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Determining Insufficiency of scientific Evidence under the SPS Agreement

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1 Social values in the assessment of risk

The WTO-panels' approach of measures taken by states in order to protect human, animal or plant health rests on a division of labour: Scientific experts conduct a risk assessment and heads of states implement the results of the risk assessment in their policy. And if the experts are not able to conduct a risk assessment then the heads of states are allowed to build their measures on this negative evidence. It is the scientists who decide on the existence and magnitude of a risk, and it is the politicians who decide on whether to accept the risk or, more generally, on what should be done in order to protect their country from its entry. According to the panels a quantitative scientific analysis can neatly be separated from its political assessment. The Appellate Body instead takes a more integrative view.

What discerns risk assessment from the decision to take a protective measure is that it is free from social values. It applies the laws of nature – which are applicable irrespective of any social regulations, legal norms or political systems – and determines the occurrence of adverse effects under hypothetical constellations. Thus, risk assessment identifies effects adverse to human, animal or plant health and evaluates their potential entry, following the rules of science, not of policy. The performance of a risk assessment is no 'exercise involving social value judgments'.¹ Consequently the panels prefer numbers in a risk assessment, numbers that indicate the probability of an adverse effect. This preference however makes them liable to consider quantified results as objective evidence which actually lack empirical support.²

The Appellate Body corrected the panel's approach in that qualitative elements, too, form part of a risk assessment and may provide evidence for the existence and magnitude of adverse effects, and moreover that a risk assessment which respects social aspects is compatible with the SPS agreement. Risk assessment under article 5(1) SPS is neither restricted to quantitative analyses nor to science laboratories working under strictly controlled conditions. Risk to be evaluated in a risk assessment implies 'risks in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.'³

The Appellate Body's correction of the panel seems to allow states to socially frame the risk appropriate to their domestic circumstances which then is to be evaluated in a risk assessment. States thus may first articulate their standards of public health protection before a scientific risk assessment is going to be performed against this standard. The outcome of the risk assessment would then be the basis for the state's decision which measures should be taken. This interpretation of the Appellate Body's ruling amounted to a two-step procedure with regard to sanitary and phytosanitary measures. In a first step the state determines its level of protection, and in a second step it determines its level of acceptable risk. The first step is based on the circumstances a state considers to be appropriate; the second step is based on the (probabilistic) result of the pertinent risk assessment.

The level of protection is equivalent to the framing of a risk when identifying it. The identification of a risk involves selections and characterizations of objects, situations or models which shape the occurrences a state considers to be risky.⁴ Risks are socially framed, not

¹ WT/DS26/R, WT/DS48/R EC – Measures concerning Meat and Meat Products (Hormones) (1998), para 8.94.

² Pauwelyn (2002), p.349.

³ WT/DS26/AB/R, WT/DS48/AB/R EC – Measures concerning Meat and Meat Products (Hormones) (1998), para 187.

⁴ Winickoff (2005), p.94.

found.⁵ Risks imply social judgments on natural occurrences; in framing a risk an occurrence is qualified as adverse effect on health, i.e. something men have an interest in preventing. Because risk framing is a social activity each level of protection inherently embodies social convictions – expressly and tacitly. And the same applies then for risk assessment. It is dependent on the risk framed. Hence, simplified assumptions incorporated in the chosen level of protection are transposed in models and procedures of risk assessment which help preventing a risk, but not the occurrences. Risky occurrences are only preventable to the extent they are framed, other occurrences necessarily pass the assessment. To the extent for example women are underrepresented in risk assessments they do not enjoy the same level of protection. The same counts for individual variations in the susceptibility of diseases.⁶

For the conception of any risk assessment social values are indispensable. In order to conduct a risk assessment a clear definition of the assessment endpoint is critical.⁷ Assessment endpoints declare what shall be protected, i.e. what is considered valuable to an extent that deserves protection, for example the reproduction of piscivorous birds. On the basis of the definition the endpoints can be measured in a risk assessment. But even measurements presented quantitatively do not reveal risks unequivocally. The risk of coalmines appears contrary when represented by deaths from accidents per ton of coal, or when represented by deaths from accidents per employee.⁸ Risks derive their importance from their social perception, and therefore risk assessments are only appropriate for particular purposes and in particular content.⁹

The European Union invoked its level of protection with regard to biotech products against the level of precision achievable with current risk assessment procedures – to no avail. Current risk assessments do not serve the level of protection the Union is pursuing. It argued that the higher level of protection in the European Union required a more detailed risk assessment than was possible with the available scientific data.¹⁰ The European Union obviously framed the risk of genetically modified objects to a higher level of protection than with regard to other objects and claimed an adequate risk assessment for this higher level of protection. The higher level gains legitimacy from the irreversible consequences of genetically modified organisms: what is at stake here are no longer individual lives, but potentially entire ecosystems.¹¹

The panel turned the European Union's argument down with the remark that risk assessment must be adequate to Annex A(4) SPS and not to the purpose of the legislator.¹² Risk assessment is still conceived as an autonomous, self-contained procedure without social implications. Though the panel concedes that the adequacy of scientific data for the performance of a risk assessment must be determined on a case-by-case basis, it does not hold the level of protection to be relevant for such a determination. In respect of the level of protection a state may decide what kind of risk it wants to assess, yet 'there is no apparent link between a

⁵ Jasanoff (1993) p.126; Slovic (1999), p.690.

⁶ Jasanoff (1993) p.125.

⁷ Hoffman (1994) p.708.

⁸ Slovic (1999), p.690.

⁹ Lang (2008), p.15.

¹⁰ WT/DS291/R, WT/DS292/R, WT/DS293/R EC – *Measures affecting the Approval and Marketing of Biotech Products* (2006), paras 7.3227 and 7.3241.

¹¹ Eliason (2008), p.363.

¹² WT/DS291/R, WT/DS292/R, WT/DS293/R EC – *Measures affecting the Approval and Marketing of Biotech Products* (2006), para 7.3239.

legislator's protection goals and the task of assessing the existence and magnitude of potential risks.'¹³

Apparently, the panel still applies the dichotomy of risk and risk acceptance – it does not consider the upstream level of protection which reflects the socially framed risk assessed in a risk assessment. When the panel states 'We do not think that scientists need to know a Member's acceptable level of risk, in order to assess objectively the existence and magnitude of a risk'¹⁴, it refers to risk as something objective comparable to Russian roulette with a bullet in the gun – and even here a state's conception of risk may comprise not only the lethal shot, but the inhalation of gunpowder, the ear damages caused by the bang, or psychic traumata. To the panel however the scientists determine the risk, and the politicians decide how to cope with it. If, of course, states are only allowed to define their level of acceptable risk then their decisions would not interfere with the risk assessment and the intended level of protection could be disconnected from the performance of a risk assessment.¹⁵

This shows the importance to distinguish between a state's level of protection and its level of acceptable risk. In terms of science, the former is creative, the latter receptive: On its conception of risk (and intended protection) a state receives from scientists a likelihood of the risk's presence. Now, the distinction explains that risk assessments are not 'purely scientific in nature'¹⁶, i.e. value neutral; likewise are a state's decisions on the respective levels not purely non-scientific in nature because the risks need to be conceptualized not in values but in concepts, which is to the best executed with the precision of scientific neutrality. Thus, the distinction helps to serve scientific expertise and respect for popular choices.¹⁷ It reflects the formation of international standards like the Codex Alimentarius where governments state their requirements on standards and finally approve them.¹⁸

Most importantly, however, the distinction enlightens the only relationship panels deem to be relevant: 'that between the scientific evidence and the obligation to perform a risk assessment'.¹⁹ This relationship entails whether a given body of scientific evidence is sufficient to conduct a risk assessment. The European Union failed to meet article 5(1) SPS because the studies presented by it did not contain an evaluation of the likelihood of adverse effects and thus did not count as risk assessment in the sense of Annex A(4) SPS.²⁰ From a scientific point of view however, the submitted studies must be read in the sense that an evaluation of the likelihood would have been premature without further tests.²¹ For the European Union therefore, in order to rely on article 5(7) SPS, it had been crucial to demonstrate that the relevant scientific evidence is insufficient to assess the risk of the genetically modified objects concerned.

¹³ WT/DS291/R, WT/DS292/R, WT/DS293/R *EC – Measures affecting the Approval and Marketing of Biotech Products* (2006), para 7.3238.

¹⁴ WT/DS291/R, WT/DS292/R, WT/DS293/R *EC – Measures affecting the Approval and Marketing of Biotech Products* (2006), para 7.3243.

¹⁵ WT/DS320/R *US – Continued Suspension of Obligations in the EC-Hormones Dispute* (2008), para 7.612.

¹⁶ Walker (2003), p.198.

¹⁷ Howse (2000), p.2330.

¹⁸ FAO/WHO (2006), p.16.

¹⁹ WT/DS291/R, WT/DS292/R, WT/DS293/R *EC – Measures affecting the Approval and Marketing of Biotech Products* (2006), para 7.3234.

²⁰ WT/DS291/R, WT/DS292/R, WT/DS293/R *EC – Measures affecting the Approval and Marketing of Biotech Products* (2006), para 7.3040.

²¹ Eliason (2008), p.395.

2 Scientific evidence and uncertainty in the assessment of risk

Unlike many domestic legal systems, WTO procedures do not set out criteria for the admissibility of evidence. Parties are free to submit any evidence, but they can hardly predict how the panels then weigh the evidence.²² The panels regularly reject irrelevant or unspecific evidence. General studies are not considered;²³ whereas specific and relevant studies are considered irrespective of the authors' experience or alleged neutrality.²⁴ While it is usually controversial when evidence is sufficient to convict someone, under the SPS it is the insufficiency of evidence which is controversial in order to apply article 5(7) SPS, especially when international standards exist or risk assessments have already been performed elsewhere.

Scientific evidence is deemed to be insufficient when 'the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under article 5(1) SPS'.²⁵ In the Biotech case the panel interpreted the adequacy such that the risk assessment must be adequate to Annex A(4) SPS and not to a state's chosen level of protection, and apparently falls short of the Appellate Body's ruling because it specified in its review that scientific evidence is insufficient when it does not lead to 'reliable and conclusive results'.²⁶ Reliability and conclusiveness now are characteristics of scientific evidence in relation to the values of a particular state in a particular regulatory context,²⁷ embodied in its level of protection. This level of protection informs risk assessment such that the sufficiency of scientific evidence depends on the intended protection because 'the more vital or important interests or values pursued, the easier it would be to accept as "necessary" measures to achieve those ends.'²⁸

The panel however rejected any relativity of risk assessment to risks socially framed. A risk assessment once performed becomes then applicable to any member state. The risk assessment does not cease to be a risk assessment within the meaning of Annex A(4) SPS merely because a state judges that the risks have not been assessed with the necessary degree of precision.²⁹ In other words, the body of scientific evidence is considered to be sufficient for the performance of an adequate risk assessment when any assessment of the risk concerned has been performed. After such a performance article 5(7) SPS is no longer applicable. In the Biotech case the Member States of the European Union could thus not claim insufficiency of scientific evidence because the EC Scientific Committee on Plants was able to perform a risk assessment.³⁰

Against the background of the importance of levels of protection for the performance of a risk assessment the panel's reasoning is little convincing. The results of a risk assessment are not equivalent to sufficient evidence, in particular not for the performance of a risk assessment framed by a higher level of protection. Hence, what might be sufficient evidence for one

²² Pauwelyn (2002), p.347.

²³ WT/DS26/AB/R, WT/DS48/AB/R *EC – Measures concerning Meat and Meat Products (Hormones)* (1998), paras 198-201.

²⁴ Pauwelyn (2002), p.355.

²⁵ WT/DS245/AB/R *Japan – Measures affecting the Importation of Apples* (2005), para 179.

²⁶ WT/DS245/AB/R *Japan – Measures affecting the Importation of Apples* (2005), para 185.

²⁷ Winickoff (2005), p.113.

²⁸ WT/DS26/AB/R, WT/DS48/AB/R *EC – Measures concerning Meat and Meat Products (Hormones)* (1998), para 182.

²⁹ WT/DS291/R, WT/DS292/R, WT/DS293/R *EC – Measures affecting the Approval and Marketing of Biotech Products* (2006), para 7.3240.

³⁰ Eliason (2008), p.405; Gruszczinsky (2008), p.25.

scientist might be insufficient for another.³¹ For the panel however the reservations of some scientists with respect to the performance of an adequate risk assessment have been wiped out by scientists of the EC Scientific Committee on Plants. That is, the scientific evaluations of the body of evidence from contradicting experts have not been reasoned to be unreliable or inconclusive but have been simply discarded given the performed risk assessment. Such an interference with science is unprecedented in panels' rulings and obviously beyond their task, because the purpose of the SPS Agreement is the elimination of measures restricting trade which are not based on scientific evidence, and not to impose one uniform view of science on states.³²

The panels remain reluctant to accept counter-evidence to the evidence of established risk assessments. For the panels singular evaluations do not do the job. Rather a critical mass of new evidence shall be necessary to render previous scientific evidence no longer sufficient to perform a risk assessment.³³ Again, this ruling has been too narrow for the Appellate Body who ruled that instead of a paradigm shift in science any evidence which casts the sufficiency of the existing body of evidence into doubt should be sufficient.³⁴ Hence, had the European Union appealed the findings of the panel in the Biotech case, very likely they would have been reversed and article 5(7) SPS found to be applicable.

The panels' approach leaves only scope for protective measures under article 5(1) SPS based on the choice of acceptable level of risk. This scope is fenced in by the probability and inherent uncertainties of a risk assessment.³⁵ The higher the probability of a risk's entry, or the higher the uncertainties inherent in a risk assessment the more room for manoeuvres states have to determine their acceptable level of risk. Whereas probabilities refer to known risks, uncertainties refer to unknown risks. A known risk is a risk as it is expressly framed, an unknown risk epitomises the framing's deficiencies. The uncertainty of a risk assessment expresses the confidence in the assessment – or the lack of it.

Uncertainty should not be equated with insufficiency of evidence: The 'existence of unknown and uncertain elements'³⁶ does not justify a departure from article 5(1) SPS. On the other hand does sufficient evidence to conduct a risk assessment not mean 'free from uncertainties',³⁷ for example uncertainties linked to assumptions made in the course of a risk assessment. In view of these uncertainties a given risk assessment may arguably support a range of protective measures: "If there are factors which affect scientists' level of confidence in a risk assessment, this may be taken into account by a Member in determining the measure for achieving its appropriate level of protection."³⁸

Six types of uncertainties have been classified.³⁹ Some of them are highly sophisticated and play to any degree with the idea that the world could be very different from our scientific conception of it. For example may factors hidden to mankind mask causal action. Against the

³¹ Gruszczinsky (2008), p.22.

³² Gruszczinsky (2008), p.25.

³³ WT/DS320/R US – *Continued Suspension of Obligations in the EC-Hormones Dispute* (2008), para 7.648.

³⁴ WT/DS320/AB/R US – *Continued Suspension of Obligations in the EC-Hormones Dispute* (2008), para 705.

³⁵ Hansson (2006), p.231.

³⁶ WT/DS26/AB/R, WT/DS48/AB/R EC – *Measures concerning Meat and Meat Products (Hormones)* (1998), para 194.

³⁷ WT/DS291/R, WT/DS292/R, WT/DS293/R EC – *Measures affecting the Approval and Marketing of Biotech Products* (2006), para 7.1525.

³⁸ WT/DS291/R, WT/DS292/R, WT/DS293/R EC – *Measures affecting the Approval and Marketing of Biotech Products* (2006), para 7.3240.

³⁹ Walker (1990), p.572.

concept of a closed causal system which is ‘completely understood’, the decision of ‘what level of causal uncertainty is acceptable’⁴⁰ sounds rather miraculous, for how should one determine under such circumstances a level of acceptability which is not doomed to be arbitrary? And how can one under the epistemic uncertainty ascertain that the evidence based medicine is the true protector of health and not the doctrines of Chinese medicine? No one would doubt that scientists can never eliminate all these uncertainties altogether.⁴¹ The Appellate Body freely concedes that science never provides absolute certainties, and in the same line it makes clear that such ‘theoretical uncertainties’ are not the kind of risk to be assessed under article 5(1) SPS.⁴²

Uncertainties pertaining to a risk assessment are uncertainties that go beyond qualitative statements of confidence in the result of an assessment.⁴³ These relevant uncertainties adhere to the concepts, methods and models employed in a risk assessment. They are revealed in scientific analyses of a risk assessment and relate for example to its statistical adequacy or predictive reliability.⁴⁴

3 Outline for a risk framework under the SPS Agreement

To sum up: In order to achieve a coherent and functional framework for justified health protecting measures under the SPS Agreement it is neither necessary to debunk the myth of science as a neutral arbiter,⁴⁵ nor to reconcile legal logic with scientific logic.⁴⁶ Although science may be exploited for protectionist purposes, the scientists’ codex of independency, transparency and universality⁴⁷ is nowhere else comparably established than in science itself, which is why law’s legitimacy is grounded in its quasi-scientific character.⁴⁸ What instead is required is the scientific framing of levels of protection. The scientific framing includes clear and precise assessment endpoints and thus allows developing an adequate risk assessment which suffices the depth and precision of the framed level of protection. The more scientific the level of protection is framed, the easier is the determination of whether a given body of scientific evidence is sufficient to conduct a risk assessment. Only after a risk assessment has been conducted a state must determine its level of acceptable risk, a determination which is restricted by a reasonable weighing of the actual risk and the negative effects of protective measures on trade under article 5(4) SPS.

Is a level of protection determined which is higher than the one ensured by international standards one has to check whether a risk assessment pertaining to this level has already been performed. If this is the case article 5(1) SPS applies. Does the resulting likelihood of a risk’s entry not justify the desired measures of protection, the state may conduct its own risk assessment and challenge or replace the other assessment, or it may challenge the assessment by scientific concerns with regard to its validity or reliability. The first challenge doubts the probability; the second reveals implicit uncertainties of the already performed risk assessment.

⁴⁰ Walker (2003), p.211.

⁴¹ Walker (2003), p.203.

⁴² WT/DS26/AB/R, WT/DS48/AB/R *EC – Measures concerning Meat and Meat Products (Hormones)* (1998), para 186.

⁴³ Hoffman (1994), p.707.

⁴⁴ Mayo (2006), p.806.

⁴⁵ Arcuri (2005), p.36.

⁴⁶ Eliason (2008), p.389.

⁴⁷ FAO/WHO (2006), p.22.

⁴⁸ Shaffer (2008), p.8.

If an adequate risk assessment has not yet been performed, then the question of the sufficiency of scientific evidence to do so arises. In this case one might argue that a state always can determine a level of protection that high that the scientific evidence for an adequate risk assessment is insufficient and article 5(7) SPS applies. This objection is legitimate. However, the application of article 5(7) SPS has its price. Measures under article 5(7) SPS are only provisional and the state is obliged to gather further evidence which allows for a more objective risk assessment. Hence, depending on the level of protection the reliance on article 5(7) SPS may add up to a considerable investment in science and thus steadily improve the available risk knowledge. Moreover, the scientifically framed level of protection determines a threshold of sufficiency for scientific evidence. And with the growing body of scientific evidence an adequate risk assessment becomes finally inevitable.

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