The burden of persuasion is placed on proponents and consideration extends to the flexibility, adaptability, reversibility and diversity displayed by different policy options.

Where a threat is directed to treatment by '***extended risk assessment***' it is, by definition, susceptible to characterisation by probabilistic techniques. In such cases, regulatory appraisal uses conventional methods (including systematic modelling and safety margins) applied in a transparent and accountable fashion by interdisciplinary groups of external independent specialists. On the other hand, where screening has identified 'socio-political ambiguity', then

the choice of appropriate management instruments will be a ***discursive process***, subject to inclusive participatory procedures designed to clarify and so help resolve this ambiguity. The specific type of process will vary from case to case, but will respect general principles such as representativeness, transparency, accessibility and unconstrained scope.

As shown by small two-headed arrows in Figure 1, the different approaches to regulatory appraisal are not necessarily mutually exclusive. If characteristics of uncertainty, complexity/scale or ambiguity are encountered at a later stage in appraisal, then a threat may be assigned to the appropriate appraisal approach.

3.5. Evaluation, Management and Oversight

As in conventional understandings of the regulatory process, the third major element in the general model after screening and appraisal is management. This involves the ***evaluation*** of the information yielded by the different regulatory appraisal processes and the consideration of this information alongside other relevant social and economic factors. As in conventional risk analysis, the purpose of the evaluation process is to take account of the results obtained in regulatory appraisal, weigh this up against wider social and economic issues and consider the pros and cons of different possible instruments. With full involvement by all interested and affected parties and based on the principles of proportionality and non-discrimination, this involves the application of various forms of regulatory impact assessment to identify the most appropriate regulatory instrument in different contexts. As in established regulatory practice, it is at this point in the process that a decision is taken. Depending on the information generated in appraisal, this might take the form of one or more courses of action from a spectrum of management measures, ranging from highly restrictive (such as bans and phase-outs) to entirely permissive (such as unrestricted activity). This is shown by the shading from red, through yellow to green in Figure 1.

The presumption is that, where serious threats have been identified without scientific uncertainty, then preventive measures will be applied. Likewise, the presumption is that approval will be granted for threats that have been evaluated certainly to be non-serious, unambiguous and non-complex and so subject to standard risk assessment. However, as in established management approaches, both of these cases will still be subject to a basic evaluation process. For threats that are addressed by other forms of regulatory appraisal (precautionary, discursive or extended risk assessment), there is no implication that any one will necessarily lead to any one form of management measure.

Finally, it is important to note that the design of the process portrayed in this general model is not as closed or as linear as might be suggested in Figure 1. As in conventional regulation, the process is subject to general political and administrative oversight and open to development in the face of new learning and to feedback between various stages. In practical terms, it is the process of design, development and oversight that governs the selection, characterisation, implementation and review of the threat criteria employed in screening and of the various elements in the different approaches to subsequent regulatory appraisal. In particular, this will determine the relative priorities attached to different agents and threats and ensure that a justifiable and proportional balance is being struck in the allocation of resources to different aspects of screening, appraisal and management.

The design, development and oversight function addresses any unforeseen difficulties that may arise and ensures that the overall process is robust to changes in circumstances and to the perspective of all interested and affected parties. As such, it will necessarily involve a range of procedures and a variety of institutions and is subject to general principles of good governance, including competence, transparency, efficiency, legitimacy and accountability.

Against the background of the general architecture of the proposed model for precautionary risk regulation described above, the following section concretises the required concepts for selecting objectives, assessing and handling data, and finding the most appropriate procedure for balancing pros and cons when dealing with serious, uncertain, complex and/or ambiguous risks. These different tools are integrated in the formal decision analytic concept.

4. Risk Analysis According to the Precautionary Principle (Section C)

The main task of risk analysis according to the precautionary principle is to develop the adequate strategies and tools for dealing with the inherent problems of ***uncertainty, complexity and ambiguity***. Based on the characteristics of these three major problems we distinguish ***five approaches to risk analysis***: Routine, risk-based, precaution-based, discourse-based and preventive approaches. These five approaches include different concepts for selecting objectives, assessing and handling data and finding the most appropriate procedure for balancing pros and cons.

Dealing with ***routine risks*** requires hardly any changes to the traditional decision making framework in risk analysis agencies. The data is provided by statistical analysis, the goals are determined by law or statutory requirements and the role of risk management is to ensure that all risk reduction measures are implemented and enforced. Traditional risk-benefit analysis combined with cost-effectiveness are the instruments of choice for finding the right balance between under- and overprotection of the public. In addition, monitoring the risk situation is important as a reinsurance that no unexpected consequences may occur.

Resolving ***complexity*** requires some deviation from the conventional methods of risk assessment and risk management. Data collection and interpretation are less obvious than in the routine case and demand more sophisticated methods. Simple statistical data is either not available or insufficient to calculate the risks for humans or the environment. In our analysis we recommend novel data collection and interpretation procedures such as the Delphi process as a means to get the best expertise and experience represented in characterizing causal chains from the initiating event to the final damage. Once the probabilities and their corresponding damage potentials are calculated risk managers can proceed in a similar way as they have done in the routine case. They should set risk reduction priorities according to the severity of the risk, which may be operationalised as a linear combination of damage and probability or as a weighted combination of the two components. When it comes to balancing pros and cons, the traditional methods such as risk-risk-comparison, cost-effectiveness and cost-benefit analysis are well-suited to facilitate the overall judgment. These instruments if properly used provide effective, efficient and fair solutions with respect to finding the best trade-off between opportunities and risks. The proper use of these instruments requires transparency over the subjective judgements and the inclusion of knowledge elements that have shaped the parameters on both side of the cost-benefit equation. These inputs could be provided by an ***epistemological discourse*** aimed at finding the best estimates for characterizing and evaluating the risks under consideration.

If ***uncertainty*** plays a large role, in particular ignorance, the risk-based approach becomes counter-productive. Judging the relative severity of risks on the basis of uncertain parameters, does not make much sense. Under these circumstances, management strategies belonging to the precautionary approach are required. With respect to the objectives, there is a need to add objectives that promise to enhance resilience and decrease vulnerability. These goals may conflict with the aim of efficiency based on optimizing trade-offs between costs and opportunities. Yet the possibility of irreversible harm necessitates protective measures beyond the point of optimal resource allocation. Strategies based on resilience include specific

measures of precaution, such as ALARA or BACT, or the strategy of containing risks in time and space.

This suggestion does, however, entail a major problem: Looking only to the uncertainties does not provide risk managers with a clue where to set priorities for risk reduction. How can one judge the severity of a situation when the potential damage and its probability are unknown or highly uncertain? In this dilemma, risk managers are well advised to include the main stakeholders in the assessment process and ask them to find a consensus on the extra margin of safety that they would be willing to invest in exchange for avoiding potentially catastrophic consequences. We have called this type of deliberation ***reflective discourse*** since it rests on a collective reflection about balancing the possibilities for over- and under-protection based on uncertain data and ignorance.

Different from many other analyses of the precautionary principle, our concept distinguishes clearly between uncertainty and ***ambiguity***. Uncertainty refers to a situation of being unclear about factual statements; ambiguity to a situation of contested views about the desirability or severity of a given hazard. Uncertainty can be resolved in principle by more cognitive advances (with the exception of indeterminacy and ignorance), ambiguity only by discourse. Discursive procedures include ***legal deliberations as well as novel participatory approaches***. If ambiguities are associated with a risk problem, it is not enough to demonstrate that risk regulators are open to public concerns and address the issues that many people wish them to take care of. The process of risk evaluation itself needs to be open to public input and new forms of deliberation. This starts with setting the objectives. In situations of high ambiguity, we recommended value-tree-analysis as one promising exemplary model for involving different stakeholders and members of the public. The aim is to find consensus on the dimensions of ambiguity that need to be addressed in the phase of data collection. The data collection process turns into a multi-disciplinary and cross-sectional analysis once ambiguity is present. This means that natural as well as social scientists and representatives of the humanities should become involved. The third and last step, i.e. balancing pros and cons, requires a larger input from social groups. We recommend a set of deliberative processes that are, at least in principle, capable of resolving ambiguities in risk debates. Those processes include citizen panels, consensus conferences, ombudspersons and other participatory instruments.

The ***preventive approach*** does not add any new elements to the decision analytic framework. If any of the other four approaches leads to a negative decision on the respective risk under consideration the preventive approach provides the tools or instruments for banning or phasing-out the risk. The only objective here is to eliminate the risk-bearing activity in a economical and socially compatible fashion. In extreme cases a risk may be tolerated if the benefits are so overwhelming that even a clearly unacceptable risk seems proportional to the benefits, or if there exist countervailing risks, or there are unavoidable constraints on control. In such cases, depending on whether the qualification takes the form of uncertainty or ambiguity, the threats in question will be assigned for further attention either (respectively) to precautionary or discursive approaches to regulatory appraisal In either case, the presumption of prevention will be augmented by critical examination of such potential mitigating factors or grounds for conditional relaxation as part of an comprehensive and inclusive deliberative process, involving relevant interested and affected parties.

Deliberative processes are needed for all five approaches to risk analysis based on decision analysis. The routine approach needs a discourse among agency staff and enforcement personnel *(instrumental discourse).* The objective here is to find the most cost-effective method for a desired risk reduction level. If necessary, stakeholders may be included in the deliberations as they have information and know-how that may provide useful hints for being more efficient. The risk-based approach relies on *epistemological discourse,* the uncertainty-

based approach on *reflective* and the discourse-based approach on *participatory discourse* forms. These types of discourse form an ***analytic-deliberative procedure for risk evaluation and management*** as demanded by a recent publication of the US Academy of Sciences (cf. Stern and Fineberg 1996).

5. The Legal Dimension of Developing a General Model for Precautionary Risk Regulation (Section D)

An important aspect of the PrecauPri project is to develop a model of precautionary risk regulation that is compatible with the EC Treaty, principles of EC law, and international trade obligations. In each case, there is a rich and dynamic body of case law and academic discussion and there should be no pretence that compliance with these obligations is straightforward. The project's full document identifies some of the most significant legal issues. It also includes a discussion concerning how the PrecauPri model builds on the European Commission's Communication on the Precautionary Principle. It should be noted, as the model is an innovative model, the direct concern of the project is not to develop a model compatible with all existing risk regulation regimes, although in many cases these regimes could be adapted in accordance with the PrecauPri model.

The precautionary principle is a legal principle and as such it 'states a reason that argues in one direction, but does not necessitate a particular decision' (Dworkin). Precaution is thus akin to other legal principles such as proportionality and non-discrimination. It is flexible and how it operates will depend on context, legal culture, and the other principles it interacts with. It is best described as a legal principle concerned with the *process* by which a decision is made and can operate at numerous levels including that of institutional design, process design, and the exercise of individualised discretion. Common concerns about the principle are that it is 'trump card' that hides ulterior motives, that it is an excuse for arbitrary action, and that it encourages unilateralism.

There is no simple checklist that can be developed to ensure the legal robustness of the PrecauPri model or a decision made pursuant to it. This is for two reasons. First, as a general model it can apply to wide variety of subject matter and each different area will give rise to a distinct set of legal issues. Thus for example, sanitary and phytosanitary measures will be subject to different legal obligations from environmental measures in the WTO context. Second, any EC regulatory regime will by the subject of overlapping legal cultures and thus 'bound' by different and even contradictory legal requirements. Thus for example, a food safety measure will be subject to requirements arising out of the EC law, the SPS agreement if it also covers exports, and if implemented in national administrations the legal culture of each of the Member States. While different legal cultures may use the same language of non-discrimination and proportionality, such terms may have quite different legal definitions.

With that said, a careful analysis of the major legal obligations (the EC Treaty, EC case law, and the SPS Agreement) to which EC risk regulation regimes are likely to be subject does reveal some common themes: public reason, proportionality/non-discrimination; and governance/accountability. These are important if a regime is to comply with any of these obligations and the PrecauPri model has been developed on the basis of these three principles. First, the model ensures a ***public and logical reasoning process*** by requiring the transparent assessment and evaluation of 'threats' and how they are managed. It adjusts those regimes built on the risk assessment/risk management divide by recognising that the nature of risk assessment and regulatory appraisal needs to vary with the nature of the 'threat' and the information available about it. Risk assessment is both a mainstay of the WTO SPS and the EC legal regimes and this model requires an adaptation not an abandonment of it. In the

assessment process, precaution and scientific uncertainty are distinguished from other types of factors that may affect the risk assessment and management process such as complexity and socio-political ambiguity. As such, precaution cannot be used as a justification for arbitrary action or a 'trump card' for an ulterior motive. Second, the principles of ***proportionality and non-discrimination*** are ensured. This is in the screening process and most importantly in risk management where management decisions are only taken after a more accurate picture of risks and the uncertainties in relation to them have been developed. Measures are far more likely to be least restrictive and to treat like products alike if the nature of the risks is better understood. Finally, the model ensures ***good governance and accountability*** by having a transparent and inclusive regulatory design that incorporates and tailors deliberative processes. These deliberative processes are focused on particular issues to ensure efficiency and effectiveness.

6. Precautionary Pre-Selection of New Organic Chemicals – a Case Study on the Application of the General Model for Precautionary Risk Regulation (Section E)

Having described the proposed concept of precautionary risk regulation and illustrated its legal dimensions, we present in the following section the results of the empirical case study which exemplify the practical feasibility of the concept.

Within PrecauPri, the regulation of chemicals serves as a test case for the design of appropriate procedures in the application of precautionary reasoning in industrial innovation. More precisely, the PrecauPri case study adds some specific types of precautionary screening to the established assessment routines for chemicals, and then examines the results of the screening when substances of known environmental characteristics are used as test chemicals.

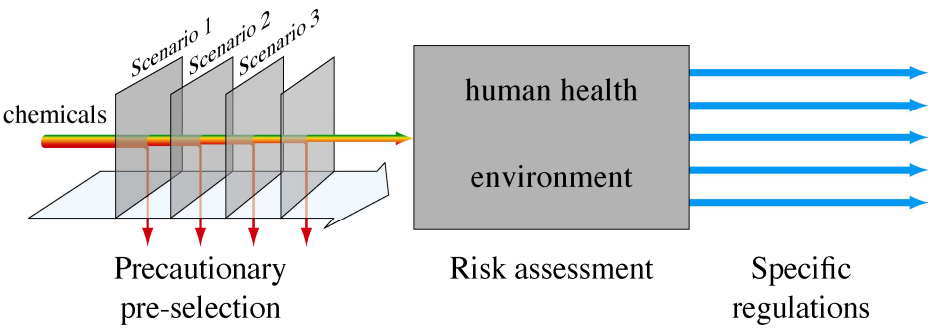
6.1. Precaution and Chemical Risk Assessment

In many respects the current practice of chemical assessment corresponds to the stages "appraisal" and "management" of the proposed general model (see Figure 1): the appraisal stage is realized as an extended assessment of risks for human health and the environment. The detailed outcome then leads to specific regulations depending on exposure, tonnage and use pattern - in accordance with the management stage of the general model. At several places in this scheme, precaution-type arguments can be identified, particularly the well-known "safety" or "assessment" factors that contribute to the final result.

In the PrecauPri case study this procedure is complemented by a precautionary screening stage as provided in the general model. Screening is introduced in order to identify chemicals deserving special attention or even to eliminate substances of high concern at an early stage. In the future, screening might help to avoid the unpleasant experiences in the long history of environmental chemicals, and should also save manpower, money and time.

For the screening stage a so-called filter series approach was developed and applied. Each filter corresponds to a special threat scenario and fulfils a set of requirements to guarantee the overall performance of the series. The filters under consideration in the case study are tailored to large-scale environmental threats.

Figure 2: Extended assessment scheme for chemicals including pre-selection

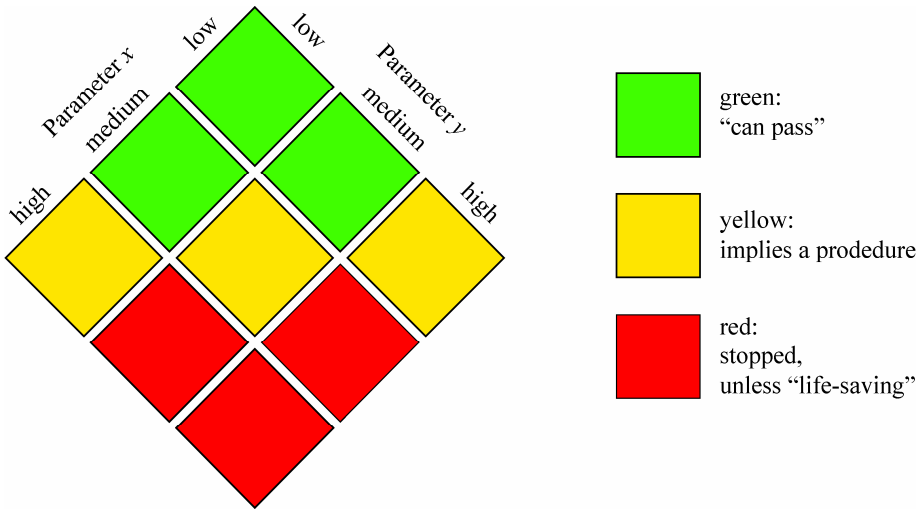


The filter series approach is not entirely new, and some of it may be found in the screening routines of pharmaceutical or pesticide producers, albeit in less formalized versions.

In the case study, precautionary filters were realized as a two-parameter classification schemes with three outcomes: green ("may pass"), yellow ("needs further consideration"), and red ("will be stopped"). For filters based on two parameters – with each parameter having the grades *high / medium / low* - the outcomes are defined using these grades of the two parameters (Figure 3).

green:	medium/low, low/low, low/medium
yellow:	high/low, medium/medium, low/high
red:	high/medium, high/high, medium/high

Figure 3: Two-parameter filter with three grades



If a substance is classified as "red" by at least one filter it definitely constitutes a serious threat. According to the general model (Figure 1) this triggers preventive measures: such a chemical should be eliminated - with the possible exemption of "lifesaving" pharmaceuticals or some intermediates in industrial synthesis if contained under extreme safety standards. Chemicals not classified as "red" enter the normal chemical risk assessment (Figure 2).

6.2. A Case Study with Two Filters: Pandora and Bioaccumulation

In the PrecauPri case study, Pandora and bioaccumulation are taken as scenarios for large-scale environmental threats. The Pandora scenario is named after the Greek myth of Pandora's box that contained all evils and complaints. When the box was opened, all of its

contents were unleashed upon the earth, causing irreversible harm. The enduring ubiquity of persistent organic pollutants (POPs) is regarded as the epitome of the Pandora scenario. For the construction of a related filter, one observes that the Pandora situation is essentially due to the interplay of *two* intrinsic properties: mobility and longevity. The potential for mobility and longevity is expressed by characteristic isotropic global (CIG) half-life τ and characteristic isotropic spatial (CIS) range ρ:

- characteristic isotropic global half-life τ is the typical overall lifetime of a molecule under earth-like isotropic conditions where concentrations quickly equilibrate between atmosphere, the surface layer of the oceans and the upper layer of soils;
- characteristic isotropic spatial (CIS) range ρ is the typical distance a molecule would travel before degradation – under earth-like spatially isotropic conditions where concentrations quickly equilibrate between atmosphere, the surface layer of the oceans and the upper layer of soils.

Bioaccumulation is a phenomenon combining bio-concentration and bio-magnification. The corresponding threat scenario takes into account the fact that substances can have adverse effects on living organisms even if their concentrations in e.g. the oceans are extremely low. As fat tissue is the relevant storage medium in an organism and as the partition of a chemical between water and organismic fat tissue is modelled through its octanol-water partition coefficient K_{ow}, this coefficient is one of the relevant parameters for bioaccumulation. In analogy to the Pandora case, the bioaccumulation filter is based on two parameters: a combination of high K_{ow} values and increased global characteristic persistence τ . (In order to bio-accumulate a chemical has to survive a minimal period of time before degradation.)

The construction of filters ends with the definition of the parameter grades leading to the filter outcomes “green”, “yellow”, and “red”. For two-parameter filters with three grades for each parameter one has to find limiting values separating low / medium and medium / high for the respective filter parameters.

For the PrecauPri case study the parameter values of both the Pandora filter and the bioaccumulation filter have been calculated. The calculation was based on data of the top 35 US High Production Volume (Organic) Compounds as paradigms for chemicals posing no large-scale environmental threats and of a relevant selection of 44 Montreal/Kyoto/ Stockholm compounds as paradigms for precarious chemicals.

The results show that in the Pandora setting the Montreal and Kyoto compounds are well separated from the High Production Volume Chemicals (HPVCs) whereas the POPs and the HPVCs slightly overlap. In the bioaccumulation setting the separation between the HPVCs and the Montreal/Kyoto/Stockholm chemicals is perfect.

Figure 4.1: Outcome of the Pandora parameters

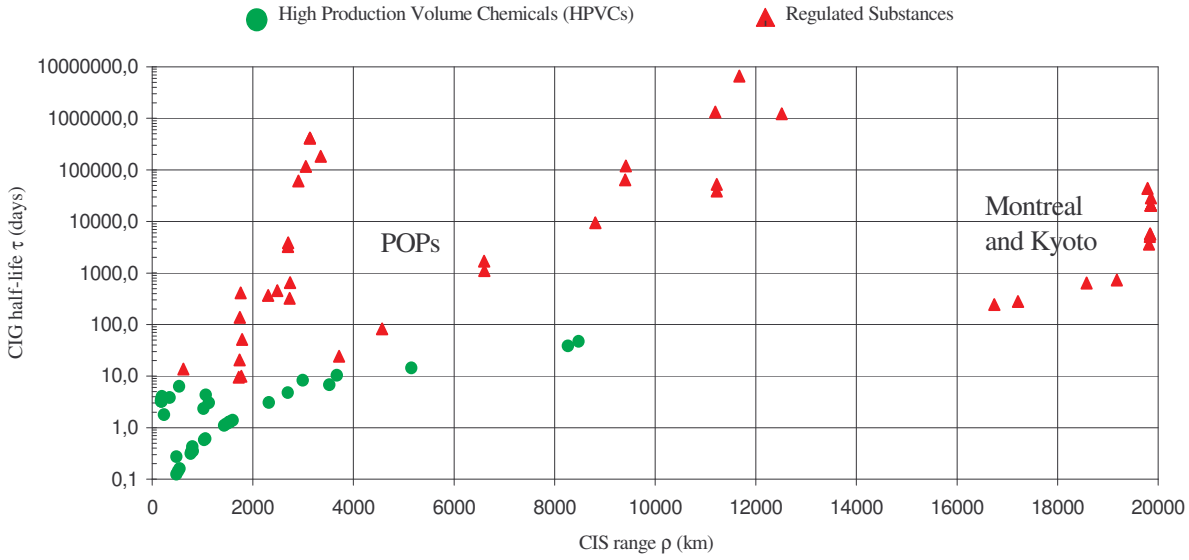
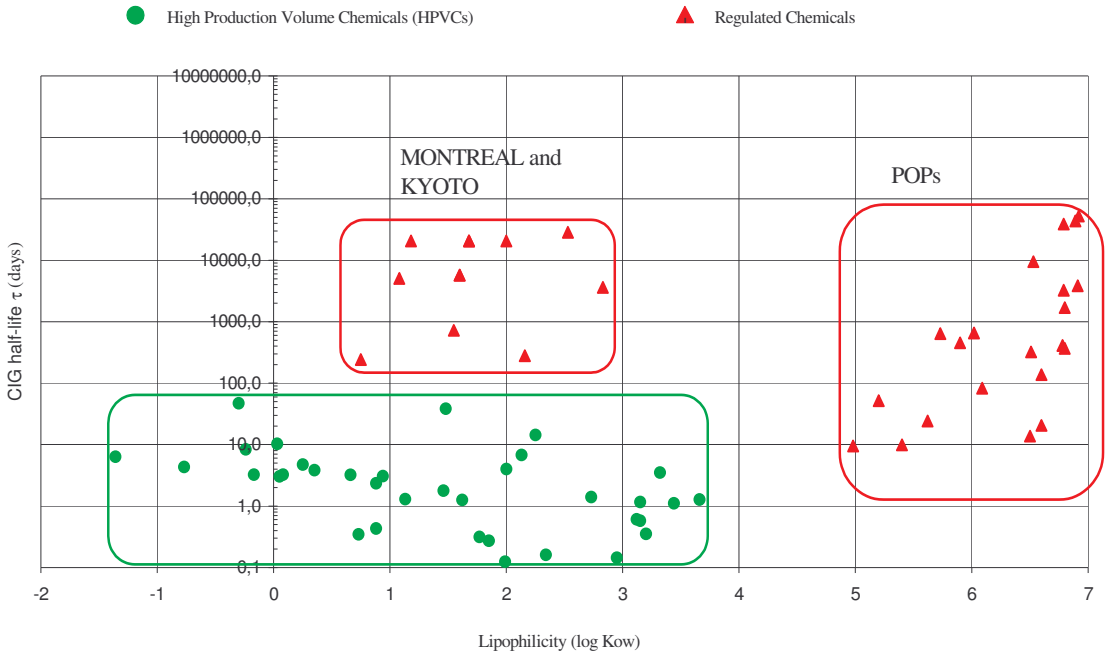


Figure 4.2: Outcome of the bioaccumulation parameters



6.3. Results of Screening

The real test of the case study was the question: How well does the series of the two filters Pandora and bioaccumulation perform if substances of known environmental characteristics are submitted to the screening?

With respect to the large-scale threats in question there are four basic outcomes: a substance can be classified as

a. inconspicuous (two green marks) when being inconspicuous (HPVCs)
b. inconspicuous (two green marks) though being precarious (Montreal / Kyoto, etc.)
c. precarious (at least one red mark) though being inconspicuous (HPVCs)
d. precarious (at least one red mark) when being precarious (Montreal / Kyoto, etc.)

The following limiting values were extracted through special search algorithms developed by T. Jarimo and O. Schucht

Pandora

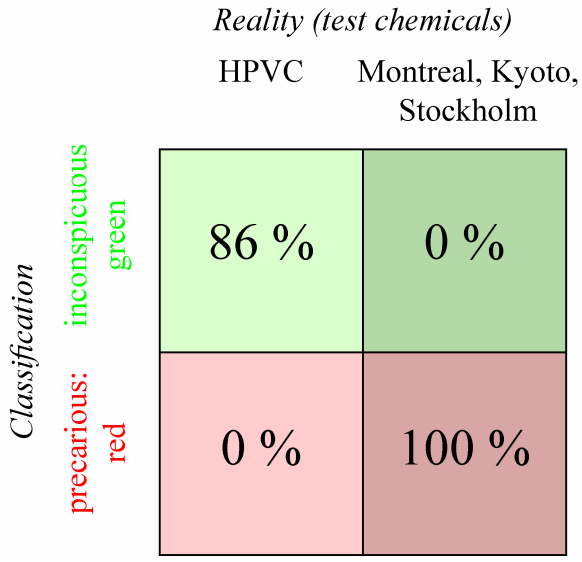
ρ: low/medium: 340 km; medium/high: 8600 km
τ: low/medium: 9 days; medium/high: 50 days

Bioaccumulation

Log K_{ow}: low/medium: 0.75 medium/high: 4.3
τ: low/medium: 9 days; medium/high: 243 days

and lead to the results of Figure 5.

Figure 5: Result of the chemical classification problem. (As "green" + "yellow" + "red" add to 100% "green" + "red" can add to less than 100%, i.e. to 86%.)



The screening filtering completely reproduces the present situation: no HPVC received a "red" (which would stop it). Most of them (86%) even were given two "green" (can pass). Only five substances received one or two "yellow" (14%) indicating that closer examination should follow. Concurrently, each of the universally itemized Montreal / Kyoto / Stockholm chemicals were given one or two "red", completely in line with the outcome of the above conferences.

6.4. What has been Achieved?

Foremost, the filter series approach has been presented as a recipe for the handling of precautionary aspects in chemicals. It should be stressed that the idea of using sequences of two-parameter filters for screening and the results of this method if applied to chemicals should be appreciated as two separate points. As a formal scheme, in fact, the filter series procedure is independent of particular hazards. Secondly, in a case study dealing with special features of global hazards of organic chemicals two types of filters have been constructed and calibrated with recourse to historical and present-day chemicals. This sequence of two filters was shown to reproduce in a shortcut important results of a long and cumbersome historical development. Thirdly, spatial range is now introduced as an additional new assessment parameter, complementing persistence and bioaccumulation which have been used in chemical assessment for a long time. Fourthly, the interplay of screening parameters in the diverse threat scenarios is taken into account using two-dimensional filters. Finally, the usual practice of defining limiting values for individual parameters through body of experts has been complemented by new search algorithms for the optimal gauge of two parameter filters. In essence, there is a rapid, inexpensive, and straightforward procedure available for the screening of organic substances that proves itself in the re-assessment of old and existing substances.

Although the approach to precautionary screening presented here was developed as an answer to the needs of regulative authorities, a far more extended application is conceivable: ideally, a chemist designing a new compound on paper could directly "send it through the filters." At this early stage, of course, the measurable input parameters had to be replaced by theoretical or estimated values. In combination with a suitable software solution, a first preliminary precautionary assessment could be undertaken directly after the molecule has first appeared on a chemist's drawing table. In this way precaution could come into play - prior to the synthesis of one single molecule of a precarious substance. This would be prevention at the source.

7. Some schematic examples from the food safety area to illustrate the whole model

This final section further illustrates and substantiates the formal description of the general model. It does this by discussing the way in which a number of concrete cases might be handled in the proposed screening, appraisal, evaluation and management processes. The examples discussed here are selected to address certain possible complexities in the practical application of the model and so warrant more detailed discussion. For the sake of contextual comparability, all are drawn from the food safety area.

Of course, the particular path taken by any one such hypothetical example will depend crucially on the precise choice of criteria adopted in each of the screening filters, the nature of the appraisal process concerned and the outcome of the evaluation. As has been emphasised, the structure of the general model itself is independent of such details. However, these examples should suffice for the present purpose simply of illustrating the 'sense' of the general model.

7.1. Alfatoxins

The first example concerns a food product that is subject to aflatoxin contamination. Assuming that one of the criteria used to define a 'definitely serious' threat is the hazard property of carcinogenicity then aflatoxin contamination would be classified as 'definitely serious' since aflatoxin is a known, undisputed liver carcinogen. As such the food product would be appraised under a *preventive approach*. Appraisal would therefore focus, for example, on identifying the justifications for use of the food product, the availability of alternatives, the presence of countervailing risks and the specific conditions of application. Such considerations might constitute important mitigating considerations that would be weighed against a default assumption of highly restrictive risk management measures during a subsequent evaluation stage. In the case of the new food stuff, a presumption that the product is not permitted for human consumption, or only permitted for use under certain conditions, might hypothetically be offset by a justification of the need for the product, and, if affirmative, specification of the conditions under which the product is produced and stored. That presumption might also be offset by the identification of countervailing risks, such as the impacts of restrictive risk management measures on the livelihoods of those responsible for producing the product.

7.2. Transmissible Spongiform Encephalopathy

The second example concerns the emergence of a novel transmissible spongiform encephalopathy (TSE) in cattle. The threat in question here concerns the possible transmission of the disease to humans. Unlike the first example, the novel TSE would not constitute a 'definitely serious' threat since one of the steps in the initial threat characterisation (the uncertainty filter) would almost certainly identify scientifically founded suspicions concerning the theoretical basis for our understanding of the phenomena (the possible transmission of the TSE to humans). Thus the assessment of the possible risks posed by BSE, and the identification of possible options for reducing those risks, would be subject to *precautionary appraisal.* Invoking the 'broader based' procedures of precautionary appraisal would imply that as much pertinent knowledge and experience as possible is brought to bear on regulatory decision-making. Here it is worth pointing out that the history of BSE policy-making indicates that a broader-based and more plural appraisal process would almost certainly have delivered a better and earlier understanding of the epidemic and the possible risks; in other words a diminution of what we have earlier termed *institutional ignorance*.

7.3. Food Irradiation

The third example concerns the introduction of food irradiation as a means to reduce bacterial contamination of fresh food stuffs. The technology would not be classified as posing a 'definitely serious' threat. Nor would there be any uncertainties pertaining to that classification because there would be no scientific doubt, in this case, about our theoretical understanding of irradiation as a technology, and it is not an entirely new technique. Similarly, we would be unlikely to have any serious doubt about the evidence and analytical techniques used to establish the effects of irradiation on fresh food stuffs. As far as issues of complexity and scale are concerned, it is conceivable, for example, that irradiation might alter the nutritional constituents of a food stuff and do so for very large populations. It is possible therefore that food irradiation would be subject to an *extended risk assessment* in subsequent regulatory appraisal. There are also, however, a number of public concerns about food irradiation which thus far have derailed any attempt to introduce the technology on a widespread commercial scale. Those concerns pertain, for example, to the possibility that food irradiation might be used to disguise a failure to ensure production and distribution of fresh food. In this case, the technology might therefore trigger the filter on socio-political ambiguity. This would be a matter for the *discursive* process in tandem with the *extended risk assessment*.

7.4 *Dichlorodiphenyltrichloroethane*

The fourth example is a pesticide that has been in use for over 50 years, dichlorodiphenyltrichloroethane, or DDT. It is known that DDT bioaccumulates and that at high concentrations it can have adverse effects on certain bird species. For this reason (and as a result of concerns about carcinogenicity) it has been banned or heavily restricted in most industrialised countries. It is, however, a cheap and effective means of controlling the insect vector of malaria and is still in wide use in less developed countries. The issue then of the agricultural versus the public health uses of DDT might be appropriate for a presumption of prevention in tandem with a *discursive* approach to appraisal. The reason for this is that the issue in question is not the physical risks per se but rather the question of how incommensurable risks and benefits are to weighed up and questions about the availability, costs, risks and efficacy of alternatives to DDT.

7.5 Genetically Modified Organisms in Food

The final example concerns the appraisal of GM organisms in various food uses. This example also illustrates how different aspects of a technology might be subject to parallel treatment by a number of different approaches to regulatory appraisal. For instance, the process of initially licensing contained use of a GM organism for use in closed cycle processes used to manufacture products of uncontroversial utility (such as cheese) might reasonably be subject mainly to an extended risk assessment. Application of the same technologies to unconfined use in the environment might reasonably be subject to precautionary appraisal. Issues concerning the relative utility of different applications of such technologies – including questions of social benefit and need – might be held to be a matter principally for the discursive approach. Finally, depending on the screening criteria, applications of such a technology using specific techniques (such as antibiotic marker methods), might be held to trigger a preventive approach.