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Introduction food safety precautionary principle

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The precautionary principle in international food safety policy-making
Theoretical framework and empirical case studies

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SUMMARY

Introduction

This report focuses on the introduction of the precautionary principle in decision-making about food safety in the context of international trade. This topic needs attention because of prevailing sensitivity about application of the precautionary principle in international politics. Several countries voice serious concerns with respect to the application of the precautionary principle. They fear misuse of the principle for protectionist motives. The regulatory objective of this report is to contribute to informal discussions, in particular between developing countries and the European Union, in a bid to clarify possible applications of the precautionary principle. It does so by presenting theoretical and empirical reflections on the pros and cons of established interpretations of the precautionary principle within the European Union. The report analyses two case studies that illustrate an interpretation of the precautionary principle without protectionist effects on the international trade in food products.

Theoretical framework

The report starts with a theoretical chapter about the precautionary principle in decision-making processes about food safety. This chapter starts with a short history of the roots of the precautionary principle and its place in international protocols and agreements. It proceeds with a description of the prevailing European interpretation of the precautionary principle. This interpretation, divided in three stages (trigger, decision and application), is the starting point for analysis and discussion of the two case studies. This three-stage precautionary approach could contribute to a balanced weighing of environmental, health, technical-scientific and socio-economic aspects of food safety disputes between in particular developing countries and the European Union. The chapter concludes with some reflections on the precautionary principle as a debate in progress.

The conclusion of this theoretical chapter is that the precautionary principle facilitates dealing with uncertainties – nothing more, nothing less. Disagreement about the application of the precautionary principle between different parts of the world centres on the fear that the principle might be misused as a means to justify (hidden) forms of protectionism. These differences of opinion may cause tension in international trade relations, since the United States in particular adopts a sceptical stance towards the European interpretation of the precautionary principle. Nevertheless, within the European Union a common understanding of the application of the precautionary principle exists, which also results in its legislative embedding. The recent *General Food Law*, for instance, embodied the precautionary principle and explicitly mentioned it in its regulations (178/2002). The prevailing European interpretation of the precautionary principle is that it should operate as a three-stage process (trigger, decision and application).

The theoretical chapter, furthermore, reveals that reflection on the precautionary principle as a debate in progress shows that the central message of the precautionary principle seems to be evident: policy-makers should not wait with preventive measures until full scientific consensus is available. This reasonable but not yet very practical guidance in applying the precautionary principle on food safety issues is further explored by distinguishing divergent precautionary strategies. Four different precautionary strategies are described (technological revision, technological revolution, political steering and ecological concern) as expressions of deeper values and attitudes towards risks. This results in the conclusion that the pursuit of one single elaboration of the application stage in a precautionary approach is futile, since this stage should always leave ample room to choose between a variety of precautionary measures.

Empirical case studies

The case studies address possible applications of the precautionary principle with retrospect to events that took place in each of the analysed cases. The case of dioxin contamination of citrus pulp pellets shows a (temporary) ban being imposed on the import, whilst consequently a pursuit of missing data has been performed. Finally, adaptation of legislation both in Europe and in Brazil, as well as a regulation that only "virgin" hydrated lime should be used, proved sufficient to stop further contamination. However, monitoring continues in a bid to stop repetition of this contamination until now. This case highlights (scientific) uncertainty about technological aspects.

The case of maximum residue levels (MRLs) for pesticides and their effects on the export of fruits and nuts from developing countries shows that novel and strict MRLs pose serious problems for exporting developing countries. Mainly socio-economic aspects are at the root of uncertainty in this case. The case could be characterised as a situation in which full scientific consensus about the dangers of pesticide residues is absent and legal consensus within the European Union determines the establishment of MRLs. The question should be whether European governments are responsible for possible harm by pesticides residues, as the established MRLs are a tangible result of political deliberations.

Conclusions & recommendations

The report recommends that if the European Union wishes to convince other countries that the interpretation of the precautionary principle as a three-stage process is a reasonable and balanced guideline for food safety policy-making, it should address the obvious response that this interpretation depends on a particular attitude towards risks and that other countries may simply adopt other risk perceptions. The only way to argue that the three-stage process is an accurate procedural account of the precautionary principle seems to leave ample room to strike a variety of balances between natural and socio-economic risks in applying the precautionary principle. This implies a whole-hearted acceptance of the socio-political – and not just (natural) scientific – nature of the precautionary principle. Hence, the conclusion should be that additional scientific information could never settle disputes in cases of scientific disagreement about some particular food safety hazard, because that would deny that such disputes are ultimately determined by divergent risk perceptions.

Furthermore, the disagreement about the application of the precautionary principle between different parts of the world centres on the fear that the principle might be misused as a means to justify (hidden) forms of protectionism or, on the other hand, that trade interests will overrule the interests of food safety and environmental protection. These differences of opinion cause tension in international trade relations, since the United States in particular adopts a sceptical stance towards the European interpretation of the precautionary principle.

Moreover, it seems reasonable to argue that (some) developing countries should be allowed differential treatment in food safety regulations because of their technological difficulties and lack of specific expertise in obeying overly high food quality standards in affluent countries. Further research is needed to determine criteria for such differential treatment of specific countries and sectors (i.e. smallholders). Finally, if communication about the European interpretation of the precautionary principle wishes to be successful, the precautionary principle at least needs to be embedded in all relevant European and national laws and regulations, such as Dutch food safety legislation (i.e. *Warenwet*). Otherwise the Dutch position on the precautionary principle is not coherent.

1. INTRODUCTION

This report introduces the precautionary principle in decision-making about food safety in an international trade context. Such an introduction is motivated by the prevailing sensitivity of the precautionary principle in international politics. Although the United States is probably Europe's principal opponent in this debate, this report focuses on the concerns of developing countries. These countries voice also serious reservations about the application of the precautionary principle by the European Union. They suspect that developed countries may use precautionary arguments to veil protectionist intentions. That would inevitably result in serious trade distortions. Distrust on part of developing countries has resulted in a stalemate in formal international discussions.

The objective of the report is to contribute to a balanced understanding of the precautionary principle in international food safety policy-making. The report will thus reflect on both pros and cons of the established (European) interpretation of the precautionary principle and its application in food safety disputes. The report presents two case studies in a bid to clarify the possible application of the precautionary principle. These case studies pay special attention to North – South relations in precautionary food safety policy-making.

Chapter 2 explains the theoretical background of the precautionary principle. This account starts with a short history of the roots of the precautionary principle in various (international) protocols and agreements. Next, the established European interpretation of the precautionary principle is presented as a framework for further analysis in the case studies of this report. This interpretation of the principle will, however, also be amended by discussing divergent strategies to use the precautionary principle for the prevention of harm to health and environment. Finally, the chapter addresses a report from the European Environmental Agency that analysed fourteen cases of scientific uncertainty that could have benefited from application of the precautionary principle.

Chapters 3 and 4 illustrate applications of the precautionary principle with two North – South case studies. The first case study concerns dioxin contamination of citrus pulp pellets from Brazil in 1998. The actual contamination of dioxin in milk in Germany is discussed and traced back to its cause – contaminated hydrated lime. Subsequently, measures to control the dioxin contamination of citrus pulp pellets at European, Dutch and Brazilian levels are clarified. This case study addresses the application of the precautionary principle from a technological angle.

The second case explains the significance of maximum residue Levels (MRLs) for pesticides for the export of food products from developing countries. On the one hand, social and economic problems of smallholders are enlightened. On the other hand, European MRL regulations (including registration, monitoring and harmonisation) are explained. This case study distinguishes itself by a socio-economic perspective to the precautionary principle.

Chapter 5 presents reflection and analysis of both case studies, using the interpretation of the precautionary principle as a three-stage process as endorsed by the European Commission. Arguments for and against the application of the precautionary principle are analysed from both a natural and a social scientific perspective.

Finally, chapter 6 draws conclusions from the presented findings of the case studies. These conclusions are based on a balanced approach to possible areas of tension in the application of the precautionary principle. Hence, it includes recommendations for regulatory decision-making.

2. THE PRECAUTIONARY PRINCIPLE AS A GUIDELINE FOR DECISION-MAKING ABOUT FOOD SAFETY IN AN INTERNATIONAL (TRADE) CONTEXT

2.1 Introduction

This chapter sets out to develop a framework for analysis of and discussion about applications of the precautionary principle in cases of food safety policy-making in contexts of international trade between developing countries and the European Union. It starts by presenting a short history of the advent and further development of the precautionary principle in national and international regulatory efforts to protect the natural environment and human health (2.2). It proceeds by presenting the European Commission's interpretation of the precautionary principle as a three-stage process as a framework for analysing and discussing food safety disputes in an international trade context (2.3). It concludes by reflecting on the prevailing European interpretation of the role of the precautionary principle – and its relation to risk assessment – in food safety policy-making (2.4). This reflection on a debate in progress also includes an intermezzo about cultural theory as a tool to address divergent risk perceptions in and between countries.

2.2 A short history of the precautionary principle[1]

Vorsorgeprinzip

The historical roots of the precautionary principle may be traced to German environmental discourse of the early 1970s. Dying trees signalled severe environmental stress on German forests. At that time, however, no proof was available that acid rain caused this unfortunate state of affairs. The government nevertheless acted firmly and imposed several restrictive measures on fossil power plants *out of precaution*. This was the birth of the so-called *Vorsorgeprinzip* – or precautionary principle – as one the key constituents of prospective environmental politics in Germany.

This precautionary principle became a welcome additional guideline to natural scientific risk assessment in the late 1970s. This risk assessment hitherto by-and-large ignored unintended (negative and long-term) ecological and health consequences of the application of novel technologies. The difficulty in quantifying particular risks regularly implied that these risks were underscored in natural scientific risk assessment. Consequently, the absence of measurable and proven harm would mean unhampered further technological development, unless something like a precautionary stance was adopted (Pollan, 2001).

North Sea Conferences

The precautionary principle transgressed the German borders and raised the first international debates in the 1980s. A series of international conferences on the protection of the North Sea should be given the credit, retrospectively, of being the first international forum to fully recognise that in some cases timely and preventive action is needed in the absence of (scientifically) proven harmful effects on the natural environment. In short, these conferences stated that a precautionary approach should be adopted – and appropriate measures taken – to protect the North Sea against possibly harmful effects, even before causal relations between certain pollutants and ecological damage were established beyond reasonable scientific doubt.

Such a precautionary principle was prominently present in the Ministerial Declarations of the North Sea Conferences in 1984 (Bremen), 1987 (London), 1990 (Amsterdam) and 1995 (Esbjerg). Close reading of these declarations would reveal meaningful differences in its wordings

[1] Trouwhorst (2002) offers a more extensive overview of the historical development of the precautionary principle in an international context.

– e.g. timely and preventive action becomes precautionary approach becomes precautionary principle becomes the pursuit of (almost) zero-risk for the ecosystems of the North Sea. This terminological development signals the ever-rising awareness of ecological risks among the participants to these conferences. However, it should not obscure the otherwise pretty obvious continuity in its calls for precautionary action to protect the natural environment (Kaiser, 1997).

Rio Declaration

The precautionary principle gained its prospective status as overarching principle for (national and international) environmental policy-making with the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro (1992). The following circumscription of the precautionary principle in Article 15 of the Rio Declaration became the standard terms of reference for future debates: *"Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".*

Although ambiguity characterises this phrase from the Rio Declaration, environmentalists and others assumed that it called for a reversal of the burden of proof in environmental politics, i.e. environmentalists were no longer called upon to proof that some technological application or development would entail detrimental consequences for the natural environment – the absence of negative environmental repercussions should be proven by the proponents of a certain technological application or development from now onwards. In the words of O'Riordan and Jordan (1995), *"the core of the precautionary principle is the intuitively simple idea that decision makers should act in advance of scientific certainty to protect the environment (and with it the well-being interests of future generations) from incurring harm. […] In essence, it requires that risk avoidance becomes an established decision norm where there is reasonable uncertainty regarding possible environmental damage or social deprivation arising out of a proposed course of action"* (1994).

Codex Alimentarius

The Codex Committee for General Principles (CCGP) of the Codex Alimentarius has taken the lead in the international discussion about applications of the precautionary principle on food safety issues since the early 1990s. The Codex recognises that both (natural) scientific and other legitimate factors are relevant for decision-making about food safety issues at the interface of protection of public health and fair trade in foods. The precautionary principle seems to play a crucial role in these debates on consumer protection and trade protectionism in international food safety policy-making. However, both sides of the Atlantic seem reluctant to look for common ground in their apparently principally opposing positions – i.e. the European Union embraces its version of the precautionary principle, whereas the United States of America prefers its own familiarity principle ("substantial equivalence"). Thus, the EU focuses on long-term and global environmental risks and the US focuses on short-term and domestic socio-economic risks. (Groth, 2000).[2]

The principal opponents in the Codex nonetheless recognise the importance of ongoing discussion about this topic: *"The conference called upon all parties to recognise that precaution has been and should remain an essential element of risk analysis in the formulation of national and international standards and agreed that the Codex Alimentarius is the most appropriate forum to*

[2] The debate about the precautionary principle between the European Union and the United States is most heated in the context of genetic modification. The European Union justifies its *de facto* moratorium on the market introduction of GM foods with reference to lacking scientific knowledge about long-term negative repercussions on human health and natural environment of these novel food products. It tends to ignore the enormous socio-economic costs of this hostile stance towards a promising technological development. The United States simply argue that no substantial difference exists between traditional and genetically modified foods and that the safety of these products should thus be monitored under the same regulatory regime. This line of argument is also motivated by the enormous and direct contribution of producing GM crops to the domestic American economy.

discuss this item" (Melbourne, 1999). A recommendation from the meeting of the CCGP in 2000 stated more substantially: *"When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, and where there is reasonable evidence to suggest that adverse effects on humans may occur, but it is difficult to evaluate their nature and their extent, it may be appropriate for risk managers to apply precaution through interim measures to protect the health of consumers, without awaiting additional scientific data and a full risk assessment"*. A footnote to this recommendation saying that *"some members refer to this concept as the precautionary principle"* reveals that discussion would continue. Thus, the Codex formulated the following compromise in 2001: *"When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence"* (Codex Alimentarius, 2001).

Cartagena Protocol

The precautionary principle has also been applied in the context of genetic modification. The Cartegena Protocol on Biosafety (Montreal, 2000) is broadly summarised as follows: "It is recognised that governments have the right to ban the import of genetically modified organisms, if they hold it that these organisms entail harmful effects for the environment or public health, on the basis of the precautionary principle, i.e. without full scientific certainty about possibly harmful effects of genetically modified organisms*"* (Vandendriessche, page 11, 2002). The protocol formulates a framework for safe transfer and use of genetically modified organisms based on precautionary principle, taking into account risks to public health and emphasising border crossing activities. During the negotiations about the protocol differences of opinion arose between countries of the Miami group (United States, Canada, Australia, Argentina, Chile and Uruguay) on the on hand and the European Union and several developing countries on the other hand. The EU has always defended strict rules; the Miami group has been in favour of slacker rules concerning trade in GMOs. In the end both parties had to compromise. The most difficult subject was the relation between the biosafety protocol and the international trade regulations of the WTO. This was settled with the final text of the Cartagena Protocol on biosafety:

> *Recognising,* that trade and environment agreements should be mutually supportive with a view to achieving sustainable development.
> *Emphasising,* that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements.
> *Understanding,* that the above recital is not intended to subordinate this Protocol to other international agreements.

World Trade Organisation

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) is one of the WTO-agreements of 1995 that is of crucial importance for food safety policy-making in an international trade context. The agreement says that sanitary and phytosanitary measures will be considered to be trade disturbing, unless these measures are based on (natural) scientific risk assessment. Article 5.7, however, states an important exception: *"In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary and phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time".* The European Union tends to interpret this phrase as an implicit reference to the precautionary principle. However, it is not only the United States but also several developing countries that simply do not appreciate the introduction

of the precautionary principle in international food politics. Developing countries mainly fear that the European call for precaution opens the door to a new round of protectionist measures.

The European Commission would like an interpretation of the precautionary principle to be included in SPS that is consistent, predictable, proportional, non-arbitrary, non-discriminatory, non-protectionist, and based on scientific evidence and cost-benefit analysis (Committee on Agriculture, 2001; European Commission, 2001). Although international agreement exists about the inclusion of such general principles in food safety policy-making, two dispute cases already showed that the Dispute Settlement Body of the WTO is not likely to accept claims of consistency, predictability, proportionality, non-arbitrariness, non-discrimination and non-protectionism at face value. Substantiation of these claims by Members will be judged on a case-by-case basis. The Dispute Settlement Body concluded in the Japan varietals case that:

- A measure should be imposed in respect of a situation where relevant scientific information is insufficient;
- A measure should be adopted on the basis of available pertinent information;
- A Member should seek to obtain additional information necessary for a more objective assessment;
- A Member should review the measure accordingly within a reasonable period of time.

The Japanese precautionary measure was considered to be non-provisional, since Japan did not seek to obtain additional information (third clause). In the EC hormones case the European Commission tried to introduce the precautionary principle as general principle under international law. The European Union prohibited the use of certain hormones for growth promotion in farm animals in 1988. The United States and Canada contested this prohibition, and a panel of the WTO ruled that the measure was not in line with SPS in 1997. The European Union appealed against this ruling, and the WTO Dispute Settlement Body reversed most of the findings of the panel in 1998. It only confirmed the finding that the prohibition of imports of meat from hormone-treated animals to the European Union did not comply with the requirement that such measures should be based on a relevant risk assessment. In response to these findings, the European Union performed several complementary risk assessments. The conclusion of these studies was that no acceptable daily intake (ADI) could be established for any of the evaluated hormones. May 2000 the European Commission proposed to definitively prohibit the use of one hormone (oestradiol 17ß) and to provisionally continue the application of the prohibition on the other five hormones for growth promotion until more complete scientific information would become available (http://www.europe.eu.int). Again, the Dispute Settlement Body did not consider the precautionary measure to be provisional and it was also reluctant to accept the suggestion of some principle overriding the obligation to base measures on risk assessment (Committee on Agriculture, 2001; WTO).

2.3 The precautionary principle as a three-stage process according to the European Commission

The European Union kept in pace with international developments and included the precautionary principle in its Maastricht Treaty (1992): *"Environmental policies of the Community are based on the precautionary principle, the principle of preventive action, and the principle of the polluter pays"* (Article 130R Section 2). The Amsterdam Treaty (1999) included a similar but more extensive phrase about the precautionary principle as one of the key constituents of European environmental policy-making (Vanderdriessche, 2002).

Until recently the context of application for the precautionary principle was restricted to policies to abate environmental or ecological risks. This changed with the Commission's Green Paper on the general principles of food law in 1997, which applied the precautionary principle on relations between food and human health. It stated that *"if full risk assessment is impossible, measures should be based on the precautionary principle"* (COM(97) 176 def.). In 1998 the

European Commission added that *"the Commission will structure its risk analysis by the precautionary principle in cases where scientific evidence is insufficient or uncertainty persists"* (COM (97) 183 def.). The White Paper on Food Safety (2000) repeated the importance of the precautionary principle for food policy-making and stated: *"If applicable, decision-making about risks will follow the precautionary principle".* Parallel to the introduction of the precautionary principle in European food safety policy-making one could witness a shifting focus from market interests (Green Paper) towards market and public health interests (White Paper) and, finally, public health and market interests (General Food Law).

The established European interpretation of the precautionary principle was formulated in a Communication from the European Commission in 2000 (CEC, 2000), which was discussed and endorsed at the Nice Summit of the same year (EU-Nice, 2000). This interpretation will be used for further (international) analysis and discussion. The key characteristics of the established European interpretation of the precautionary principle are that it should 1) offer a moral guide to behaviour when (natural) scientific risk assessment is inconclusive, and 2) operates as a three-stage process for (food safety) policy-making. It might be possible to reach international agreement about these three stages in processes of applying the precautionary principle. This three-stage precautionary approach has the advantage that it is:

- An established regulatory reality in the European Union;
- An integration of (political) risk management and (scientific) risk assessment;
- A process with ample possibilities for risk communication between the European Union and opponents of the EU approach to the precautionary principle, among which developing countries.

Table 1: Three-stage process as a framework for precautionary principle in EU

Trigger Stage	**Decision Stage**	**Application Stage**
Scientific Risk Assessment	*Political Risk Management*	*Scientific Risk Assessment*
Which potentially harmful impacts on environment or health are at stake? • *Which baseline is used in determining what counts as harm?* • *What has been the frame of reference?* Has a scientific risk assessment been performed? • *Which risks were included or excluded?* • *Were indirect impacts also considered?* • *Were social and ethical impacts taken into account?* Is scientific evidence insufficient, inconclusive or uncertain? • *What is still unknown?* Do reasonable grounds for concern, nevertheless, exist?	How could the freedoms and rights of companies and third countries be balanced with the protection of health or environment? • *Has this balancing been subject to a democratic and transparent process of opinion-formation?* What counts as acceptable risks? • *Is this level also acceptable to the general public?* • *Which level of protection should be chosen?* What is the prevailing public opinion? • *What are the important relevant societal values?*	Which possible measures are available? • *What are the likely impacts of these measures?* Is a measure proportional to the objective of protection? • *Is this protection a priority?* Is a measure non-discriminatory? Is a measure similar with measures taken in similar cases? • *What counts as sufficiently similar?* • *Are standards still the same?* Has a cost-benefit analysis been performed? • *Has this been a broad societal analysis?* Have any new scientific data become available? • *Is enough known about cause-effect relations?* • *Does an operational monitoring system exist (obligatory for SPS)?*

Table 1 summarises this three-stage process as a framework for analysis of and discussion about the precautionary principle. The main questions in this framework are based on the European Commission's Communication, whereas the additional questions *in Italics* are based on Carr's (2002) critical analysis of this Communication.

The precautionary principle as a three-stage process thus, according to the European Commission, consists of three stages. The first stage would be scientific and deals with the question of whether the characteristics of a certain case call for application of the precautionary principle (*trigger*). This stage could also be labelled as risk assessment. The second stage would be political and deals with the decision to apply the precautionary principle in a certain case (*decision*). This stage could also be labelled as risk management. The third and final stage would again be scientific and deals with the question of what are the most appropriate precautionary measures to be taken in a certain case (*application*). This stage could also be labelled as risk assessment.[3]

2.4 Reflections on the precautionary principle – A debate in progress[4]

Introduction

Whereas in the previous section the precautionary principle has been described and operationalised as a three-stage process, some critical notes on the precautionary principle as interpreted by the European Commission may still be observed. It is thus obvious that the debate is in progress. Critics of European interpretation of the precautionary principle, like Pieterman & Hanekamp (2002), worry that the European Commission's interpretation of the precautionary principle opens the door towards the introduction of people's supposedly irrational fears about food safety as reasonable grounds for applications of the precautionary principle. If people's fears become the standard in food politics, the problem would be that no scientific evidence suffices to address those fears and thus that precautionary measures get a permanent character. Pieterman & Hanekamp find this situation particularly frightening, since the European Commission's interpretation of the precautionary principle would be seriously flawed as a moral principle to guide regulatory behaviour.

However, we find that their full-fledged criticism on the current interpretation of the precautionary principle ignores that the central tenet of a well-understood precautionary principle is already firmly established in the three-stage precautionary approach of the European Commission. This tenet is that policy-makers should not wait with preventive measures until full scientific consensus is available about the causal links involved in some serious harm. Two criteria ensure that the precautionary principle is indeed only applied in certain circumstances:

- Substantial empirical scientific evidence about a certain risk should be available before the precautionary principle is called upon – this need for scientific evidence forswears the introduction of irrational fears as a basis for food safety policy-making;
- Application of the precautionary principle should be symmetrical – the burden of proof needs to be shared by both proponents and opponents of a certain precautionary measure.

Hence, critics like Pieterman & Hanekamp regress to a paste stage in the ongoing debate about the precautionary principle, at least within the European context. It is probably not unfair to

[3] Please bear in mind that it could also be argued that all three stages include both (natural) scientific and political aspects, and that separating science and politics wrongly suggests a rigorous distinction between facts and values.
[4] Several collected volumes and special issues of international journals show that the precautionary principle is indeed a debate in progress (see: Graham (ed.), 2001; Kaiser (ed.), 1997; Kaiser (ed.), 2002; O'Riordan & Cameron (eds.), 1994; O'Riordan *et al.* (eds.), 2001; Raffensperger & Tickner (eds.), 1999).

disqualify their position as one-sidedly following the American arguments in this debate, while ignoring progress in the justification of the European position.

The remainder of this section, therefore, focuses on ramifications to the established European interpretation of the precautionary principle as a three-stage process that do imply progress in the ongoing debate. First, a report from the European Environmental Agency will be discussed to add flavour to the required state-of-mind in working through the respective stages of a precautionary process. Second, Kaiser's work on precautionary strategies is discussed to emphasise that, whereas consensus exists about the three-stage process as a procedural account of the precautionary approach, the final application stage of this process should leave ample room to strike a variety of balances in the preferred precautionary measures.

Late lessons from early warnings

The European Environment Agency (EEA) commissioned an important report *Late lessons from early warnings* (2001) that analyses fourteen case studies where application of the three-stage precautionary approach could have been relevant. This report recognises that the current discussion between the European Union and the United States about use and application of the precautionary principle still suffers from confusion about the precise meaning of the crucial terms in this debate. It argues, in line with the three-stage precautionary approach, that dangers of new technologies may appear at such a late state that it is no longer possible to stop negative and irreversible consequences. It questions whether some early warning system would have reduced these dangers and thus social costs. It mentions that time preference and discounting are important problems in this respect, i.e. preventive costs are mostly clear and present, whereas curative costs as a result of current inaction are only tentative and remote. It concludes that the crucial question is how to respond not only to uncertainties but also to unknowns.

Late lessons from early warnings argues that misplaced claims of certainty about the absence of some danger play a key role in the absence of preventive action in most cases where the precautionary principle should have been applied. Moreover, earlier opponents of the precautionary principle tended to ignore that its application could also promote innovative research and development in a certain – ecological and healthy – direction. Finally, the report emphasises that not only early but also late warnings still tend to be ignored as a result of political unwillingness to take appropriate but expensive measures to prevent some harm from occurring.

Thus, the main problem is not that people's irrationality tends to overrule scientific rationality, as critics like Pieterman & Hanekamp would like us to believe, but that prevailing politics is mainly about strategic behaviour of regulators, i.e. vested domestic and short-term socio-economic interests tend to dominate regulatory decision-making and this does not always entail rational or balanced weighing of the interests of spatial-temporally remote and powerless groups of people. The importance of including both trustworthy and consensual scientific information and stakeholder participation in decision-making processes about food safety and risk management cannot be emphasised enough.

The report draws twelve conclusions as lessons for prospective – European – applications of the precautionary principle. These conclusions should not be read as a critique of the three-stage precautionary approach, but rather as an elaboration on the required state-of-mind for a balanced application of this decision-making process under conditions of uncertainty. The twelve conclusions are:

- Recognise and respond to ignorance, uncertainty and risks, both in technological evaluations and in public opinion-formation. No matter how much we know, we never know everything. Unknowns will always exist and application of the precautionary principle implies a willingness to accept the possibility of such unknowns;

- Apply accurate long-term environmental and health monitoring and research as a response to early warning. Specific research and monitoring is crucial for the identification of uncertainties and should be considered to be cost-effective;
- Identify and reduce blind spots of scientific knowledge. Execute systematic and interdisciplinary research projects for this purpose of revealing false presuppositions;
- Identify and reduce interdisciplinary obstacles. Disciplinary dominion results in an unbalanced policy process and in institutional ignorance;
- Guarantee that risk assessment refers to real life situations. Risk assessment should not restrict itself to laboratory conditions and theoretical assumptions, since real life is different;
- Investigate justifications and benefits in comparison with potential risks. Claims about certain benefits should be subject to serious scrutiny;
- Evaluate alternative options and promote the introduction of robust adjusted technologies to minimise costs and maximise innovation. Try to discover ways to escape path dependencies;
- Include lay and local knowledge next to expert opinion in risk assessment. Lay knowledge is complementary to expert knowledge since it is better embedded in real life situations;
- Fully include the opinions from a variety of social organisations. Public perceptions and values are of crucial importance for policy-making and should be confronted with scientific expertise;
- Strive after regulatory independence and open processes of information and opinion-formation. By the way, opinion-formation and decision-making are two different activities that should be the job of different organisations and institutions;
- Identify and reduce institutional obstacles, i.e. crises and hypes, tensions between parties, regulatory bodies/levels and countries;
- Prevent paralysis by analysis. Act to reduce potential harm in cases of reasonable concern. You never know everything but that is not a sound excuse for inaction.

Divergent strategies

Although the final recommendations in *Late lessons from early warnings* seem reasonable enough, they do not yet give enough practical guidance in the final application stage of the three-stage precautionary approach for (international) food safety politics. Kaiser (1997) made an attempt to make this practical guidance more complete by distinguishing four different strategies in applying the precautionary principle.

Technological revision

This strategy aims at technological adjustments that may reduce future harm. Pros of this strategy are its use of the abundant possibilities of available technologies, its preference for piecemeal engineering, the restricted nature of process intervention with initial costs that will be easily compensated for by lower costs at a later stage, the willingness of companies to co-operate, and higher budgets for research in co-operation between universities and companies. Cons of this strategy are the insecurity about positive results before the harm actually occurs, and the neglect of the role of human (mis)behaviour in processes of risk management.

Technological revolution

This strategy aims at the development of radically new technologies and thus transcends existing scientific frames of reference. Pros of this strategy are the promise of operationalising hitherto theoretical solutions, its effectiveness in reducing the harm, a low probability of environmental side effects and even a lower appearance of certain risks. Cons of this strategy are its enormous costs with apparent negative repercussions for national economies, possible ecological and socio-economic side-effects and conflicts of interest, reluctance among consumers to accept the new technologies, the introduction of new and unknown risks for vulnerable groups of people and ethical concerns about the ever increasing dominance of economics and technology over all spheres of life.

Political steering
This strategy aims at addressing the socio-political dimensions of some harm in a national and international context of food safety policy-making and explicitly includes an assessment of the human factor in risk management processes. Pros of this strategy are a substantial reduction of harmful effects without major socio-economic repercussions, ample room for flexible responses to new information, and the possibility to leave implementation to decentralised bodies. Cons of this strategy are that it fails to address the roots of a certain harm, may cause regional economic imbalances, and that it involves heavy governmental regulation which is not always that popular among the wider public because they distrust regulators to be engaged in strategic power games.

Ecological concern
This strategy aims at the establishment of a deep partnership between humans and nature in which ecological concerns have the highest priority. Pros of this strategy are its immediate and effective abatement of risks including unintended side-effects, its emphasis on respect for nature and stewardship, and its promise of a long-term development of a sustainable society that is adjusted to natural conditions and puts strict limits on technological development. Cons of this strategy are its idealism and the enormous economic costs accompanying its radical solutions, resistance from private companies and the public at large, its utopian thinking that does not befit pluralistic democratic societies and hence its lack of political legitimacy.

Intermezzo – Cultural theory and risk perceptions[5]

Kaiser's distinction of four different precautionary strategies is heavily influenced by so-called "cultural theory" as a framework for analysing and discussing divergent risk perceptions among and between populations of countries. Cultural theory claims that in any specific spatial-temporal context four basic – and opposing – attitudes towards natural and social risks will prevail.

Individualists
Individualists mainly focus on socio-economic risks. Their overriding value is individual autonomy. They believe that unlimited pursuit of individual preferences results – with a little help from the hidden hand of the market – in the best of all possible states of affairs. Since they also believe that nature is benign, individualists tend to downplay risks for the natural environment or human health. Generally, they believe that technological development is perfectly capable of repairing any harm done to the environment or food safety. Kaiser's *technological revision* and *technological revolution* are both precautionary strategies that would suit individualists quite well. Individualism is probably the dominant risk perception – or culture – in the United States and that explains much of its position in international food safety discussions.

Hierarchists
Hierarchists hope to strike a perfect balance between environmental, health and socio-economic risks. Unlike individualists, who embrace a consequentialist rationality, they think much of procedural rationality. This implies that environmental or food safety policy-making should be structured by strict procedures in order to develop a balanced approach towards natural and social risks. Environmental and food safety regulations should focus on the establishment of minimal but strict standards to ensure that no crises will occur. However, regulators should leave economic actors more freedom to act, if these minimal standards are secured. Since hierarchists

[5] This description of cultural theory is primarily based on Schwarz & Thompson (1990), whereas the WRR (1994) presented an influential application of cultural theory on Dutch environmental policy-making and Douglas & Ney (1998) provide the most recent theoretical justification of cultural theory as a framework for analysing and discussing people's divergent risk perceptions.

believe that nature is tolerant – most negative repercussions on the natural environment or human health are reversible but some or not – regulation should focus on the abatement of exceptional cases. Kaiser's *political steering* would be the precautionary strategy that befits hierarchists best. It is probably not unfair to say that hierarchism used to be the dominant culture in the Old World, i.e. Europe.

Egalitarians
Egalitarians almost exclusively focus on risks for the natural environment and human health. They tend to ignore socio-economic risks for themselves or others. Since egalitarians believe that nature is ephemeral and that even really minor risks might result in catastrophic consequences, it is not that surprising that they adopt an extremely cautious attitude towards natural risks. Egalitarian concerns about the natural environment and human health are coupled with a critical rationality that entails great distrust towards companies and governments. They are not willing to settle for anything less than an outright ban on any technological development with possible negative repercussions for health or environment. Egalitarians would like to live up to the slogan that small is beautiful. Kaiser's *ecological concern* is the ideal precautionary strategy for egalitarians. Egalitarianism seems to be quite strong among European environmental and other non-governmental organisations. Critics of the prevailing European interpretation of the precautionary principle – at home and abroad – probably fear that this interpretation is too much fuelled by egalitarian sentiments.

Fatalists
Fatalists are an unhappy bunch of people. They are typically absent from socio-political debates, although maverick politician Fortuyn tried to give them a voice in Holland. Fatalists feel that they live in a risky world but do not believe that it makes much of a difference whether they act or not. Nature is capricious and they are not in a position to change the ongoing course of events. Fatalists do not recognise themselves in any of Kaiser's precautionary strategies, since they basically do not believe in politics. Although it definitely would not be fair to characterise the dominant attitude in developing countries as fatalism, it cannot be denied that they have the lesser possibilities to influence international food safety policy-making at the interface of consumer protection and trade protectionism.

Kaiser's four different precautionary strategies represent four different reductions of some initial problem that called for application of the precautionary principle. It is not an easy task to combine these reductions in some overarching strategy since each strategy finds support amongst different social groups. In practice this implies a need to compromise. Most companies will probably embrace technological revision, whereas most scientists tend to fancy technological revolution. Some citizens may embrace ecological concern, whereas most regulators tend to be attracted by political steering. Moreover, the intermezzo on cultural theory and risk perceptions showed that the four strategies are also expressions of deeper values and attitudes towards risk and danger. These deeper risk perceptions are incommensurable according to Kaiser and cultural theory. The four strategies may all aim at effective reduction of the chance that some harm will occur but they seem to do this in fundamentally different ways and to highly different degrees. Kaiser's important conclusion is thus that the pursuit of one single interpretation of the precautionary principle is futile, at least beyond the already established procedural account of the three-stage precautionary approach. Hence, a modest interpretation of the precautionary principle should leave ample room to choose between a variety of precautionary measures in the application stage of this process. Application of the precautionary principle should in particular pay attention to the following three observations:

- People differ in their judgement of whether a certain risk is serious enough to call for application of the precautionary principle;
- People differ in their judgement of the extent to which a certain risk should be reduced by application of the precautionary principle;
- People differ in their preference for certain measures to be taken in a precautionary approach.

2.5 Conclusion

This chapter's description of the history of the precautionary principle showed that (natural) scientific risk assessment tends to ignore (unintended) environmental and health risks of the application of new technologies. Subsequent declarations and statements of international conferences about the definition of the precautionary principle tried to keep pace with scientific developments. However, the ultimate definition of the precautionary principle, which would satisfy all stakeholders, has not been agreed upon yet. The precautionary principle thus remains a guideline that facilitates dealing with uncertainties – nothing more, nothing less. The disagreement about the application of the precautionary principle between different parts of the world centres on the fear that the principle might be misused as a means to justify (hidden) forms of protectionism or, on the other hand, that trade interests will overrule the interests of food safety and environmental protection. These differences of opinion cause tension in international trade relations, since the United States in particular adopts a sceptical stance towards the European interpretation of the precautionary principle. Within the European Union a common understanding of the application of the precautionary principle exists, which resulted in its legislative embedding. The recent *General Food Law*, for instance, embodied the precautionary principle and explicitly mentioned it in its regulations (178/2002).

The chapter further revealed that reflection on the precautionary principle as a debate in progress shows that the central message of the precautionary principle seems to be evident: policy-makers should not wait with preventive measures until full scientific consensus is available. However, a report by the European Environmental Agency, addressing fourteen case studies of activities that have been proven harmful to natural environment and human health at a later stage showed that the main problem of current food safety politics is strategic behaviour of regulators. The importance of including both trustworthy and consensual scientific information and stakeholder participation in food safety policy-making processes could thus not be emphasised enough. Moreover, application of the precautionary principle on food safety issues was further explored by distinguishing divergent precautionary strategies. Four different precautionary strategies were described (technological revision, technological revolution, political steering and ecological concern) as expressions of deeper values and attitudes towards risks. This resulted in the conclusion that the pursuit of one single interpretation of the application stage in a three-stage precautionary approach is futile, since this stage should always leave ample room to choose between a variety of precautionary measures.

The remainder of this report will embrace the established European interpretation of the precautionary principle as a three-stage process (trigger, decision and application), taking into account the ramifications introduced by the European Environment Agency and with respect to the application of precautionary measures. This three-stage process will be used as a framework for analysis of the two case studies (dioxin contamination of citrus pulp pellets from Brazil and maximum residue levels of pesticides in fruits and nuts from developing countries). This three-stage precautionary approach has the advantage that it is:

- An established regulatory reality in the European Union;
- An integration of (political) risk management and (scientific) risk assessment;

- A process with ample possibilities for risk communication between the European Union and opponents of the EU approach to the precautionary principle, among which developing countries.

A three-stage precautionary approach should thus be able to contribute to a balanced weighing of environmental, health, technical-scientific and socio-economic aspects in cases of food safety disputes between developing (and other) countries and the European Union. The embodiment of the precautionary principle in the *General Food Law* substantiates this three-stage process.

3. CASE – DIOXIN CONTAMINATION CITRUS PULP PELLETS

Contaminated milk and dairy products

Elevated concentrations of dioxin in milk were detected in Germany from the middle of 1997 until March 1998. The concentrations were of the same order as those found in the early 1990s before dioxin-reduction action had been introduced in Germany. Later the same observation was found in a butter sample in The Netherlands.

Consequently, a comprehensive study was started to localise the source of the dioxin contamination. In the first instance the focus was on pesticides, disinfectants and detergents used on dairy farms but also on feeds. These feeds in general have dioxin concentrations of 100 to 300 pg I-TEQ/kg (International – Toxic EQuivalents). After an intensive study in Germany it appeared that a certain compound feed for milk production, which was found at two different dairy farms, contained 1,800 pg I-TEQ/kg. These findings were ultimately traced to an individual ingredient of the compound feed. After analysis, finally, citrus pulp pellets (cpp), which were used as feed ingredient (20-40%), were detected as the source of the dioxin contamination. All other compounds were in the range of normal background contamination (Malisch, 1998).

Dioxin analysis was performed on samples collected from nine dairy farms providing milk to consumers in Baden Württemberg. The results from these analyses showed that the highest dioxin concentrations in milk (> 1,5 pg I-TEQ/g fat) were found on five farms. All of these five farms fed between 3-8 kg of compound feed containing cpp. The other farms registered a dioxin concentration in cows' milk below 0.9 pg I-TEQ/g fat. Two of these farms fed with compound feed that did not contain citrus pulp, whereas the two remaining farms did not use any compound feed. Therefore, these results provided the final evidence that citrus pulp was the source of the milk contamination (Malisch, 1998).

In the State of Baden-Württemberg 14 samples of cpp used by the six biggest feed producers were analysed in March 1998, resulting in the observation that all samples were contaminated at approximately the same level and exhibited the same pattern of PCDD and PCDF congeners. The average contamination was about 7,000 pg I-TEQ/kg, with a range from 4,600 tot 10,100 pg I-TEQ/kg (Malisch, 1998).

Contaminated citrus pulp pellets

The process of producing orange juice involves cutting and filtration of the orange fruits and generating three products: juice, citrus pulp and orange oil. Therefore, citrus pulp is a by-product from orange juice production and contains all remaining solids of the fruit: core, peel and seeds. This pulp is quite acidic and has a pH of about 2-3. To raise this pH to a higher level (6-7) and to facilitate the drying process, lime is added. After the drying process (in open systems) cpp is transported to the harbour of Sao Paulo (Brazil) and shipped to Europe as feed materials. The dioxin contamination was found in the peel of the oranges. Therefore, possible sources of contamination were limited to substances that had been in physical contact with the peels, such as:

- Pesticides in the orange peel;
- Formation of dioxin during the drying process through contamination of the burning material (fuel additive tetrachloroethylene or sugar cane bagasse-fired drying);
- Additives such as lime.

The dioxin analysis found that lime was the source of contamination, with concentrations of up to 32,000 pg I-TEQ/ kg. The production process of cpp allows the addition of 1g lime to 100 g citrus pulp. The contaminated lime originated from a lime converter that mixes lime milk ($Ca(OH)_2$), saturated in water (a by-product of an industrial process), with quicklime (CaO) to produce powdered hydrated lime ($Ca(OH)_2$). Lime milk is a by-product from acetylene production (used to

produce PVC). Quicklime is processed limestone, which is mined. The hydrated lime is usually used for civil construction. However, as the lime had low contamination levels of magnesium (Mg), manganese (Mn) and heavy metals, it appeared to be suitable for the production of CPPs and was used for this purpose. Dioxin contaminations have never been reported in the past (EU DG XXIV, 1999a). However, the dioxin contamination in the lime milk is not obvious from the acetylene production process in the lime converter, since no chlorine is involved in this process. After all the production process of acetylene consists of bringing calcium carbide (CaC_2) in contact with water (H_2O), which results in the production of acetylene (C_2H_2) and the by-product lime milk ($Ca(OH)_2$ according to the equation:

$$CaC_2 + 2\ H_2O \rightarrow Ca(OH)_2 + C_2H_2$$

Measures to control dioxin contamination in cpp by the EU

The first and immediate instrument to control the dioxin contamination was the identification and ban of the cpp lots and compound feed lots containing cpp. In The Netherlands these lots were used as fuel for power plants. The observation of high concentrations of dioxin in cpp in EU member states have led to urgent and decisive measures to prevent further imports of contaminated cpps. After this incident all shipments of cpp are stopped at the outside borders of EU countries and are examined on dioxin contamination. A shipment of cpp should be analysed for possible dioxin contamination twice: once by a Brazilian appointed laboratory and once by an EU member state appointed laboratory for which the shipment is destined. The shipment will only be released, when the analysis of samples reveals that the dioxin concentration is below the (later established) maximum limit of 500 pg I-TEQ/kg (according to directive 74/63 EEC on fixing maximum permitted levels for undesirable substances and products in feeds).

Ultimately, directive 98/60 (amending directive 74/63 EEC) establishes maximum dioxin limits of contaminated citrus pulp pellets. This directive states: *"Whereas all sources of contamination by dioxins at such unacceptable levels have not been possible to be determined with sufficient certainty within the short time limits available. Therefore, no sufficient guarantees exist for the moment that the possible sources of contamination have been removed from the production process of citrus pulp pellets. A more complete scientific assessment of the tolerable maximum level for dioxins cannot be performed within short notice. It is therefore urgent to fix provisionally the maximum limit at the detection level (500 I-TEQ/kg) whilst awaiting the scientific assessment of the risk involved".* This directive had a provision of review before 1 January 1999, according to the availability of evidence concerning the sources of contamination or a scientific risk assessment. However, the Belgian dioxin crisis in the beginning of 1999 has accelerated legislative measures regarding the presence of dioxin in feeds and foodstuffs. The establishment of maximum levels as well as action and target levels for feed and food are set by respectively amending Commission Regulation EC/466/2001 and Council Directive 1999/29/EC.

Measures at the Dutch level

The commitments made in directive 98/60/EU are implemented at the Dutch level in the regulation "Import control citrus pulp 1998". RIKILT (Institute of Food Safety) is appointed to analyse the samples of citrus pulp in The Netherlands. In 1999 the samples of citrus pulp were sent to The Netherlands for analysis before the shipment had left the Brazilian port. If the results of the analysis were negative, the ship would be allowed to sail. The import regime was eased after the Brazilian government had provided information concerning the measures taken to prevent dioxin contamination of cpp. Nowadays, two analyses are still performed, but sampling in The Netherlands is done on arrival of the shipment in a Dutch port.

Measures to control dioxin contamination in cpp by Brazil

The Brazilian authorities have acted by developing the necessary legal measures, in line with the tolerance of 500 pg I-TEQ/kg and in co-operation with the respective associations of cpp and lime producers. Furthermore, the exclusion of lime of "not virgin origin" from cpp production was established. Also regulations for production, marketing, monitoring, inspection and sampling were finalised. A supervision program was prepared to co-ordinate sampling of cpp and lime in all production steps, including shipment to Europe. Analysis of representative samples is to be executed by registered laboratories only. The responsibility for the appropriate supervision and registration of all involved companies lies with the Ministry of Agriculture in Brazil (EU DG XXIV, 1999b).

4. CASE – EU MAXIMUM RESIDUE LEVELS FOR PESTICIDES

Introduction

A recent study by LEI, RIKILT and PD (in Dutch: *Plantenziektekundige Dienst*) on pesticides residues on imported products from developing countries into The Netherlands showed in more than 50 percent of the examined fruit and nut samples pesticide residue levels between level of detection (LOD) and Maximum Residue Level (MRL) (Buurma *et al.*, 2001). During the last five years a trend could be witnessed that the percentage of imported fruits and nuts that equals or exceeds the relevant MRL increases. In 2000, 10 percent of all examined samples were above tolerance levels, whereas this was only 5 percent in 1997. With regard to the focus countries of the Dutch Ministry of Foreign Affairs, Department of International Co-operation (among which Least Developed Countries), the figures are even more serious. In 2000, 16 percent of all examined fruit samples equals or exceeds the relevant MRL, whereas this was 11 percent in 1997. It is unclear whether this increase of pesticide residue levels is caused by downward adjustments of EU-MRLs or by increasing pesticide use and/or pest control problems in exporting developing countries.

The EU review and registration of pesticides

The EU is implementing a programme to harmonise MRLs for pesticides in food sold in the EU under the provision of Directive 91/414/EEC. This directive requires that all pesticides used in products for plant production purposes that were on the market within the EC on or before 26 July 1993 be subject to review. The first stage of the review programme has ended in 2000 with the publication of the first review regulation. All the EU-MRLs set down until 2000 were approved and implemented as national legislation by all member states (Chan & King, 2000; quoted in Wilson & Otsuki, 2001). The completion of the whole review programme is scheduled for 2010.

Between 1993 and 2000, the EU established MRLs for approximately one hundred crop and pesticide (i.e. active ingredients) combinations. For those combinations for which no data were available the MRL has been set at the LOD. Hence, the use of these active ingredients is no longer possible in practice. Moreover, in 2003 the authorisations of 324 so-called 'old-compounds' will be withdrawn and MRLs will be set at LOD.[6]

Measures taken within the EU

EC legislation (Directive 90/642/EEC) requires member states and non-member states to monitor pesticide residues in food. Most EU-MRLs are lower or equal compared to the Codex CXLs (Codex Maximum Residue Limits) (Buurma *et al.*, 2001). Among EU countries, monitoring schemes and their implementation are highly variable in terms of products and pesticides to be tested, national maximum residue levels and sampling strategies (*ibid;* p. 25-26). Non-compliance with Directive 90/642/EEC by some member states to monitor pesticide residues in food led to suspension of imports from 43 countries by March 2000 (Wilson & Otsuki, 2001).

Significance of maximum residue levels for developing countries

Many developing countries depend on food exports for their exchange earnings. Buurma *et al.* (2001) report that the import of vegetables, fruits/nuts and cereals from developing countries into the EU amounted to more than 8 billion Euro in 1999[7]. Export of fruits (pineapples, papayas and bananas) and vegetables, for example, from Ghana into the EU represented a value of 37 million Euro in 2000 (Boselie & Muller, 2002). The total value of vegetables, fruits/nuts and cereals

[6] The toxicity of the pesticides for which MRLs have been or will be set at LOD is highly different (see: http://europa.eu.int/comm/food/fs/ph_ps/pest/index_en.htm).

[7] Fruits/nuts have by far the most important share (73%) within this package. The most important products within this package are bananas (23% of import value), citrus fruit (9%), other nuts (8%), grapes (7%) and apples/pears (7%)(Buurma *et al.*, 2001).

imported into EU from the least developed countries, among which Ghana, amounted to 0.12 billion Euro in 1999.
In developing countries the world's most hazardous pesticides are still used (Wilson & Otsuki, 2001). Many of these pesticides are banned or heavily regulated in Europe and other developed parts of the world. [8] Producers of so-called minor crops (e.g. tropical fruits) in developing countries bear the negative consequences of the EU-MRLs on LOD. They use many of the active ingredients set on this level (Buurma, 2001; Boselie, 2002). Buurma *et al.* (2001) report that eleven of the thirty-three active ingredients of pesticides included in Directive 2000/42/EC were found on products imported into The Netherlands from developing countries (p. 32). Moreover, MRLs of seven out of the eleven pesticides cited by Buurma *et al.* are set on LOD, i.e. analytical zero for that combination. In turn, the actual fixing of maximum residue levels has negative consequences for food imports from developing countries. For example, the recent EU food safety regulation (EU Regulation 1525/98), aiming at increased consumers protection against aflatoxins, partly bans groundnuts and cereals imported to the European Union (DFID, 2001; NRET, 2000). DFID estimates that this regulation can cost the average African producer about 750 EURO a year in lost exports of these products.
A precautionary approach justifies the establishment of this MRL policy. The pesticides concerned are not used in the EU and, therefore, no residue data are being generated (*ibid*, p. 41).
Developing countries are especially vulnerable to European MRL policies. Henson & Loader (2001) claim that SPS measures, such as MRLs, are a major factor influencing the ability of developing countries to exploit export opportunities for agricultural and food products in developed country markets (p. 99).

The EU-MRL for ethephon (Directive 2000/42) illustrates the direct effects of changes in food safety standards for developing countries. In 2001 enforcement of this regulation has cost exporters of pineapples from Ghana into Europe some ten-thousands of EUROs after shipments to Europe were cancelled for three weeks when an unacceptable level of ethephon was found on a cargo sample (Boselie & Muller, 2002; p. 35). In Ghana multiple problems are associated with compliance to EU-MRLs:

- The communication on EU-MRL regulations to exporters and producers falls short;
- Technical facilities and human resources for monitoring MRLs are lacking; and
- Pesticide quality control is absent. [9]

These problems are also present in other developing countries, such as for example Zambia (see: Achterbos & Van Tongeren, 2002). Compliance costs with EU-MRL regulations are especially significant for the many smallholders in developing countries involved in the production of export food products. This group generally lacks the necessary information on food safety standards and also lacks the financial and technical resources to adapt their production processes to EU-MRL regulations. Therefore, these regulations represent a real threat to their subsistence base.

[8] The Rotterdam Treaty (1998), which was ratified in the beginning of December 2002, includes agreements on the international trade of dangerous chemicals and pesticides, among which agreements on information exchanges between developed and developing countries.
[9] International organisations, as well as the Dutch government, recognise the problems developing countries encounter with regard to the implementation of international standards on food safety, in particular through their capacity and institution building initiatives, such as for example the Standards and Trade Facility Fund of the World Bank and WTO.

5. REFLECTION AND ANALYSIS

5.1 Introduction

Following the presentation of the two case studies in the previous two chapters a reflection on and analysis of these case studies will be performed now. The reflection uses the interpretation of the precautionary principle as a three-stage process as endorsed by the European Commission. The analysis of arguments for and against the application of the precautionary principle employs both a natural and a social scientific perspective.

5.2 Reflection on the case of dioxin contamination citrus pulp pellets

The general conclusion of the Food and Veterinary Office (FVO) of DG XXIV of the European Commission with regard to the dioxin contamination of citrus pulp pellets was that:

- The control systems set up by the competent authorities in Brazil for cpp and lime are reliable;
- These systems provide sufficient guarantees for cpp exports to resume.

The recommendation of the FVO to the Commission Services regarding this contamination was that they should consider the implication of the environmental contamination with dioxin in Brazil for possible further contamination incidences. FVO's conclusions and recommendations implicate that the chance of future (environmental) contamination is not quite eliminated.

Case analysis according to the precautionary principle as a three-stage process

The three-stage process, as described in section 2.3, includes a trigger, decision and application stage. Each stage is identified by questions to help the analysis and discussion of the dioxin contamination of citrus pulp pellets case and the possible application of the precautionary principle.

Trigger stage

Public health and the environment will be at stake, if raw materials are contaminated with dioxin. It seems that producers of these materials show little or no interest in the processes further down the food chain and in the consequences dioxin contamination may have for the health of animals and humans. North – South relations are tested and tried in cases of contamination. Control systems in developing countries have proven to be insufficient and exposure limits in the European Union are absent. The public at large is thus faced with a situation of uncertainty, because specific limits for dioxin in food are as yet absent, as only the general requirement (maximum levels) applies. Environmental organisations keep up public pressure on contaminated waste to be cleared. Hence, the European Commission is forced to act.

Which potential harmful impacts on environment or health are at stake?

Dioxin contaminates the soil, as this part of the environment is a natural sink for dioxins. In the case of the contaminated citrus pulp pallets hydrated lime is stockpiled in an enormous heap. In Brazil erosion from this heap can contaminate the soil or water supplies. Dioxins are also poorly soluble in water, but can adsorb onto mineral or organic particles in suspension in water. Dioxin concentrates in the fatty tissue of beef and dairy cattle or seafood. Meat, eggs or milk may also be contaminated above background levels by dioxins from feeds (citrus pulp pellets). In Germany the highest concentration of dioxin was detected in a cow's milk sample, which gave 7.86 pg I-

TEQ/g fat and thus exceeded the concentration of 5 pg I-TEQ/g fat, i.e. the maximum permissible concentration to place milk products on the market.

Has a scientific risk assessment been performed?

No, analyses of contaminated compound feed in Germany showed levels (1,800 pg I-TEQ/kg) above concentrations that are typical for feed samples, which are in the range of 100 to 300 pg I-TEQ/kg. The provisionally fixed maximum limit for dioxin in citrus pulp was set at the detection level (500 pg I-TEQ/kg) by the EC, awaiting scientific assessment of the risk involved.

Is scientific evidence insufficient, inconclusive or uncertain?

The scientific evidence at the time of the contamination showed the results of analyses of feed components (cpp) and foodstuffs (milk, butter). The actual cause of the dioxin pollution of the hydrated lime was unknown. The dioxin contamination was not obvious from the synthesis process (PVC production) as no chlorine is involved in this process. With respect to the subject of toxicokenetics, research has shown that an accumulation and elimination of dioxins in milk exists, due to an exposure to contaminated cpp. Traag *et al.* (1999) found that the exposure of lactating cows to a dioxin contaminated feed ingredient (cpp) leads to rapid accumulation of dioxins in milk. On the other hand, the excretion of dioxins, after a relatively short period of exposure, is also rapid. It appears that dioxin levels in milk fat exceeded the Dutch tolerance level (6 pg I-TEQ/kg) after 2 to 3 weeks of exposure and decreased below the MRL within a week.

Are there nevertheless reasonable grounds for concern?

In the case of contamination of feeds with dioxin reasonable grounds for concern sometimes exist, since the environmental effects of dioxins are enormous. As long as feed is manufactured with a multitude of ingredients and regulations are abused by suppliers or producers contaminations will occur. Monitoring systems however will, now and again, flush out some irregularities and show trends.

Decision stage

The European Commission has put forward proposals to limit the presence of dioxin in food and feed. This dioxin strategy is evaluated as a sound response to the complicated cycle of contamination. The application of the precautionary principle is in force due to the limited time available to assess the causes of contamination. Furthermore, (natural) scientific assessment of tolerable maximum levels of dioxin cannot be determined. Awaiting the final results of scientific research, the Commission proposes to establish provisional maximum levels and follows by determining action levels and target levels of dioxins. A public demand to simply forbid dioxins should be disqualified as utopian. Dioxins are not produced intentionally, as their formation and distribution is an often-unavoidable by-product in a number of activities.

How could the freedoms and rights of companies and third countries be balanced with the protection of health or environment?

This is hardly an issue in the cpp case as no question of freedoms and rights of companies exists. However, the integrity of the companies and the control of products and processes are at stake. Those issues can cause a threat to the environment in developing countries and also to the protection of health in both developing and developed countries.

What counts as acceptable risks?

To set a certain level, which is acceptable to the general public with regard to dioxin, is not an easy task. As dioxin accumulates in the human body during a lifetime, the toxicity is expressed in the so-called body burden. This is used for the assessment of toxic effects, as it is a much better estimate of the continuous exposure than the daily intake. To assess the risks for public health arising from the presence of dioxins, the Scientific Committee for Food (SCF) from the EC has established a tolerable weekly intake (TWI) of 14 picogram toxic equivalents (TEQ) per kilogram body weight for dioxins. This TWI is in line with the provisional Tolerable Monthly Intake (PTMI) of 70 pg/kg bodyweight/month established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The level of protection to be chosen for the European population is set at the TWI, which includes a safety factor. However, the SCF concludes that a considerable part of the population in Europe exceeds the tolerable intake. The dietary intake of individuals varies widely among Europeans because of different eating habits and different food sources.

What is the prevailing public opinion?

Dioxins highlight the urgent need to find ways of reducing current body burdens of chemicals in people. Various incidents with dioxins have had their impact on the public opinion, i.e. the evidence of PCB contamination of breast milk. On the other hand, dioxins are not produced intentionally (these contaminants are sometimes unavoidable by-products in a number of activities). This is also recognised by the Stockholm Convention (2001) on Persistent Organic Pollutants (POPs), which was adopted in response to the urgent need for global action to safeguard human health and the environment from POPs. In spite of the fact that the production and use of PCBs has been discontinued in almost all industrial countries, large amounts of PCBs remain present as a result of their widespread use in the past. The Basel Convention on control of transboundary waste and its disposal was adopted in response to concerns about toxic waste from industrialised countries being dumped in developing countries. The Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade was adopted in response to the dramatic growth in chemicals' production and trade and the potential risks posed by such chemicals.

Application stage

The establishment of maximum limits for dioxins in feeds is set at the detection level and has as such serious consequences for raw materials included in feeds of a plant origin. The exporting country has amended its regulation for such materials in citrus pulp. At the level of sampling and monitoring a programme had been adapted to guarantee appropriate supervision and registration. Continued monitoring of consignments at port of entry level should elevate the danger to the European public. The ultimate goal is to minimise the release of dioxins into the environment. At the same time the presence of dioxins in feeds, and consequently in foodstuffs, needs to decrease in order to achieve target levels. These levels are to ensure that human dioxin exposure falls below the tolerable weekly intake (TWI) as recommended by (natural) scientists. However, the next calamity could be lurking around the corner, as accidental or intentional contamination could become reality. Nevertheless, the *temporary* application of the precautionary principle has played an important role in this case to step up legislation at the European level.

Which possible measures are available?

Measures available in this case are first and foremost an import ban of cpp. Establishing a maximum level for dioxins in EC countries follows this, while in Brazil the establishment of the use of "virgin lime" only was one of the main measures. As far as dioxins in general are concerned,

the ultimate goal must be to minimise the release of dioxins into the environment. At the same time a decrease of the presence of dioxins in feeds and consequently in food is necessary in order to achieve target levels ensuring that human exposure drops below the Tolerable Weekly Intake as advised by scientists. The protective measures proposed by EC at the level of food and feed consist of the establishment of maximum levels, action levels and target levels, all with a view on protecting public health.

Is a measure proportional to the objective of protection?

The measures taken in the cpp case have resulted in an improved control of the production and safety of this particular feed ingredient. In the case of dioxins in general the establishment of maximum levels is interpreted as a strict but feasible level in food and feed. The establishment of the action levels is designed as a tool for early warning of higher than desirable levels of dioxin in food or feed. The establishment of target levels is to bring, over time, food and feed within the limits recommended by the EC scientific committees, i.e. to bring human exposure below the tolerable weekly intake of 14 pg dioxins.

Is a measure non-discriminatory?

The measure is non-discriminatory, since it does establish a level playing field between countries on the basis of international agreement. Furthermore, global consensus exists concerning the danger of these so-called unintentionally produced POPs.

Is a measure similar with measures taken in similar cases?

In other related cases (i.e. pesticides) the measures are deemed similar. The standards are discussed and established by expert meetings on a global scale (FAO/WHO) and set in hazardous chemicals and waste conventions.

Has a cost-benefit analysis been performed?

The assessment of the economic costs and benefits always proves to be the most difficult question. There is no credible way of reducing pros and cons of certain measures to a single figure, not least because the pros and cons are unlikely to be distributed evenly among all affected groups. The ultimate costs of the total effects of dioxins can only be estimated in rough terms.

Are there any new scientific data?

The exact cause of the dioxin contamination of cpp is still not known. Recent scientific data on dioxins state that 80% of the daily dioxin intake is contributed by food. Groups most at risk include people with particular diets (high fish consumption) and sensitive groups like women of childbearing age. Furthermore, a downward trend in human exposure to dioxin exists, halving the exposure over the last 10-15 years. Finally, maximum levels alone cannot solve the problem of contamination, an overall strategy, including environmental measures, is necessary to reduce exposure to dioxins.

5.3 Reflection on the case of EU maximum residue levels for pesticides

Trigger stage

The case of EU maximum residue levels for pesticides shows that the risk of such food safety standards operating as *de facto* trade barriers and causing socio-economic costs in developing countries does not automatically enter the picture in the established European interpretation of the precautionary principle as a three-stage process.

Which potential harmful impacts on environment or health are at stake?

Pesticides are diverse and omnipresent. Approximately 1,400 pesticides are being used world wide (Wilson & Otsuki, 2001). The global market value for pesticides is estimated at 32 billion EURO in 2000, with the share of developing countries being around 3 billion EURO (FAO/WHO, 2001). Approximately 30% of pesticides marketed in developing countries, with an estimated market value of 900 million EURO annually, does not meet internationally accepted quality standards (*ibid.*). For example, in many pesticide products, the active ingredient concentrations are above internationally accepted tolerance limits. FAO and WHO report that the problem of poor-quality pesticides is particularly widespread in sub-Saharan Africa. All pesticides are toxic by their nature and, hence, are potentially harmful to human and animal health by dietary intakes. Pesticide residues can also affect human and animal health through exposure by air, soil and surface water. In general, health hazards for humans and animals vary with the type of pesticides and also with the extent of exposure. Furthermore, the risk of accumulation of pesticides in the food chain is ever present.

Has a scientific risk assessment been performed?

In all EU countries pesticide residue standards are based on maximum residue limits according to Good Agricultural Practices (GAP) or so-called 'critical GAP' (Buurma *et al.*, 2001, p. 36). Relevant risks assessments, such as for example consumer health hazards by dietary intake, are performed only after the maximum levels for certain contaminants in certain food products have been established. The European *General Food Law* (Directive 178/2002/EEC) clearly permits precautionary measures when no sufficient scientific evidence is available for a definitive decision on the safety of a product. The socio-economic risks associated with subsequent import bans are hardly considered, except on part of the social scientific research community (e.g. studies on the problems of MRLs for developing countries). These risks involve a significant loss of market share on high-income food markets for developing countries. A special issue of concern is the involvement of smallholders in the export chain. Research shows that economies of scale associated with the production of residue free products tend to squeeze smallholders out of the export chain (De Jager & Smelt, 2001; Boselie & Muller, 2002).

Is scientific evidence insufficient, inconclusive or uncertain?

In high-income countries, scientific findings with regard to pesticide residue concentrations on food products are generally portrayed by governments, and also by the media, as genuine health problems. Moreover, western consumers are very concerned about pesticide residues in their food. However, scientific debate prevails on the effects of pesticide residues on consumers' health. Some scientists report on this subject in terms of negligible risks, while others emphasise the health risks associated with pesticide residues. Scientific findings on pesticide hazards do indicate, however, that greater risks are pertinent for farm workers and those exposed to pesticide residues in the air, soil and drinking water (Wilson & Otsuki 2001). Moreover, health hazards are predominantly located in developing countries simply because of relatively more

unsafe techniques involved in pesticide use, poor health condition among the population and the use of more toxic pesticides (*ibid.*).

Are there nevertheless reasonable grounds for concern?

Beginning even before birth, humans (in affluent countries) are exposed to low levels of pesticide residues by dietary intakes. Consumers in high-income countries are very concerned about pesticide residues on food. In developing countries the use of pesticides is much higher and the toxicity of these partly forbidden pesticides is greater. Thus, exporting developing countries have serious problems to comply, or demonstrate compliance, with EU-MRL measures.

Decision stage

Application of the precautionary principle does not exclude scientific assessment of the risks of pesticide residues. Specific and applied research of pesticides is definitely an appropriate response to concerns about effects for environment and health. The important thing is that the application of the precautionary principle should be an open and transparent political judgement, which also includes an assessment of socio-economic risks in food exporting countries. Such decisions about what counts as a reasonable balance of costs and risks are necessarily of a socio-political nature. Moreover, stakeholders should be involved in this political process of weighing risks and costs.

How could the freedoms and rights of companies and third countries be balanced with the protection of health or environment?

The important thing is that the application of the precautionary principle should be an open and transparent political judgement, which also includes an assessment of socio-economic risks in food exporting countries.

What counts as acceptable risks?

Decisions about what counts as a reasonable balance of costs and risks are necessarily of a socio-political nature. Stakeholders, such as governmental and non-governmental representatives from developing countries and producers' organisations, should be involved in this political process of weighing risks and costs. Besides, the prevailing process of establishing MRLs is considered discriminatory by in particular developing countries, especially in view of the lack of international agreement about these norms.

Application stage

The establishment of lower maximum residue levels, in particular if set on the level of detection, based on the best technological practices, on the basis of the precautionary principle causes enormous social and economic costs for food exporting developing countries. Mostly these countries do not have the technological facilities and human resources for monitoring maximum residue levels. This means that the export position of these countries is endangered (*cf.* Henson & Loader, 2001). Therefore, a need for technological assistance exists. Moreover, communication about EU-regulations to exporters and producers is as yet insufficient. The danger exists that only the big players in the food chain will be capable to comply with the demands from the European Union. This poses a serious threat for the subsistence base of smallholders in developing countries, as far as their livelihood depends on export crops. It remains obscure what exactly the implications of setting strict maximum residue levels would be for smallholders in developing countries. The necessary data for most countries are simply not available, and this suggests a recommendation for more research.

5.4 Conclusion

The application of the precautionary principle as a three-stage process as a framework for analysis of and reflection on two cases of food safety disputes between developing countries and the European Union shows that application of this guideline needs to be done with an open mind to the specific details of the case at hand. Although such a three-stage process might contribute to a balanced weighing of all relevant aspects of some food safety issue in theory, the proof of the pudding is – as always – in the eating. This entails a willingness to attune the framework of the three-stage process to the practicalities of the case at hand.

Moreover, even if application of the precautionary principle as a three-stage process contributes to a balanced weighing of divergent interests in the two analysed cases, it appears that all three stages are not always analysed at the same level of intensity. A broad socio-economic cost-benefit analysis is often performed insufficiently. Hence, the need for a comprehensive and rigorous application of the three-stage process in occurring cases.

One final remark: a major difference between the two analysed cases appeared to be that the precautionary measures in the cpp case were temporary, whereas the measures in the MRL case were not. This difference heavily influenced our evaluation of the application of the three-stage precautionary approach in the respective cases. The obvious recommendation would be to include the temporary character of precautionary measures as an item to be checked in the application stage of the three-stage process. This would also attune the prevailing European interpretation of the precautionary principle to the spirit of SPS.

6. CONCLUSIONS & RECOMMENDATIONS

This report has investigated possible applications of the precautionary principle in the context of food safety policy-making. The aim was to illustrate that the precautionary principle can be a useful guideline to facilitate transparency and to guarantee an open process of decision-making about food safety issues in the context of international trade. In this manner the report contributes to a balanced understanding of the precautionary principle.

6.1 Conclusions

Theoretical observations

The description of the development of the precautionary principle showed that (natural) scientific risk assessment tended to ignore (unintended) environmental and health risks of the application of new technologies. Subsequent declarations and statements of international conferences about the definition of the precautionary principle tried to keep pace with scientific developments. However, the ultimate definition of the precautionary principle, which would satisfy all stakeholders, has not been agreed upon yet. The precautionary principle thus remains an instrument that facilitates handling uncertainties – nothing more, nothing less. The disagreement about the application of the precautionary principle between different parts of the world centres on the fear that it might be misused as a means to justify (hidden) forms of protectionism. These differences of opinion cause tension in international trade relations, since the United States in particular adopts a sceptical stance towards the European interpretation of the precautionary principle.

Within the European Union a common understanding of the application of the precautionary principle exists, which resulted in its legislative embedding. The recent *General Food Law*, for instance, embodied the precautionary principle and explicitly mentioned it in its regulations (178/2002). The prevailing European interpretation of the precautionary principle is that it should operate as a three-stage process (trigger, decision and application). The analysis of the two case studies in this report (dioxin contamination of citrus pulp pellets from Brazil and maximum residue levels of pesticides in fruits and nuts from developing countries) has been done within the framework of questions as posed in the description of these three stages.

The report further revealed that reflection on the precautionary principle as a debate in progress shows that the central message of the precautionary principle seems to be evident: policy-makers should not wait with preventive measures until full scientific consensus is available. A report by the European Environmental Agency, addressing fourteen case studies of activities that have been proven harmful to natural environment and human health at a later stage, indicated that the problem of prevailing food safety politics is strategic behaviour of regulators and not that people's irrationality tends to overrule scientific rationality. The importance of including both trustworthy and consensual scientific information and stakeholder participation in food safety policy-making processes could not be emphasised enough. This reasonable but not yet very practical guidance in applying the precautionary principle on food safety issues was further explored by distinguishing divergent precautionary strategies. Four different precautionary strategies were described (technological revision, technological revolution, political steering and ecological concern) as expressions of deeper values and attitudes towards risks. This resulted in the conclusion that the pursuit of one single interpretation of the precautionary principle beyond the procedural account of the three-stage process is futile, since the application stage should always leave ample room to choose between a variety of precautionary measures.

Empirical observations

The case studies addressed possible applications of the precautionary principle with retrospect to events that took place in each of the analysed cases. The case of dioxin contamination of citrus pulp pellets showed a (temporary) ban being imposed on the import, whilst consequently a pursuit

of missing data has been performed. Finally, adaptation of legislation both in Europe and in Brazil, as well as a regulation that only "virgin" hydrated lime may be used, proved sufficient to stop further contamination. However, monitoring continues to prevent repetition of this contamination. This case highlights (natural) scientific uncertainty about technological aspects.

The case of maximum residue levels for pesticides and their effects on the export of fruits and nuts from developing countries showed that novel and strict MRLs pose serious problems for exporting developing countries. Although this policy of establishing MRLs is motivated by the protection of public health, its unintended socio-economic consequences for developing countries deserve more profound regulatory attention. The case could be characterised as a situation in which full scientific consensus about the dangers of pesticide residues is absent and political consensus within the European Union determines the establishment of MRLs. The question should be whether European governments are responsible for possible harm by pesticides residues, as the established MRLs are the tangible result of political deliberations.

Discussion

The application of the three-stage precautionary approach on the case studies has contributed to a balanced weighing of environmental, health, technical-scientific and socio-economic aspects of these food safety issues. Starting with an assessment of the environmental and health risks, following with an analysis of the socio-political aspects of divergent risk perceptions among scientists, regulators, companies and the public at large, and concluding with an evaluation of the decision about the most appropriate precautionary measure, has been a fruitful approach in reflecting on these case studies. This approach results, in principle, in a systematic and transparent way of analysing potentially harmful situations in which the natural environment and/or human health are at stake. The case studies indicate that the interpretation of the precautionary principle as a three-stage process could be a useful tool to explain possible applications of the precautionary principle to sceptics.

However, this positive voice could be tempered by the conclusion that it remains rather unclear how the application of the precautionary principle is exactly related to (natural) scientific risk assessment. Our recommendation would be to increase transparency of the socio-political decision-making process in this respect by establishing a joint European definition of this relation, on the basis of which action may be taken. Such initiatives seeking to improve transparency of precautionary decision-making at the European level should be taken at the shortest possible notice.

Moreover, the interests of developing countries should have a proper place in European decision-making processes. This also implies that ways need to be found to facilitate their contribution to such processes, i.e. procedural adjustments, technological and other support. The European Union also needs to invest in more efficient information flows about the complex and regularly changing food safety regulations to food exporting sectors in developing countries. This communication strategy should also focus on smallholders. A question would be whether the Dutch and European governments should not also invest much more in improving the use of pesticides in developing countries and in developing strategies of integrated pest management, next to the establishment of food safety standards. The Dutch and European governments are also aware of this need. Furthermore, within Codex and SPS the position of developing countries is subject of discussion.

Finally, a major difference between the two analysed cases appeared to be that the precautionary measures in the cpp case were temporary, whereas the measures in the MRL case were not. This difference heavily influenced our evaluation of the application of the three-stage precautionary approach in the respective cases. Our recommendation would be to include the temporary character of precautionary measures as an item to be checked in the application stage of the three-stage process. This would also attune the prevailing European interpretation of the precautionary principle to the spirit of SPS.

6.2 Recommendations

The precautionary principle in a socio-political context

- If the EU wishes to convince other countries that its interpretation of the precautionary principle as a three-stage process is a reasonable and balanced guideline for food safety policy-making, it should address the response that this interpretation depends on a particular attitude towards risks and that other countries may simply adopt other risk perceptions;
- The only way to argue that the three-stage process is an accurate procedural account of the precautionary principle seems to leave ample room to strike a variety of balances between natural and socio-economic risks in the application stage of a precautionary approach. This implies a whole-hearted acceptance of the socio-political – and not just (natural) scientific – nature of the three-stage precautionary approach;
- Hence, the conclusion should be that additional scientific information will not settle disputes in cases of scientific disagreement about some particular food safety hazard, because that would deny that such disputes are ultimately determined by divergent risk perceptions between countries. In cases of scientific uncertainty the choice for a certain precautionary measure inevitably becomes a socio-political endeavour, for which a variety of forms of dispute settlement needs to be developed;
- The interpretation of the precautionary principle as a three-stage process could thus contribute to a balanced weighing of all relevant aspects and interests in food safety disputes, if properly applied.

Openness and transparency

- Once the socio-political nature of the precautionary principle for food safety decision-making is accepted, it will become clear that regulatory attention should shift towards openness and transparency in decision-making processes about food safety. Consultation of stakeholders and the public at large should thus become a standard element of these decision-making processes;
- Openness and transparency of food safety decision-making processes should also entail an improvement of the possibilities for developing countries to participate in international policy-making bodies in this field.

Differential treatment

- It seems reasonable to argue that (some) developing countries should be allowed differential treatment in food safety regulations because of their technological difficulties and lack of relevant expertise in obeying high food quality standards in affluent countries;
- Further research is needed to determine criteria for such differential treatment of specific countries and sectors (i.e. smallholders);
- Moreover, it seems that the introduction of strict food safety standards poses similar (socio-economic) problems for small food companies in Western countries. Their socio-economic costs of food safety regulations should also be a topic of further research.

Coherence

- If communication about the European interpretation of the precautionary principle wishes to be successful, the precautionary principle deserves a more substantial inclusion in all relevant European and national laws and regulations, such as Dutch food safety legislation (i.e. *Warenwet*[10]). Otherwise the Dutch position on the precautionary principle is not coherent;

[10] Currently, the *Warenwet* only refers to the precautionary principle in its considerations about application of the general principles of food law in EU-regulation 178/2002 (articles 19, 20 and 21).

- The EU should be consistent in its application of the three-stage precautionary approach. The Netherlands should fully implement European regulations about the precautionary principle in its national food safety legislation.

Research

- Progress in the transatlantic or international debate on the role of the precautionary principle in food safety policy-making may profit from the establishment of an interdisciplinary scientific platform for ongoing discussion about this principle and its function in the protection of public health;
- Such a platform might be established as a specific support action under the Sixth Framework Programme of the European Commission.

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