# EU-US TRADE DISPUTES ABOUT RISK REGULATION

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## 1 Introduction: the present dispute about "Genetically Modified Organisms"

In the mid 1990s "Genetically Modified Organisms" (GMOs) were for the first time commercially cultivated in the USA. Today, amongst others, 51 % of soybeans, 12 % of cotton and 9% of corn is produced from transgenic seed worldwide.[1] 99 % of the GMO-cultivated area is located in the USA, China, Argentina and Canada.[2] Since the mid 90s both the scale of use of GMOs as well as the political and societal debate over them have multiplied. My presentation is meant to unveil the origin of this debate, which has recently culminated in the establishment of a WTO Dispute Settlement Panel as requested by the United States.

The biotech issue is inherently laden with informational deficits. The nature and the probability of adverse effects are often uncertain or even unknown and thus the trade-off between risks and benefits is difficult to assess. As is well known, the precautionary principle is a contemporary approach to these problems. My assertion shall be that the present dispute is not caused by contrary opinions about the recognition of the precautionary principle, but by different conceptions of precaution based on different cultural approaches to risk, which lead to contradicting legal positions. I will suggest that the cultural character of risk management be respected and integrated into the WTO-System. Before investigating these issues in depth, however, some basic information about GMOs needs to be provided.

### *1.1 Benefits and risks of GMOs*

A GMO is created by transferring a particular gene from one organism to another, endowing the latter with a new, desired trait. Unlike classic-breeding or natural events of that kind, the use of biotechnology allows one to cross the species barrier. Expected benefits are manifold. Agricultural output may increase, the use of insecticides could be cut back, resistance to herbicides could be strengthened and the nutritional value of food could be improved.[3]

On the other hand, there are worries that GMOs could cause a multitude of adverse effects. Interaction of GMOs with the environment may trigger unexpected crop behaviour, altering the products of the GMO.[4] If resistance to herbicides can be transmitted to weeds, that could contravene crop protection strategies.[5] An uncontrollable spread of particularly well-adapted GMOs may occur. The composition of species in natural plant populations may change, for instance if virus-resistant kinds come to dominate.[6] Toxins produced as genetically built-in insecticides may develop an unexpected degree of toxicity.[7] Furthermore genetic modifications may cause allergic reactions.[8] Finally a global use of similar kinds of GMOs may make them prone to new pests or diseases, threatening the nourishment of mankind.[9] The scope of scientific evidence for the pros and cons, however, remains under debate. The EU

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[1] First Submission of the US (WT/DS 291, 292, and 293), 11; Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft (BMVEL), 6.
[2] BMVEL, 6-7.
[3] First Submission of the US (WT/DS 291, 292, and 293), 7-8; BMVEL, passim.
[4] Rat von Sachverständigen für Umweltfragen (Rat), 654.
[5] Bartsch, 5; Rat, 655; Wissenschaftlicher Beirat (WBGU), 114.
[6] WBGU, 78, 110, 115.
[7] WBGU, 115.
[8] WBGU, 80.
[9] WBGU, 80, 114; such an event already occurred in 1970 with a high-yield corn created by classic-breeding, where a previously harmless mycotic disease destroyed a significant amount of the crop.

deems the results at best inconclusive, whereas the United States stress an alleged "proven safety record".[10]

## *1.2 Case Description*

### 1.2.1 The Case

The United States has accused the EU of having suspended the approval of biotech products, including pending applications, since October 1998.[11] This so-called “moratorium” is deemed inconsistent with several WTO provisions. The particular focus of the US submission is on the violation of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, the so-called SPS Agreement.

### 1.2.2 Legal Situation according to SPS

#### 1.2.2.1 The Relevant Provisions

Article 2.1 states the Members' right to take measures necessary for the protection of human, animal or plant life or health. Article 2.2 stresses that those protective measures are to be applied only to the extent "necessary", must be based on scientific principles and are not to be maintained without sufficient evidence, except as provided in Article 5.7.

Article 2.3 makes it clear that protective measures must not arbitrarily or unjustifiably discriminate between members, and they must not entail disguised restrictions on international trade.

Article 3.3 allows for members to introduce or maintain protective measures which result in a higher level of protection than would be achieved by measures based on the relevant international standards, if the Member considers that level appropriate and if there is a sound scientific justification or the measure is in accordance with Article 5.

Article 5 requires protective measures that ensure an appropriate level of protection to be based on a risk assessment. Available scientific evidence is to be taken into account. Negative effects on trade should be minimized. Unjustifiable or arbitrary distinctions in the level of protection are to be avoided. Annex A 5 defines the "appropriate level of protection" as the level of protection deemed appropriate by the Member.

Article 5.7 allows for the adoption of provisional protective measures if relevant scientific evidence is insufficient. Yet, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time.

Art. 8 together with Annex C call for the completion of control, inspection and approval procedures without undue delay.

#### 1.2.2.2 Summary

Thus, under the SPS-agreement each member may define its own level of protection and may apply corresponding protective measures based on scientific risk assessment. Those measures must not result in arbitrary or unjustifiable discrimination between members or contain disguised restrictions on international trade. Members are recommended to base their measures on international standards, but are granted a higher level of protection if there is scientific justification. In cases where relevant scientific evidence is insufficient, provisional measures may be adopted.

#### 1.2.2.3 The Legal Discussion

The opposing positions in the present dispute about GMOs can be summed up as follows: The United States considers the moratorium a protective measure not based on scientific findings as required by various SPS provisions. The EU did not present any risk assessment supporting its action. Accord-

[10] First Submission of the US (WT/DS 291, 292, and 293), 9; see also Robertson, 207-212.
[11] Commission (a), 3.

ingly, the moratorium can not be based on such an assessment, violating Article 5.1 SPS. The EU claims that there has not been a moratorium but only a delay in the application process caused by additional information requests put to the applicants.[12]

It has to be noted, however, that during the so-called delay, the GMO-legislation was revised, explicitly with the aim to restore confidence of the consumers and the public toward the use of GMOs.[13] The new "comprehensive regulatory framework" is meant to enable the EU to harvest the potential of biotechnology and reverse the exodus of researchers in the GMO field. Furthermore, consumers shall be given the chance to choose between genetically modified and traditional items by new labelling provisions. After establishing its new directives the EU has resumed processing applications of biotech products, approving of sweet maize Bt 11 on May 19th 2004.

#### 1.2.2.4 The Key Issue

It is obvious that the halt in the application processes has not been motivated by health and environmental concerns. Neither could the need for additional information from the applicants alone have resulted in a complete abstinence from approving of GMOs for several years. Instead, as members of the Commission made clear elsewhere, the worries of consumers were the driving force behind the EU's course of action.[14]

Consistently, the introductory statement of a communication of the commission on the precautionary principle reads: "A number of recent events has shown that public opinion is becoming increasingly aware of the potential risks to which the population or their environment are potentially exposed. Enormous advances in communications technology have fostered this growing sensitivity to the emergence of new risks, before scientific research has been able to fully illuminate the problems. Decision-makers have to take account of the fears generated by these perceptions ..."[15]

Thus, key to the debate is not the quarrel about the existence of a moratorium but the question whether the EU was legally barred from giving consideration to public worries. To examine this further we must take a look into the nature of the problem posed to the EU: the selection of the proper means of risk management.

## 2 Risk and Risk Management

### *2.1 The Issues of Uncertainty and Ignorance*

In decision theory the term "risk" usually refers to the expected value, i.e. the probability of an adverse effect of an action, multiplied by its gravity. If this probability is unknown, decision theory speaks of "uncertainty". If, due to a lack of knowledge even the very existence of an adverse effect is unknown, we have a case of "ignorance". In the following, however, I will use the term “risk” in a broader sense, comprising all three components mentioned.

Contemporary science grants us the opportunity continuously to increase the understanding of the physical and social world. As it reveals more and more of the world’s complex interdependencies, science allows us to intervene more specifically if considered necessary. But science also provides us with a continuously increasing understanding of how much we do not know. It is this growing awareness of our lack of knowledge that boosts the urgency for measures of precaution.

Measures of precaution determine the impact of technologies or other innovations at stake. Thus, regulations and adverse effects are inextricably intertwined. This is obvious for a case where permissive regulation has allowed damage to occur. But it must be noted that a preventive stance may impart adverse effects as well, e.g. economic stagnation for a country having opted out or legal damage by an unjustified restriction of civil rights.[16] Thus, we have to consider two types of risk: the possible harm

[12] First submission of the EU (DS291/DS292/DS293), para. 486, 561.
[13] Commission (a), 2; Brack/Falkner/Goll, 3.
[14] Commission (a), 2.
[15] Commission (b), 7.
[16] Scherzberg, 225; Gleich, 292.

caused by new technologies or substances – which I call 1st order risk - and the possibility of damage being caused by an inappropriate legal risk management, "2nd order risk".[17]

### *2.2 The Limits of Science*

Traditional risk assessment rests upon the belief in the efficiency of science. Regulations such as the WTO treaties rely on scientific evidence in evaluating the harms and benefits to society associated with particular measures and policies. An assessment based on science can obviously not at the same time be based on political schemes or interests. The WTO makes this point very clear when it contrasts "scientific evidence" with disguised restrictions on international trade. Whilst independence from political reasoning indeed should be a basic property of any scientific endeavour, it remains to be seen whether science can really provide for the clear and “objective” answers decision-makers expect: harmful, yes or no? Let us explore this in three steps.

At first we have to note that a particular technological innovation may be good for a multitude of adverse effects. Human health may be threatened by toxicity, insufficient nutrition or unexpected cross-effects. Environmental issues may be biodiversity and toxicity to flora and fauna.[18] Economic losses may occur if, for instance, external effects of innovation are not internalised. There may also be social impacts like unease about the new technology or the loss of public trust in authorities to handle possible threats, making it more difficult to introduce new technologies in the future. Mistrust towards GMOs in Europe for example may well be attributed to the BSE experience.[19]

To ensure completeness of the assessment, all possible effects would have to be taken into consideration. But it is simply not feasible to explore all effects.[20] Constraints are time and money. Thus often enough, cumulative or indirect effects are omitted[21] and their multitude is narrowed down to immediate and severe consequences to nature and to human health. This choice, however, is a political one and cannot be based on science. An additional, particular trait of GMO risk control is that it is unclear whether certain effects are to be considered "adverse" at all. Gene flow, i.e. the exchange of genetic information among individuals and populations even beyond the species level is a biological principle, not necessarily to be considered an 'ecological' damage.[22] Therefore, in this context the term "damage" requires an ethical or culturally based definition.[23] In other words, treating an effect as relevant and qualifying it as "adverse" presupposes a political decision.[24]

Secondly the notion of completeness calls for the comparison of all relevant effects including their different qualities. For example aspects like severity, immediacy or reversibility are to be considered.[25] These qualities, however, are mostly incommensurable. This finding applies even more to the trade-off between potential harms and benefits.[26] Regarding of starvation problems in developing countries for instance, the use of GM crops may well reduce problems of subsistence but may also cause risks to biodiversity and harm to some consumers. To weigh and compare these risks is a matter of social and political judgment[27] – "sound" science is of no help.

Thirdly, science is often unable to provide a statistical probability for the manifestation of an adverse effect. To provide scientific evidence for a certain benefit of a new technology or substance is relatively easy – that is what the innovation is created for. But as for their side effects, science mostly offers only estimates based on deliberately chosen premises which lead to contradicting results. This is

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[17] Scherzberg, 219-220; Karthaus, 87-88; Sunstein, 99-102, Chapter 6; Gleich, 288.
[18] Stirling, 10.
[19] Economic & Social Research Council (ESRC), 7-8.
[20] Rat, 658.
[21] Stirling, 11.
[22] Bartsch, 5; WBGU, 109.
[23] Bartsch, 4.
[24] Rat, 647.
[25] Stirling, 11; Scherzberg, 231.
[26] Stirling, 11; Scherzberg, 231-232.
[27] Stirling, 10.

so because most side effects develop only during the application of the technology or substance in practice - transforming the whole society into a laboratory.

Without a clear picture of the likelihood of adverse effects, it is impossible to determine a rational course of action scientifically. A fortiori if science does not even indicate the possibility of an adverse effect. Naturally, "the absence of evidence" must not be portrayed as "evidence of absence".[28] On the contrary, practical reason forbids us from excluding adverse effects of sustained impacts of civilization on the environment.[29] This is the lesson to be learnt from the CFC disaster. The European Environment Agency comments:

> "There can be little doubt that a conventional risk assessment, in say 1965, would have concluded that there were no known grounds for concern. It would have noted that CFCs were safe to handle, being chemically very inert, [..] and having very low levels of toxicity. [...] The assessment might have pointed out that it was not known what happens to CFCs when they are released to the atmosphere, but would no doubt have added that they had been released for more than 30 years with no apparent harm being done."[30]

The harm, however, was merely not apparent yet.

### *2.3 The Rationale of Risk Management*

If there is no sound scientific way to address the issues of the uncertainty and incommensurability of effects and the incompleteness of their analysis,[31] risk assessment is a volitive operation.[32] That does not mean, however, that taking ignorance and uncertainty into account is not scientific. Science, being unable to provide the answers, is not forced to abjure responsibility for the matter. As scientists, we are fully aware that referring to the issues of uncertainty and ignorance is scientific to the core! On the ground of Popper's "critical rationalism", science can never claim to have found a final truth. Furthermore the philosophy of science reminds us that clear-cut standards to determine soundness of theory are hard to come by. Alternative paradigms exist, various premises have to be made and different disciplines often produce conflicting results.[33]

If science cannot provide an "objective" basis for decision, it remains to be explored how sound decisions of risk management are possible. The required decision must not be arbitrary. Therefore, the rationale of a decision based not only on science must be developed.[34] Let me make four suggestions:

- As a *first requirement*, administrative risk control must neither neglect issues of uncertainty and ignorance, nor prevent a gain of knowledge.[35] Recognizing the existence of 2nd order risks, decisions are to be kept open to revision by continuous monitoring and evaluation, and the ability of society to learn is to be sustained. This calls for controlled procedures of trial and error which enable authorities to detect the manifestation of unknown dangers at an early stage and allow for their confinement.[36] Simultaneously however, risk management should also investigate alternative techniques and substances with similar benefits and reduced uncertainty.

- A *second requirement* is explicitly to address the underlying assumptions of the scientific risk evaluation.[37] Thus, it becomes transparent for decision-makers and the public what effects have been considered and how they are rated. Such transparency would allow for discourse on the choices made. It would also display the inevitable simplifications that come with any choice of that kind. Transparency is required especially with reference to uncertainty and ignorance. As we learn from Charles

[28] ESRC, 7.
[29] Scherzberg, 252; Gleich, 287-288.
[30] European Environmental Agency (EEA), 82.
[31] Stirling, 10, 12.
[32] Scherzberg, 249; Dose, 3; Holland/Kellow, 238.
[33] Stirling, 19.
[34] Douglas, 194.
[35] Scherzberg, 233.
[36] Scherzberg, 258.
[37] Stirling, 12.

Perrow there appears to be an inclination to resort to traditional, probabilistic assessment techniques where they are not applicable.[38] Mainly when transferring the results from the scientific community to decision-makers and the public, scientists should insist that certain questions remain unanswered.[39]

- Since risk assessment is a value-based job, it inherently and inevitably presupposes the interaction of science and society. Naturally there are conflicting, incongruent social values and resulting options. Arrow's Impossibility Theorem[40] teaches us that trying to aggregate those various values is a futile exercise. Therefore the decision on if and how to introduce a new technology or handle a new risk phenomenon falls to the political system.[41] The *third requirement* would thus be for the political system to establish clarity about the necessity of political risk evaluation and to resume its responsibility for it, instead of resorting to the alleged authority of "sound science".[42]

- Political risk management, however, is different from most other political decisions. It concerns fundamental human values and resources,[43] has to answer the question of cultural acceptability of risks to life, health and collective goods and needs to maintain society's balance between innovation and protection. A *fourth requirement* takes up this cultural element of risk management and calls for the provision of a societal risk communication.[44]

Avoiding the arousal of mistrust towards new technologies not only assuage people's mood, but also maintains a society's capacity for innovation. If a new technology evokes public resistance this may well force industry to renounce the innovation even if the specific regulations are permissive, as we saw in the field of nuclear energy in Germany. Therefore it is imperative to address public concern and respect and integrate public risk evaluation.[45] It is well known that the individual and societal acceptance of risks depends on factors like their voluntariness, familiarity, accountability or controllability.[46] This indicates that social risk evaluation follows certain patterns. In these patterns and their modi of processing ignorance and uncertainty, the respective culture defines itself, as can be shown in many instances. In Europe for example genetic engineering as such encounters severe resistance, while it finds broad acceptance in the field of pharmacological research. While this distinction seems completely intelligible to Europeans, it confuses some American authors.[47] Another example of cultural risk evaluation would be road traffic. A German all-time-high of 21,000 fatalities from traffic accidents in 1970, figuring today at 6,600, neither kept people from using cars, nor motivated the public to call for general speed limits. Think of the uprising, though, if it turned out that GMOs cause a comparable amount of fatalities a year. Global warming is another acute instance showing the relevance of culture in risk evaluation: just remember the difference in viewpoints between most of Europe and the US about the handling of climate related risks.[48] Obviously there are risk-averse and risk-friendly communities and different viewpoints about the evaluations of specific risks.[49]

If risk assessment is a matter of social evaluation, politics must interact with society to determine the acceptability of risks. This is so not only to ensure the fair chances of innovation in society but also to ensure the legitimacy of the political processes of risk management itself.[50] Here are some key ideas for such an interaction:

- Risk communication is meant to initiate a societal discourse on the risks and benefits of an innovation including any alternatives.

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[38] Perrow, passim.
[39] Dose, 14.
[40] Stirling, 12.
[41] Sundermann, 122; Dose, 3, 5.
[42] Bartsch, 2; Hennen, 565, Meyer-Abich, 309, 311, 316.
[43] Meyer-Abich, 316.
[44] Deane, 111-114.
[45] Deane 114-115.
[46] Stirling, 11; Deane 107-111, Scherzberg, 231.
[47] Robertson, 207-208, 217.
[48] WBGU, 135140.
[49] Robertson, 3.
[50] Hennen, 565.

- The societal discourse should not be delayed until the development of the new technology is completed or the innovation process is ready to be launched. Rather, the discourse should begin as soon as new technologies or phenomena loom.[51]
- The main conflicting opinions among the public and stakeholders must be disclosed and introduced into the discourse.
- Available scientific data must be delineated. The limits of any scientific statement as well as the dependence of such statements on framing assumptions must be clearly addressed.[52]
- The discourse must be moderated in a way that makes clear that the different perspectives – unless falsified - are equally valuable.[53]
- At any stage of the discourse, it must be apparent to everybody how far the respective decision is open to revision.
- The political-administrative system must explicitly name those values or conceptions that eventually become the basis of the decision.
- The public must be made aware that remaining risks due to yet unknown dangers could only be avoided if society were to renounce any and all innovation. Even "unsuspicious" technologies may entail unexpected effects.[54]

Risk communication is meant to create credibility and acceptability.[55] Its appropriate modi depend on each nation's individual culture. The proposed discourse would probably not lead to a society-wide consensus, but would create a "modulated process of active scepticism and dissent".[56] The public negotiation process would, however, inform the authorities of the different values, conceptions and approaches in society relevant to the issue. Only when decision-makers possess that kind of information are they able to make informed decisions which are coupled to society. The societal risk discourse would have to be organised and carried out with the objective of satisfying also those participants, whose opinions would at the end not prevail. The final decision would then not appear arbitrary or unjustified, because even if not based on sound scientific facts, it is based on a sound rationale.[57]

### *2.4 Conclusions*

My previous findings indicate that risk assessment and risk management are inherently dependent on the contemplation of social values and conceptions. Risk – as a whole – is a construct.[58] It begins with the question of which classes of effects to consider, of how to rank the concerned individual and collective goods and of how to evaluate the trade-off between the uncertainty of known or unknown dangers and the certainty of known benefits of an innovation. It ends with the political decision under which assumptions and conditions the assessed risks are acceptable.

Thus strategies of risk management must be understood not only as "technical" provisions to minimize adverse effects, but also as procedural guidelines to reflect on, define and select social values and preferences and thus ensure political accountability. These characteristics and specific requirements of risk management suggest a specific course of action of the political-administrative system. This course of action is often referred to as the precautionary principle.

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[51] Stirling, 25; Sundermann, 121.
[52] Dressel, 192-197; Sunstein, 110; Hennen, 566; Dose, 14-15.
[53] Stirling, 12.
[54] For instance, the direct current used in solar electricity systems is prone to creating self-sustaining electric arcs which may spark blazes, and recent studies indicate that radiation from cellular phones may render males sterile.
[55] Deane, 113-114.
[56] Stirling, 24.
[57] Hennen, 570.
[58] Scherzberg, 258; Sunstein, 108-110; Douglas, 186-198; Deane, 108.

## 3 The Precautionary Principle: a risk management strategy

The precautionary principle is a risk management strategy.[59] It is applicable where preliminary scientific evaluation indicates that there are reasonable grounds for concern that potentially dangerous effects may be inconsistent with the chosen level of protection.[60] How far uncertainty and ignorance are to be taken into account is very much disputed.[61] Before discussing its reflection in the SPS-agreement, let me depict its general reception in international and European law.

### *3.1 The precautionary principle in international and EU-law*

#### 3.1.1 International law

The application of the precautionary principle in international law is based on the Rio Declaration on Environment and Development and on specific conventions like the Cartagena Protocol on Biosafety and the UN Framework Convention on Climate change.

In Principle 15 of the Rio Declaration[62] the issue of uncertainty is explicitly taken into account. Ignorance, though, is ignored. There have to be "threats of serious or irreversible damage" for the principle to apply, implying that those specific threats are known. The value aspect is completely disregarded, as the principle allows actions where there is a lack of "full scientific certainty". This implies that "full scientific certainty" is generally possible. My previous remarks make it clear that this is an illusion.

The Cartagena Protocol on biosafety explicitly pronounces the objectives of the protocol to be in accordance with the precautionary approach contained in principle 15 of the Rio Declaration. The specific provisions of the protocol, however, by far exceed that principle.

Articles 10.6 and 11.8 allow for decisions where there is a lack of scientific evidence regarding the extent of the potential adverse effects. That phrasing seems to include hitherto unknown effects and thus incorporates the issue of ignorance. Article 12.1 enables learning, as decisions may be revised in the light of new scientific evidence.

Articles 15 and 16 uphold a clear distinction between risk assessment and risk management. The risk assessment shall be carried out in a "scientifically sound manner", taking into account "recognized risk assessment techniques". Annex III specifies what that is supposed to mean. Interestingly, the Annex recognizes that lack of scientific knowledge or scientific consensus should not indicate a particular level of risk, an absence of risk or the acceptability of risk.

Article 23 deals with public participation and refers to the respective laws of the participating states. It calls for information and the raising of awareness about safety measures and risk, but does not demand the integration of public feedback into the decision-making process. Art. 26, however, allows for consideration of socio-economical aspects in a decision on the import of living modified organisms.

#### 3.1.2 The EU's understanding of the precautionary principle

##### 3.1.2.1 The European Commission's official reading

The precautionary principle is mentioned in Art. 174 EC-Treaty. The Commission, in a memorandum on the application of the principle, names two defining presuppositions: the identification of potentially negative effects and a scientific evaluation of the risk which because of the insufficiency of the data, i.e. their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question.[63]

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[59] Commission (b), 8.
[60] Commission (b), 2.
[61] Scherzberg, 221.
[62] "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. 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."
[63] Commission (b), 14.

Decision-makers may face unacceptable risk, scientific uncertainty and public concerns. All these factors have to be taken into consideration.[64] The compulsory cost-benefit analysis is required to include non-economic considerations, such as public acceptability.[65] There are products that countries may deem dangerous a priori.[66]

To take measures before all the necessary scientific knowledge is available is identified to be a precaution-based approach. At the same time, a structured decision-making process with detailed scientific and other information is required.[67] The precautionary principle does not justify arbitrary measures.[68] Thus the Commission deems its application compatible with WTO provisions.[69]

#### 3.1.2.2 The directive on the deliberate release into the environment of genetically modified organisms

In the context of my present analysis, the directive on the deliberate release into the environment of genetically modified organisms explicitly refers to the precautionary principle.[70] Particular emphasis is put on transparent public consultation.[71] Moreover the introduction of GMOs into the environment has to be carried out on a step-by-step-basis. The scale of release is to be increased gradually, dependent on the evaluation of the earlier steps.[72] An environmental risk assessment is required before submitting a notification to the competent authority.[73] "In accordance with the precautionary principle", the assessment should be carried out in a scientifically sound and transparent manner, based on available scientific and technical data.[74] Any characteristics of the GMOs linked to the genetic modification that may result in adverse effects on human health or the environment shall be identified.[75]

#### 3.1.2.3 The regulation on genetically modified food and feed

The regulation on genetically modified food and feed also refers to the precautionary principle, calling for a scientific evaluation of the highest possible standard of any risks which such food or feed presents for health or the environment prior to the authorization of placing them on the market.[76] No GMO food or feed shall be authorised unless the applicant has adequately and sufficiently demonstrated that it does not have adverse effects on health or the environment, that it does not mislead the consumer, and that it does not differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.[77] Clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, is required in order to meet "the demands expressed in numerous surveys by a large majority of consumers". Labelling is meant to facilitate informed choice and preclude potential misleading of consumers about methods of manufacture or production.[78]

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[64] Commission (b), 3.
[65] Commission (b), 4.
[66] Commission (b), 4.
[67] Commission (b), 7.
[68] Commission (b), 13.
[69] Commission (b), 10-12.
[70] Directive 2001/18/EC, Preamble (8) and Article 1, Annex II B.
[71] Directive 2001/18/EC, Preamble (9, 10, 46) and Articles 9, 24, 29.
[72] Directive 2001/18/EC, Preamble (24).
[73] Directive 2001/18/EC, Articles 4.2, 13.
[74] Directive 2001/18/EC, Annex II B.
[75] Directive 2001/18/EC, Annex II C.2.1.
[76] Regulation (EC) No 1829/2003, Preamble (9), Article 6.4, 18.4.
[77] Regulation (EC) No 1829/2003, Articles 4.1, 4.3, 16.1, 16.3.
[78] Regulation (EC) No 1829/2003, Preamble (21).

## *3.2 The precautionary principle in the SPS-agreement*

### 3.2.1 The ruling of the Appellate Body

SPS does not explicitly refer to the precautionary principle. It is inherent though in Articles 3.3 and 5. For the understanding of these provisions I refer to the rulings of the Appellate Body in the beef hormone case.

The Appellate Body explicitly left the question as to whether the precautionary principle represents customary international law unanswered.[79] It stressed that the principle has not been explicitly written into the SPS Agreement in order to avoid conflicts with obligations set out in other provisions of the agreement.[80] Still, it recognized that the principle indeed finds reflection in Article 5.7 and in Article 3.3, as these explicitly recognize a Member's right to establish its own appropriate level of protection.[81] The Appellate Body stated that it does not override the provisions of Articles 5.1 and 5.2, which call for risk assessment and scientific evidence,[82] and that these requirements are essential for the carefully negotiated balance between the interests of promoting international trade and of protecting human life.[83] However it also admonished the panel charged with determining whether "sufficient scientific evidence" exists, to bear in mind that responsible governments commonly act with prudence and precaution where risks of irreversible damage to human health are concerned.[84]

While acknowledging the precautionary principle, the Appellate Body gave no consideration to the cultural impact of risk assessments nor to the question of uncertainty as previously discussed. Following the wording of Article 5.7, members are granted “a reasonable period of time” to obtain additional information only in case scientific evidence is insufficient. Accordingly members are allowed to establish a level of protection higher than the relevant international standards only if evidence is produced for the possibility of specific risks as well as for their probability.[85]

### 3.2.2 The inadequacy of this ruling

By relying on scientific evidence as its main criterion, the Appellate Body favours the proponents of new technology over those potentially harmed, since the desired benefits of the innovation are generally known whereas the multitude of possible adverse effects is rarely fully examined. Furthermore, in the Appellate Body´s reading, Article 5.7 does not even provide for the necessary time for additional scientific research as long as no specific adverse effects have been identified.

Thus the WTO-System would ignore some relevant findings of modern risk-related science:

- the selection of adverse effects and their qualification as adverse being value-laden and thus partly trans-science
- a complete risk assessment often not being achievable within constraints of time and money
- indications of specific adverse effects being visible often only after a longer period of applying the innovation in practice
- the dealing with uncertainty and ignorance being a culturally based phenomenon.

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[79] EU Measures Concerning Meat and Meat Products, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para. 123.
[80] EU Measures Concerning Meat and Meat Products, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para. 124.
[81] EU Measures Concerning Meat and Meat Products, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para. 124.
[82] EU Measures Concerning Meat and Meat Products, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para. 125.
[83] EU Measures Concerning Meat and Meat Products, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para. 177.
[84] EU Measures Concerning Meat and Meat Products, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para. 124.
[85] Cottier, 52.

With this in mind, the question arises whether the Appellate Body's reading is the only possible way to reflect the rationale of the SPS Agreement correctly. According to its preamble, SPS is meant to provide for the necessary protection of human, animal or plant life and health and at the same time desires to prevent arbitrary discriminations and disguised restrictions on international trade. So its intention is to create a balance between free trade and protection.

Following this rationale, one has to consider that the suggested alternative between disguised trade restrictions and science-based protective measures is not as exclusive as the Appellate Body believes. Since risk assessment in the area of uncertainty and ignorance is a value based process which can not fully rely on standards of science, there may well be measures of protection which are motivated by societal and cultural risk evaluation but not regarded necessary by science – and which according to their reason and intent are nonetheless neither arbitrary nor created as disguised trade restrictions.[86]

For actions of this kind SPS leaves a regulatory gap. According to the wording of its provisions they are not covered. According to the rationale of the preamble, however, they might well be. If members are allowed to set their own goals of protection - including a "zero-risk-strategy" concerning known risks – it would appear contradictory to bar them from also defining society's limits to cope with unknown risk and the uncertainty of a particular risk to manifest. Authorizing culturally based precaution would also ensure compatibility of SPS with other international agreements like the Cartagena Protocol which acknowledges the issue of ignorance and incorporates socio-economical evaluations. To avoid a conflict of this kind, the Appellate Body implied in the shrimp-turtle case that trade restrictions emanating from multilateral environmental agreements might indeed have to be permitted by the WTO.[87]

A modified interpretation of SPS taking into account the issue of ignorance and allowing for cultural based measures of precaution is thus to be preferred. In this reading, preventive action would be justified if science does not exclude the possibility of an adverse effect and the member state substantiates that the manifestation of the specific risk would be unacceptable to society. The wisdom of such an approach can easily be recognised from the BSE experience.

## 4 Excursus: A lesson already learnt: BSE and precaution

### 4.1 Brief history of BSE[88]

In December 1984, the first "mad cow" was observed in England, and "BSE" was diagnosed seven months thereafter. The first official BSE case was confirmed in November 1986. In November 1987, the transmissibility to mice was demonstrated, indicating that BSE is able to cross the species barrier. In June 1987, the British Ministry of Agriculture, Fisheries and Food (MAFF) was informed by the Chief Veterinary Officer of the existence of a new disease in cattle. In December 1987, some evidence was found suggesting that ruminant-derived "meat and bone meal" (MBM) is a factor in the cause of BSE. Still, it took until June 1988 to make BSE notifiable and until July 1988 until the ruminant feed ban was enacted. In August 1988, slaughter policy for affected cattle was enacted, at a compensation rate of only 50 %. Although transmissibility to mice was confirmed in October 1988, the Southwood Report from February 1989 called the risk to humans "remote" and "most unlikely". In May 1990, the Minister of Agriculture stated that British beef is perfectly safe to eat, and national press is advised accordingly. The Minister also was featured in the media feeding hamburgers to his young daughter. By 1993, it also became clear that BSE is transmissible to apes. In 1995, an alarming number of new variant Creutzfeld-Jacob-Diseases were diagnosed. In 1996, the British government finally admitted a danger to humans. By 2004, 139 people were reported dead in the UK.

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[86] See Byron, 28, 34

[87] United States - Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58/AB/R, adopted 6 November 1998, para.185.

[88] For the following compare Report of the BSE Inquiry, Stationery Office, 2000; National Meat Association Resource, http://meat.tamu.edu/pdf/BSEresource.pdf.

In the US, a BSE surveillance program was established in 1986. The following year, BSE was made a reportable disease. In July 1989, importation of live ruminants was banned from countries where BSE was known to exist. The FDA feed ban was enacted August 1997, banning the use of mammal-derived animal by-products in cattle feed. In December 1997, imports from Europe were entirely banned. The first U.S. BSE case was unearthed in December 2003. Thus the United States, by establishing protective measures early on, even though based on insufficient or even lacking evidence, succeeded in keeping infection figures low.

5.2. Some comments on the handling of the BSE-case

Even though transmissibility to humans was not ruled out by MAFF officials from the very beginning, the probability was considered negligible, as it was initially – and fallaciously – concluded that BSE could derive from scrapie to which humans are not susceptible.[89]

Scientific evidence was initially scarce. The exact pathogen was unknown, it was also unknown what parts of the animal body could become infected. Due to the long incubation period, the scope of the epidemic could not be estimated at an early stage. Very soon, though, it became clear that the feeding of animal protein spread the epidemic. Still, the feed ban only concerned ruminants. Furthermore, the feed ban was imposed with several months delay from the date the information was available.

In general, the lack of definite scientific evidence encouraged officials not to take action at all, or to take insufficient or late action.[90] The British Government was "preoccupied with preventing an alarmist over-reaction to BSE because it believed the risk was remote".[91] A major concern was "the short-term adverse impact of BSE on the profitability of the food industry".[92] Information on the new disease was held back, instead of fostering a broad scientific exchange.[93] Not until the first fatalities occurred and evidence of the BSE-CJD link became compelling did the UK government react.

The UK government chose not to initiate an open public discourse as proposed above. Such an open discourse may still have resulted in the political decision to favour economic interests against public health, as long as scientific evidence was inconclusive. It would, however, have created a broad public awareness of the problem giving the consumer the chance to decide for herself or himself on how to deal with his potential risk. If that path of risk management had been chosen in the UK, many lives could have been spared.

The public, when asked, would probably not have accepted health risks for the sake of some individuals' economic welfare. A strong public call for effective governmental action would have indicated underlying values being broadly shared, which needed to be considered by the government. Even if public responses do not always appear rational in a scientific sense, the UK government's approach was even less so, not achieving any of its objectives: in the end many lives were lost and the meat industry was shattered.

## 5 Conclusions

Let me return from BSE to GMO and conclude: The EU's approach to GMOs is as "scientific" as that of the United States, only the social values and conceptions underlying the assessment of the risk diverge, indicating the difference between a risk-friendly and a risk-averse society. The present WTO-system, however, is not well equipped to resolve these kinds of culture-based disputes.[94] The value-laden aspect of decision-making is neglected and the issues of uncertainty and ignorance are not sufficiently recognized.[95]

To avoid further legal conflicts of this genre WTO has two options: either to permit its members to base their measures of risk management on the results of the societal risk discourse, as proposed

[89] BSE Inquiry, Executive Summary, 19; EEA, 157.
[90] Dressel, 50-51.
[91] BSE Inquiry, Executive Summary, 18.
[92] EEA, 159.
[93] BSE Inquiry, Executive Summary, 19; EEA, 159; Dressel, 68-75.
[94] Sampson, 24-25; Cottier, 42.
[95] Cottier, 53.

above, or to establish such a discourse on the international level.[96] As regards risks which transcend national borders and cannot be confined by legal measures on the regional or national level, the WTO Committee on Trade and Environment (CTE) could be entrusted with the task to initiate supranational risk communication and collect societal feedback. Based on its findings the WTO-bodies would then develop a general stance towards a given new technology or innovation which respects the cultural differences of its members.

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[96] Cottier, 53, suggests polls and expert hearings „to look into factors such as acceptance of new technologies and ethical considerations“

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