

# **Politicisation of Science in the Process of Dealing with Manufactured Risk**

An Interdisciplinary Case Study

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# 1. Introduction

The irony of [manufactured] risk here is that rationality, that is, the experience of the past, encourages anticipation of the wrong kind of risk, the one we believe we can calculate and control, whereas the disaster arises from what we do not know and cannot calculate.

U. Beck, 2006, p. 330

A key feature of modern society is the emergence of new characteristics of risks, which have been conceptualized by U. Beck as 'manufactured risk'.<sup>1</sup> Whereas in the past, risks principally consisted of natural hazards, which were limited in both time and space, manufactured risks are man-made, have a global effect, are potentially catastrophic, and can only be assessed speculatively. The global dimension of these risks has rendered apparent the latent divergence in the conceptions of risks that exist among different nations and regulatory regimes, thus resulting in tensions at and between national, regional, and international levels.

One of the entities where these conflicts are most visible is the World Trade Organisation's (WTO) dispute settlement body, which has recently been faced with several cases relating to manufactured risk.<sup>2</sup> In these situations, and partially due to the WTO's need to legitimize its going beyond national sovereignty, science has gained paramount importance in providing for a neutral and objective international normative yardstick for decision-making.<sup>3</sup> Indeed, such function of science is exemplified in the *WTO Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement), which indicates that, in order to leave to Member States their discretion to set the levels of protection, the WTO only 'disciplines' the existing risk assessments, thus ensuring that the risk regulations are appropriately based on science. In this respect, a clear-cut distinction

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1 Ulrich Beck, *Risk Society: Towards a New Modernity* (SAGE Publications 1992).

2 WTO, *European Communities - Measures Concerning Meat and Meat Products (Hormones)* (13 February 1998) WT/DS26/AB/R, WT/DS48/AB/R; WTO, *European Communities - Measures Affecting the Approval and Marketing of Biotech Products (EC-Biotech)* (21 November 2006) WT/DS291, 292, 293/R.

3 Jacqueline Peel, 'Risk Regulation Under the WTO SPS Agreement: Science as an International Normative Yardstick' (2004) Jean Monnet Working Paper 02/04 <http://www.jeanmonnetprogram.org/archive/papers/04/040201.pdf> accessed 20 May 2014.

is made between risk assessment, which provides for objectivity and authority, and risk management, which is expected to appropriately respond with policy decisions.<sup>4</sup>

The undisputed reliance on science, in case of manufactured risk, is problematic concerning two central aspects. Firstly, 'risk' is still mainly conceptualised according to the traditional theory, which states that risk can be managed by rationally evaluating the probability of its occurrence and measuring it against the extent of the harm that might be caused by a disaster.<sup>5</sup> However, due to the speculative characteristic of manufactured risk, no historical data exist regarding the probability, the form, or even the existence of these risks. As these aspects can only be evaluated retrospectively, a mere positivistic<sup>6</sup> description of what manufactured risk consists of is drastically jeopardised. Secondly, the way science is being used as an 'internationally yardstick' fails to acknowledge and problematize the ways science may be politicised, thus potentially leading to a misuse of scientific knowledge when dealing with manufactured risk.

Consequently, this paper will investigate some potential effects of the current use of science with regard to manufactured risk. To start with, the WTO's approach towards science and its limiting definition of risk, appears not only incomplete vis-à-vis emerging forms of risk, but also ignores the practical inability of science to be used as a decisive tool in dispute settlement. Subsequently, the demeanour of displaying scientific knowledge as complete, unequivocal, and authoritative as well as disregarding the existence of various forms of uncertainty results in a *de facto* impediment of Member States' freedom to "determine their own appropriate level of sanitary protection".<sup>7</sup>

Therefore, this paper will empirically analyse how scientific knowledge is being politicised in the process of dealing with manufactured risks. For this purpose, the interdisciplinary analysis of a case concerning the selected genetically modified organism

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4 This is particularly visible in the objective of the SPS Agreement as interpreted by the at the WTO website "[...] the SPS Agreement allows countries to set their own food safety and animal and plant health standards. At the same time, however, the SPS Agreement requires that such regulations be based on science [...]" [http://www.wto.org/english/tratop\\_e/spse/spse\\_agreement\\_cbt\\_e/c151p1\\_e.htm](http://www.wto.org/english/tratop_e/spse/spse_agreement_cbt_e/c151p1_e.htm) accessed 14 May 2014.

5 Marjolein van Asselt, Ellen Vos, Bram Rooijackers, 'Science, knowledge and uncertainty in EU risk regulation' in Michelle Everson and Ellen Vos (eds), *Uncertain risks regulated* (Taylor & Francis 2009).

6 For sake of clarity, all further use of the term 'positive' or 'positively' will be in accordance with the meaning of "Consisting in or characterized by the presence rather than the absence of distinguishing features." Oxford Dictionaries <<http://www.oxforddictionaries.com/definition/english/positive>> accessed 13 June 2014.

7 Panel Report, *Hormones* (n2) 172.

(GMO), Bt-176,<sup>8</sup> will be presented. This specific GMO was banned in Germany, Austria, and Luxembourg, accepted by the European Communities (EC, now: European Union),<sup>9</sup> and assessed in the WTO Dispute Settlement on the *Measures Affecting the Approval and Marketing of Biotech Products (EC-Biotech)*.<sup>10</sup>

On this basis, the authors will, in the first part, propose a conceptual framework significant in evaluating how the relevant authorities at the national, EU, and WTO levels approach scientific knowledge when dealing with manufactured risks. In the following section, the paper will analyse the various facets on which the scientific evidence presented by Member States and the EC agencies conflict. Finally, the way the WTO Panel 'disciplined' the risk assessments, according to applicable law, will be investigated. Based on the analysis of the *EC- Biotech* case, diverging manners by which science is being politicised will be identified. In particular, the paper will investigate how different types of uncertainty are being ignored or disregarded, thus ultimately leading to the limitation of available evidence on which Member States can base their safeguard measures.

In conclusion, the argument substantiated in this paper is that, due to the characteristics of manufactured risk and the inherent politicisation of science, under no circumstances should science be used as the most important normative yardstick in the WTO decision-making process. Additionally, this paper claims that in order to appropriately deal with manufactured risk and its speculative characteristic, scientific risk assessment should not only attempt to positively assess the risk, but as well attribute a major importance to all identified forms of uncertainty.

## 2. Conceptual Framework

### 2.1 Manufactured Risk

It is useful to recall that 'risk' is not a natural category, but a concept that has been contingently defined to render a given reality intelligible. In this context, the definition of risk, and what it refers to, varies greatly. As the literature on risk perception demonstrates, the term 'risk' is composed by numerous factors that complexly interact and differ from

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8 ID-Number: SYN-EV176-9 < <http://www.gmo-compass.org/eng/gmo/db/51.docu.html> > accessed 20 May 2014.

9 In the following of the paper, the authors will use the term European Communities (EC) having regard to the historical context which took place before entry into force of the Lisbon Treaty.

10 Panel Report, *EC-Biotech* (n2).

one culture to another.<sup>11</sup> Consequently, the way 'risk' is defined, sets the relevant criteria in the governance of risk, thus having great repercussions on the perceptions of risk as well as on the manner it is being dealt with.

Historically, the concept of risk seems to have made its first appearance, in the western world, with reference to the danger of sailing in uncharted waters and the cost of potential loss of shipments.<sup>12</sup> However, it is only in the 19<sup>th</sup> century, that the term 'risk' became dominant over the notion of 'hazard', and its usage in the English literature has boomed since the 1960s.



Figure 1 Risk & Hazard (source: Google Ngram<sup>13</sup>)

The German sociologist U. Beck, in his influential book *Risk Society: Towards a New Modernity*, explained the change that took place in the 19<sup>th</sup> century by referring to the enlightenment and the industrial revolution.<sup>14</sup> In that time, science progressively gained a central role in western societies and, with the development of statistics, was able to introduce a rational definition of hazard, stripping away its randomness and relation to fate. In this context, the new usage of the term 'risk', referred to the quantifiable identification of the probability of a harmful event to occur. Such calculative interpretation of risk was accordingly conducted through probabilities, mathematic principles, and predominantly based on statistical data within the economic paradigm.<sup>15</sup> This way of

11 sk: A -Trust

12 Asselt, 'Perspectives on Uncertainty and Risk: The PRIMA approach to decision-support' (PhD thesis, Maastricht University 2000).

13 Results based on keyword search for 'risk' and 'hazard' using Google Ngram viewer.

14 Beck (n1).

15 Gabe Mythen, *Ulrich Beck : A Critical Introduction to the Risk Society* (Pluto Press 2004).



treating risk appeared to be greatly useful when dealing with risk that could be statistically documented and for which insurances could compensate the losses.

However, in the second part of the 20<sup>th</sup> century, and consistently with the increased use of the term 'risk' (*cf.* figure 1), Beck identified an emerging kind of risk – *viz.* 'manufactured risk'.<sup>16</sup> This type of risk arises from unforeseen implications of the growing role of technology in society and of the human design on the natural world. In contrast to natural hazards, manufactured risks are man-made, illimitable in time and space, potentially catastrophic,<sup>17</sup> and speculative.<sup>18</sup> By speculative, Giddens refers to the fact that, despite extensive scientific knowledge, uncertainties might persist with regard to whether these risks actually exist, as well as the exact form they could take or the way to calculate them.<sup>19</sup> In this regard, scientific expertise holds an unsettled role. On the one hand, many manufactured risks transcend our sensory capacities and, as such, require the help of science to render such risks manageable. On the other hand, the uncertainties caused by the futurity of the risk and its incalculability cannot be simply dispelled by yet further scientific advance.<sup>20</sup>

The authors argue that, the concept of manufactured risk is useful to grasp some of the empirical characteristics of risk relating to genetically modified organisms, and improve the quality of regulatory decisions on such kind of risk.<sup>21</sup> Firstly, GMOs are the results of scientific and technological development, and the willingness to impose the human design upon nature.<sup>22</sup> Secondly, once released in nature they become impossible

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16 While Beck argued for an ontological distinction between manufactured risk and natural hazard, the authors do not believe in such clear-cut division. Instead 'manufactured risk' is used as a useful concept to highlight the complexity and diverging characteristics of modern risks.

17 Corinne Wales and Gabe Mythen, 'Risky Discourses: The Politics of GM Foods' (2010) 11 *Environmental Politics* 121, 124.

18 Giddens (n12).

19 *ibid.*

20 van Asselt, Vos and Rooijackers (n5).

21 Certain authors such as Andreas Klinke & Ortwin Renn propose up to seven different types of risk with specific policy advice on how to deal with each of them. However, in the scope of this paper, the aim is not to render the category of 'manufactured risk' a recognised tool for policy making but merely to point at certain aspect of modern risk, which are usually overlooked in the process of risk regulation. For this purpose we find the characteristics of 'manufactured risk' more extensive than the ones presented by Klinke & Renn. See: Andreas Klinke and Ortwin Renn, 'A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies' (2002) 22 *Risk Analysis* 1071.

22 Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press 2005).

to be retrieved to the laboratory, as the manufactured risk does not disappear after the harvest. Thirdly, GMOs are traded and cultivated worldwide, thus, in case harmful effects were to be detected, the extent of the damage would be global and unlimited in time. Finally, the risk related to GMOs remains speculative and hence, the ability of science and technology to deal with them is severely impeded. Consequently, the following parts of the paper will be concerned with framing and identifying the issues arising from current perceptions of risk when dealing with manufactured risk.

## 2.2 Precaution and Types of Uncertainty

The emergence of the widely debated precautionary principle, in the last quarter of the 20<sup>th</sup> century in Europe, can be indirectly considered as an attempt to respond to manufactured risks. Indeed, in the light of their speculative nature, the lack of historical experience and of consensus on the relevant criteria to be assessed, the uncertainties surrounding the potential risk need to be addressed.<sup>23</sup> In this regard, it does not come as a surprise that the current literature on risk governance and the precautionary principle refers to 'uncertainty' as a central aspect for the establishment of precautionary measures.<sup>24</sup> However, the notion of 'uncertainty' is a broad concept that contains diverse meanings. In this respect, a meta-analysis of the various uses of the term 'uncertainty' allows the authors to distinguish four types of uncertainty.

The first, and most criticized, type of uncertainty consists of what has been referred to as the Knightian conceptualization of uncertainty.<sup>25</sup> Knight was an economist that perceived uncertainty as being clearly distinguishable from risk. From this perspective, uncertainty only amounts to a temporary lack of data that disables risk to be assessed. Once the scientific evidence is sufficient, the uncertainty is resolved. Consequently, precautionary measures can only be taken if it is proven that the current body of scientific knowledge clearly lacks some information. In such case, precautionary measures apply for

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23 Additionally, as great amount of the social science literature on the subject pointed out, the process of risk assessment should include social scientists and even the participation of the citizens. Indeed, since 'risk' is not a natural category but a social one, it is of prime relevance that all the stakeholders can adequately be represented in the definition of 'risk'. See for example: Brian Wynne, *Rationality and ritual: Participation and exclusion in nuclear decision-making* (Routledge 2013).

24 See: Everson and Vos (n5); Sylvia Noble Tesh, *Uncertain Hazards: Environmental Activists and Scientific Proof* (Cornell University Press 2001); Elizabeth C Fisher, Judith S Jones and René von Schomberg, *Implementing the Precautionary Principle: Perspectives and Prospects* (Edward Elgar Publishing 2006).

25 van Asselt, Vos and Rooijackers (n5); Ellen Vos and Marjolein van Asselt, 'The Precautionary Principle and the Uncertainty Paradox' (2006) 9 *Journal of Risk Research* 313.

a restricted period during which additional scientific evidence should be collected and the uncertainty cleared up.

The second type of uncertainty is derived from the Science, Technology & Society (STS) literature.<sup>26</sup> In this context, uncertainty is, *inter alia*, perceived as a lack of consensus among the scientific community. In reality, scientific practice bases itself on collected data, among which specific information will be selected in order to develop, through different strategies and methodologies, new theories. This complex process generally results in disagreement within the scientific community as to which data are relevant and how should they be interpreted. These disputes may persevere but will typically reach a consensus (also referred as 'closure'). Such consensus is generally not the result of the gathering of new scientific evidence, but of a complex process in which relevant actors, come to interactively construct common definitions and meanings.

The third type of uncertainty, 'system complexity', is a general tenet of ecological science,<sup>27</sup> and is particularly problematized by C. Perrow in *Normal Accidents*.<sup>28</sup> In essence, Perrow argues that, in systems which are both 'complex' and 'tightly' coupled, inherent and irreducible risk will persist. Indeed, the complexity of a system implies that, due to the multiplicity and the entanglement of the interactions between components, uncertainty will always remain. Nuclear energy or DNA changes are examples of such tight and complex systems – in such cases, the uncertainty is inherent to the physical properties of the system.<sup>29</sup> Moreover, ecological science advocates for a perspective recognising the complexity of the interactions between the components, whereas mainstream laboratory science, which attempts to identify the causal relation between components, tends to decontextualize them from the environment they would naturally evolve in.<sup>30</sup>

The fourth, and final, kind of uncertainty is tightly related to the second one, but instead focuses on uncertainty as an inherent and irreducible part of scientific practice. Due to various aspects intrinsic to the practice of science, such as the clash of scientific

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26 Bruno Latour, *Politics of Nature: How to Bring the Sciences into Democracy* (Harvard University Press 2004); Lawrence Busch, Robin Grove-White, Sheila Jasanoff and others, *Amicus Curiae Brief. Submitted to the Dispute Settlement Panel of the World Trade Organization in the Case of EC Measures Affecting the Approval and Marketing of Bio-tech Products* (2004). <<http://are.berkeley.edu/courses/EEP131/fall2007/WinikoffGMO.pdf>> accessed 14 May 2014.

27 Hugh Lacey, *Values and Objectivity in Science: The Current Controversy about Transgenic Crops* (Lexington Books 2005).

28 Charles Perrow, *Normal Accidents: Living with High Risk Technologies* (Princeton University Press 2011).

29 *ibid.*

30 Lacey (n27).

paradigms, and the fact that scientific knowledge is often noncumulative, uncertainty, with higher or lesser degree, cannot be eradicated.<sup>31</sup> However, such uncertainty is not necessarily negative as, for instance, various scientific paradigms may represent an increased array of perspectives and assist decision makers. On the other hand, the existence of this type of uncertainty undermines the possibility for the body of scientific knowledge to speak with one authoritative voice.

It is relevant to emphasise that all these types of uncertainty are not mutually exclusive. On the contrary, the authors believe that the assessment of manufactured risk should explicitly address an array of different types of uncertainty. Additionally, a distinction between, on the one hand, the kinds of uncertainty that can be dealt with (type one and two), and the ones that are irreducible and inherent (three and four), is observable. Lastly, one can notice that some types of uncertainty account for ontological characteristics while others are related to the practice of science itself (i.e. to epistemological characteristics). In general, epistemological types of uncertainty should not necessarily be equated with risk. For instance, while uncertainty as conflicting scientific perspectives does not allow scientific knowledge to authoritatively speak with one voice, it remains a beneficial kind of uncertainty as it presents differing angles on a risk.

Uncertainty that can be dealt with	Uncertainty as a lack of data (Knight, 1921) 1.	Uncertainty as a lack of consensus/closure (latour, 2004; Busch et al, 2004) 2.
Inherent and irreducible uncertainty	3. Uncertainty as system complexity (Perrow, 1984) Ontological	4. Uncertainty as conflicting scientific perspectives (van Asselt & Vos, 2007) Epistemological

Figure 2 Types of uncertainty (source: authors)

31 See: Harry M Collins and Trevor Pinch, *The Golem: What You Should Know About Science* (Cambridge University Press 2012); Thomas Kuhn, *The Structure of Scientific Revolutions* (University of Chicago Press 1962); van Asselt (n12).

### 2.3 Risk Assessment, Risk Management, and the Politicisation of Science

After the relevance of assessing uncertainties in the process of dealing with manufactured risk has been considered, it is pertinent to examine the mechanism put in place to regulate risks at the WTO level. The current approach pre-establishes a clear-cut distinction between the assessment of risk and its management. Indeed, “[...] the SPS Agreement allows countries to set their own food safety and animal and plant health standards. At the same time, however, the SPS Agreement requires that such regulations be based on science [...]”.<sup>32</sup> This model of risk governance, known as the ‘red book model’, reasserts the divide between politics, pertaining to the realm of human world and its subjectivity, and science, which focuses on the discovery of the ‘natural’ world and the unveiling of ‘facts’.<sup>33</sup> This structure, which apparently shields the process of risk assessment from the ‘values’ present in the risk management, is conducted with the assumption that ‘good’ science is on nobody’s side.<sup>34</sup>

However, as pointed out by B. Latour in his book *Politics of Nature*, the distinction between risk assessment and risk management, or between ‘facts’ and ‘values’, is highly problematic.<sup>35</sup> The notion of ‘fact’ is principally troublesome, as it is believed to refer to a closed category of undividable elements, whereas, in reality ‘facts’ are the *result* of scientific practice. The construction of ‘facts’ requires, on the one hand, data to be obtained, and on the other, their arrangement into a meaningful structure. In the process of data gathering, both advanced tools (e.g. cutting-edge technologies, expensive laboratories, etc.) and selected methodologies are essential. Once data is collected, a careful selection of significant information takes place.<sup>36</sup> In this respect, the production of preliminary data is the result of complex networks composed of both, human (scientists, engineer, etc.) and non-humans actors (technologies, laboratory, field trials, etc.). Important to add that the notion of ‘fact’ also ignores the view that isolated facts have neither significance nor

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32 WTO, ‘Introduction to the SPS Agreement’ <[http://www.wto.org/english/tratop\\_e/spse/spse\\_agreement\\_cbt\\_e/c151p1\\_e.htm](http://www.wto.org/english/tratop_e/spse/spse_agreement_cbt_e/c151p1_e.htm)> accessed 14 May 2014.

33 Erik Millstone, ‘Science and decision-making: Can we both distinguish and reconcile science and politics?’ in Marjolein van Asselt, Ellen Vos and Michelle Everson (eds), *Trade, Health and the Environment: The European Union Put to the Test* (Routledge 2013).

34 *ibid.*

35 Latour (n26). In *Politics of Nature*, B. Latour does not use the terminology of ‘risk assessment’ and ‘risk management’ but rather of ‘facts’ and ‘values’, however the authors believe that the reasoning remains extremely pertinent.

36 For e.g. data might be disregarded on the basis, that it has been contaminated by external factors, or that it provides for no significance in the context of the research.

meaning as long as they are detached from a theoretical framework which is used to put some of these facts together and tie them in a coherent scientific structure.

Values, on the other hand, have the unprivileged position of being considered only after the 'facts' have been established and disclosed. This is caused by the perception that the process of debating values, being a highly subjective endeavour, requires in the first place, to be factually informed. Thus, this artificial divide, which positions values in an unfavourable position, may trigger certain endorsed values to be clandestinely included in the supposedly objective world of things (*i.e.* of 'facts').<sup>37</sup> In the practical world of risk governance, this may result in the inclusion of value judgements in the factual scientific assessment of risk. With time, this artificially strong distinction between the 'facts' and the 'values', between risk assessment and risk management, between experts and risk regulators, will become more and more of a blurred entanglement.

This entanglement is particularly visible in cases of manufactured risk, as, on the one hand, scientific practice cannot provide for authoritative knowledge and, on the other hand, decision makers wish to use scientific knowledge to secure public trust<sup>38</sup> or to legitimise their decisions. This process has been referred to, by M. Everson & E. Vos, as 'the scientification of politics and the politicisation of science'.<sup>39</sup> In this context, and in the light of manufactured risk, different forms of politicisation of science can be identified, among which two are particularly relevant for our case study.

Firstly, science can be politicised through the claim that risk is a 'natural category' and, as such, can only be adequately defined by experts. However, with regard to manufactured risk, scientific knowledge is not in a position to take such stance. Secondly, science can be politicised by limiting the body of recognised scientific evidence. Once the amount of scientific evidence is restricted, a specific interpretation of the data can be claimed to be authoritative and unequivocal.

M. van Asselt and E. Vos identified the attitude of 'uncertainty intolerance' as one of the means through which evidence is being reduced.<sup>40</sup> 'Uncertainty intolerance' refers to the attitude of risk assessors to silence the existence of uncertainties in their risk assessment and/or of risk managers to demand risk assessors to provide them with authoritative

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37 Latour (n26).

38 Michelle Everson and Ellen Vos 'The Scientification of Politics and the Politicisation of Science' in Everson and Vos (eds) (n5).

39 *ibid.*

40 Marjolein van Asselt and Ellen Vos, 'Wrestling with uncertain risks: EU regulation of GMOs and the uncertainty paradox' (2008) 11 *Journal of Risk Research* 281.

answers that may predetermine a specific regulatory outcome.<sup>41</sup> In the context of the current analysis of manufactured risk, the term ‘uncertainty intolerance’ refers specifically to situations when particular kinds of uncertainty are being disregarded by risk assessors or decision makers. Once the scientific evidence has been politicised, the scientification of politics generally follows in the form of impeding on the discretion of Member States to set their levels of protection.

### 3. EC Biotech & Bt-176

In order to assess the politicisation of science when dealing with manufactured risks and uncertainty on a global scale, the *EC-Biotech* case and the dispute concerning the authorization of the GMO Bt-176 maize is significant. The objections brought forward by Canada, Argentina and the United States against the implementation of safeguard measures by the EC Member States reveal the difficulties arising due to the characteristics of manufactured risks. Therefore, it is an essential part of this paper to set the approach of the complaining countries in context with the arguments of the Member States, the evaluation of the Panel, and the defence of the EC.<sup>42</sup>

The various approaches of how modern manufactured risks, as exemplified by Bt-176, and the inherent uncertainty, have been coped with and valued on the national and international levels will be examined. Furthermore, in this case, science had a paramount importance for the WTO Panel to assess whether Member States’ sanitary and phytosanitary measures were appropriately based on an assessment of risk.

In particular, as laid down in the Panel report,<sup>43</sup> the complaints mainly concerned two matters. To begin with, the EC’s approval procedure for GMO products was claimed to be unfairly constructed, putting the complaining countries’ exported products at a disadvantage. Furthermore, safeguard measures maintained by Germany, Austria, and Luxembourg, which imposed marketing restrictions on GM products, were objected as allegedly violating EC’s international trade commitments, such as the SPS Agreement.<sup>44</sup>

This paper will focus on this second complaint relating to the safeguard measures established by the EC Member States. Due to the fact that the EC scientific agencies

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41 *ibid.*

42 In the *EC-Biotech* case, the EC acted on behalf of its Member States.

43 Panel Report *EC-Biotech*, para. 2.1.

44 Panel Report *EC-Biotech*, paras. 3.2(a) (United States); 3.4(a) (Canada); 3.6(a) (Argentina).

conducted risk assessments for the products in question and approved them as being safe, the complainants argued that the bans of the Member States could not be sufficiently based on scientific evidence, even though, these safeguard measures were based on scientific studies as well.<sup>45</sup>

As a result, in November 2006, the Panel adopted its decision in the *EC-Biotech* case, ruling in favour of the complaining countries.<sup>46</sup> The WTO Panel found that the safeguard measures applied by Member States constituted an SPS measure,<sup>47</sup> however, they were not based on a risk assessment in the sense of Article 5.1 of the SPS Agreement.<sup>48</sup> Furthermore, the Panel established that Member States failed to comply with the requirements laid down in Article 5.7 to implement precautionary measures.<sup>49</sup> Thus, the EC did not fulfil its obligations under Article 2.2 and 5.5 of the Agreement.<sup>50</sup>

In order to set the framework for the subsequent analysis, a factual description of the Bt-176 maize and its authorization procedure in the EC will be presented in the following section. As already assessed in the conceptual introduction, GMOs, including Bt-176 maize, exemplify the difficulties arising when dealing with manufactured risks since these can only be assessed speculatively. This specific GMO was banned in Germany, Austria and Luxembourg, accepted by the European Communities, and finally assessed by the WTO Dispute Settlement Body in the *EC-Biotech* case. Accordingly, the analysis of Bt-176 maize exemplifies the way science is being politicised in the process of dealing with manufactured risk.

Bt stands for *Bacillus thuringiensis*, a soil bacterium which produces proteins harming specific insect species.<sup>51</sup> Responsible for the production of those proteins is among others the gene CrtAb. By inserting it into the DNA of maize plants, the manufacturer confers to the plant a built-in resistance against harmful insect attacks. Bt-176 targets specifically the European corn borer, a crop pest that frequently causes damages to maize in Europe and North America. By cultivating Bt-176, instead of traditional maize plants, significant economic losses in the agricultural sector could allegedly be prevented.

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45 Panel Report *EC-Biotech*, paras. 8.9; 8.10.

46 Gregory Shaffer, 'A Structural Theory of WTO Dispute Settlement: Why Institutional Choice Lies at the Center of the GMO Case' (2008) 41 *New York University Journal of International Law and Politics* 1, 32.

47 Panel Report *EC-Biotech*, para. 4.155.

48 Panel Report *EC-Biotech*, para. 4.172.

49 Panel Report *EC-Biotech*, para. 8.9

50 Panel Report *EC-Biotech*, paras. 4.175.; 4.176.

51 <<http://www2.ca.uky.edu/entomology/entfacts/ef130.asp>> accessed 12 June 2014.



Bt-176 was developed by the Swiss pharmaceutical company Ciba Geigy,<sup>52</sup> which in 1994 applied for a market approval for the product in France. French authorities invoked Article 5.6 of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms,<sup>53</sup> and forwarded the application to the European Commission including a favourable dossier for Bt-176. The dossier was subsequently sent to the Member States' competent authorities, several of which raised safety concerns regarding the product. Accordingly, pursuant to Article 21 of the Directive, the case was transferred to a committee composed of Member States' representatives and chaired by the Commission, where the latter presented a draft decision which had to be adopted by a majority vote. As the committee failed to come to an agreement, the proposal was further submitted to the Council of Ministers, where again a majority vote had to be obtained for the product to be authorized. However, as the Council failed to meet a deadline, the final decision<sup>54</sup> was taken by the Commission.

The Commission requested the Scientific Committee on Animal Nutrition (SCAN), the Scientific Committee on Pesticides (SCPE), and the Scientific Committee on Food (SCF) for an opinion on this subject matter. In 1996, the respective agencies submitted their risk assessments, stating that the Bt-176 could be considered as equally safe when compared to non-GM maize products.<sup>55</sup> Following this assessment, in January 1997, the European Commission authorized the cultivation and marketing of Bt-176 maize in the EU. Shortly after, the French authorities also granted the final approval.

In the same year, Austria and Luxembourg invoked Article 16 of Directive on the Deliberate Release of GMOs, which allows Member States to take provisional restrictive measures regarding products approved by the Commission, provided that there are justifiable reasons to assume that such product poses a risk to human health or the

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52 Ciba Geigy in 1996 merged with its competitor, Sandoz, to start a new company - Novartis. In 1999, Novartis and AstraZeneca outsourced their agricultural branches which together formed Syngenta which is now registered by the European Commission as the producer of Bt176.

53 It has later been replaced by Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

54 Tamara K Hervey, 'Regulation of genetically modified products in a multi-level system of governance: science or citizens?' (2001) 10 *Review of European Community & International Environmental Law* 321, 322

55 SCAN, *Report of the Scientific Committee for Animal Nutrition on the Safety for Animals of Certain Genetically Modified Maize Line Notified by Ciba-Geigy in Accordance with Directive 90/220/EEC for Feeding Stuff Use* (1996); SCF, *Opinion on the Potential for Adverse Health Effects from the Consumption of Genetically Modified Maize (Zea Mays L)* (1996); SCPE, *Opinion of the Scientific Committee for Pesticides on the Use of Genetically Modified Maize Lines Notified by Ciba -Geigy* (1996).

environment. In April 2000, Germany followed this example. The countries justified their measures by expressing concerns about the safety of gene maize and the scientific uncertainties which, in their view, had not been resolved in the risk assessments.<sup>56</sup> The European expert bodies after examining the reasoning brought forward by Austria, Germany, and Luxembourg concluded that their scientific findings had already been considered in the initial risk assessments, and that no new relevant data had been submitted since.<sup>57</sup> The authorization of Bt-176 eventually expired in 2007, without Syngenta applying for a renewal.<sup>58</sup>

#### 4. Clash of Risk Assessment, Member States vs. EC scientific Agencies

Having provided the necessary conceptual and factual framework, now it will be examined how science is used as a political tool on the European and national levels. In order to do so, the wording of the EC scientific agencies when dealing with Bt-176 maize, the corresponding responses by Member States, as well as the assessment of their arguments by the agencies, will be analysed. Specifically, in this part will examine which types of uncertainty are recognised by the scientists and how these are being dealt with within the context of manufactured risk. Thereby, it becomes clear that by not taking into

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56 Bundesministerium für Gesundheit und Frauen, *Gründe für die österreichische Entscheidung, den Gebrauch und Verk auf von gentechnisch veränderten Maislinien, notifiziert von CIBA-GEIGY in Übereinstimmung mit der Richtlinie 90/220/EWG und zugelassen von Frank reich am 5.2.1997 zu verbieten* (1997) <<http://bmg.gv.at/cms/home/attachments/6/2/2/4/CH1060/CMS1085743089437/bt176-begrueundung.pdf>> accessed 16 May 2014.

57 SCPE, *Further Report Of The Scientific Committee For Pesticides On The Use Of Genetically Modified Maize Lines* (1997); SCAN, *Report of the Scientific Committee for Animal Nutrition on the Supplementary Question 88 Concerning New Data Submitted by Austrian Authorities on the Safety for Animals of Certain Genetically Modified Maize Lines Notified by Ciba -Geigy in Accordance with Directive 90/220/EEC for Feeding Stuff Use* (1997); SCP, *Opinion on the invocation by Germany of Article 16 of Council 90/220/EEC regarding the genetically modified BT-MAIZE LINE CG 00256-176 notified by CIBA-GEIGY (now NOVARTIS), notification C/F/94/11-03* (2000); EFSA, *Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Austrian invocation of Article 23 of Directive 2001/18/EC* (2004).

58 Directive 2001/18/EC which replaced Directive 90/220/EEC includes a provision requiring GMO products to be reauthorized every 7 years. See: GMO Compass <<http://www.gmo-compass.org/eng/gmo/db/51.docu.html>> accessed 14 May 2014.

consideration some of the uncertainties, the scientists of the EC agencies predetermine politicised outcomes.

The SCAN, SCF, and SCPE, which were consulted by the Commission, concordantly argued for the approval of Bt-176.<sup>59</sup> The evidence these bodies put forward support the assessment conducted by the applicant, Ciba Geigy, who wished to introduce this GMO onto the French market.<sup>60</sup> When comparing these documents with the opinions of Member States, opposing positions regarding how to interpret uncertainty become visible. It has to be acknowledged that Member States had various motivations to restrict the marketing of GMO products. However, as the analysis reveals, they seem to be generally more apt to acknowledge that possible harms caused by new technologies, such as GMOs, cannot be properly anticipated with available scientific data, which is one of the characteristics of manufactured risk.

The diverging standards of Member States and the EC agencies on how to interpret uncertainties becomes visible in their discussion on the risks associated with the antibiotic- resistance gene (*bla*-gene), which had been used as a marker to trace the GM crops. With regard to a possible horizontal transfer of the *bla*-gene to human or animal organisms, potentially causing antibiotic resistance, the SCAN states:

Another important component in the uptake process is the presence of multimeric forms of homologous DNA sequences at the same binding site on the cell surface. Therefore, in order to have bacterial uptake, multiple copies of the *bla* gene construct would have to emanate from the plant genome and aggregate at the binding site. These stringent requirements and the overwhelming amount of competitive DNA fragments *make a natural transformation unlikely*.<sup>61</sup> Even under optimal experimental in vitro conditions, a successful transformation has not been achieved.

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59 SCAN (n55); SCF (n55); SCPE (n55).

60 A more detailed examination of the risk assessment carried out by Ciba-Geigy would have been interesting for our analysis. However, the corporate affairs office of Syngenta did not reply to our request.

61 Emphasis added.

In its conclusion, the SCAN points out that “[e]xperts agreed that horizontal gene transfer from plant to prokaryotic organisms can be excluded on present scientific evidence.”<sup>62</sup> The scientific experts conclude from the low probability that the risk of a transfer can be ‘excluded’, thus not leaving discretion for varying opinions. This decision indicates that the scientists give meaning to the scientific evidence, thus shaping risk management, and influencing later political decisions.

Meanwhile, the risk assessment carried out by the Austrian *Bundesministerium für Gesundheit und Frauen* (1997) comes to a similar evaluation regarding the probability of the risk:

On the basis of the present scientific knowledge, the possibility of a transfer of the bla-ampicillin resistance gene to bacteria of the intestine of humans or animals under various conditions which then could cause a harmful clinical impact is very low.

However, the Austrian authorities’ analysis of the same examination results in a conclusion which varies essentially from the SCAN’s view:

However from the Austrian point of view especially new scientific results have questioned the present scientific possibility of a conclusive evaluation of the mechanism of gene transfer as well as the development of resistance to the B.t. toxin. Accordingly, possible risks are very hard to assess and should be avoided at the present state of the scientific discussion. Even if the probability of such a genetic transfer is low, the risk of spreading the antibiotics resistance is unacceptable.<sup>63</sup>

The word ‘unacceptable’ arguably indicates that Austria in this case takes a value-laden decision. However, this document constitutes of the Austrian letter to the Commission justifying their safeguard measures. In this regard, it is not solely a risk assessment, but also

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62 SCAN (n55).

63 Bundesministerium für Gesundheit und Frauen (n56).

a part of risk management. A normative stance is therefore not surprising, as the decision-makers are expected to take a decision with regard to the authorisation or ban of the product.

This case demonstrates how the approaches of the European and national risk experts vary significantly regarding the way they deal with uncertainties resulting from a lack of consensus in science. Both SCAN and the Austrian authorities agree that the likelihood of a gene transfer is extremely low. However, the SCAN implies in its conclusion that the product is harmless, while the Austrian authorities consider that this outcome renders the admission of the product 'unacceptable'. They perceive the currently limited scientific knowledge regarding the potential risk as a sufficient reason to invoke precautionary measures.

This viewpoint is reaffirmed in the conclusion of the Austrian opinion:

[...] the scientific evaluation of possible risks can not be conclusive, as many relevant mechanisms are not fully understood or investigated by now. Furthermore, the highly unlikely risks have to be compared to the fact that high amounts of plant material containing the relevant gene will be given to humans and animals for a long time after an admission of the product to the market. One has also to realise that this product contains the discussed ampicillin resistance gene as well as one more herbicide resistance marker gene which is not any longer state of the art for the production of genetically modified plants. There are adequate maize products already available which do not comprise these restrictions and by this there is no reason to accept risks which are difficult to assess.<sup>64</sup>

The state's authority reemphasises its refusal to take the risk of approving a product whose future impact on health and environment is uncertain. By referring to "many relevant mechanisms [that] are not fully understood", it seems that the Austrian authorities are referring to uncertainty seen as a result of system complexity which cannot be assessed. The scientists of the SCAN, on the other hand, do not acknowledge such uncertainties. Thereby, their action leads to a politicisation of the risk assessment, as the expert body

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64 *ibid.*

implicitly communicates to the risk managers at the European Commission that such complexities are negligible or do not exist. Furthermore, when analysing this paragraph, it becomes apparent that Austria is more sceptical as to whether science can resolve the system complexity in this case. This is particularly evident in the last statement providing that the cultivation of proven and tested substitute products should always be the preferable option.

With regard to the potential antibiotic resistance effect this gene might have on living organisms, the Austrian authorities argue:

Clearly, degradation and digestion would have to be expected for DNA released from plant material. But recent results show unexpected long survival of DNA under specific conditions (Lorenz and Wackemagel, 1994, Webb and Davies, 1994). Mechanisms of adsorption and release of DNA from particles are not well understood. Specific results indicate that DNA can even pass the gastrointestinal tract without being completely degraded (Schubbert et al., 1994). Proficient information is available about mechanisms and requirements for bacterial competence and transformation in vitro but only limited information is available for the evaluation of these mechanisms and their relevance in specific natural habitats.<sup>65</sup>

And further:

Also a disadvantage of strains carrying high copy number plasmids has been seen under defined conditions but in a natural situations different selective pressures might be relevant for the establishment of the genetic information.<sup>66</sup>

The Austrian authorities stress that with regard to the potential antibiotic resistance effect in humans or animals, which the spread of the *bla*-gene could trigger, only information

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65 See: Oladele Ogunseitan, 'Bacterial genetic exchange in nature' [1995] *Science Progress* 183; Bea Baur, Kurt Hanselmann and others, 'Genetic transformation in freshwater: *Escherichia coli* is able to develop natural competence' (1996) 62 *Applied and Environmental Microbiology* 3673.

66 Bundesministerium für Gesundheit und Frauen (n56).

from laboratory studies is available, while the effect under ecological circumstances has not yet been examined. In the author's interpretation, they are concerned with the uncertainty as a result of system complexity in ecological science which cannot be simulated under *in vitro* conditions. In laboratory research, only a limited amount of controllable actions between the studied objects can be included. Whereas, an ecological field study, where the product is tested in the complex natural environment, and where it is almost impossible to predict all possible influences, was not carried out by any of the Member States or agencies.

The German opinion, justifying the country's ban of Bt-176 maize, identified uncertainty in another area.<sup>67</sup> Germany put forward the study of Hansen and Obrycki that found "significant larval mortality of monarch larvae (a butterfly species) fed on host plants exposed to Bt-pollen concentrations representative of those in the field for Bt-176 [A2] and MON810."<sup>68</sup> The SCP in its response to the German measures stated that:

A number of laboratory studies have been published which have investigated the effects of Bt-modified plants or Bt-toxins in artificial diet fed to the larvae of target pests or other model insect species. Some have reported effects from tritrophic studies of herbivorous larvae and their insect predators or parasitoids whilst others have not detected any significant differences from controls. The implications of such laboratory experiments are very difficult to interpret and extrapolate to the field situation where a wide range of other factors may come into play.

Furthermore, they argued:

Most recently, Hansen and Obrycki (2000) found significant larval mortality of monarch larvae fed on host plants

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67 Unfortunately, we were not able to examine the reasoned opinions which Germany and Luxembourg submitted to the Commissions. Despite sending several emails, the respective national departments did not reply to our requests. Instead, we have retrieved the information regarding the German justification from the reaction document of the SCP (2000).

68 Laura C Hansen and John J Obrycki, 'Field deposition of Bt transgenic corn pollen: lethal effects on the monarch butterfly' (2000) 125 *Oecologia* 241.

exposed to Bt-pollen concentrations representative of those in the field for Bt-176 and MON810. However analytical results of toxin levels in the Bt-pollen used in the experiment were variable and differed from the expected toxin levels published elsewhere (EPA 1999a, EPA 1999b).

From this point the SCP scientists concluded:

The implications of such studies have to be considered against the level of expression of Bt-toxin in pollen of the different Bt-maizes, the local timing and duration of pollen release in relation to the life cycles and development of lepidopteran larvae and the rapid decline of pollen deposition with distance from the source crop. In particular, the interpretation and prediction of effects in the field should be viewed against the comparative risk assessment of alternative crop protection practices and exposure to insecticide sprays. The SCP concludes that the studies cited in the German submission in vitro tests.<sup>69</sup>

The SCP's scientists assessed here the indications for side-effects which could harm non- target organisms and came to the conclusion that the studies treating the subject are complex to assess. In addition, it was expressed that it is difficult to evaluate whether results obtained in the laboratory would also hold valid under field conditions. Additionally, the SCP pointed out that scientific findings were contradictory, and that the work of Hansen and Obrycki stands in opposition to other studies.<sup>70</sup>

While the Austrian concern with regard to system complexity in ecological circumstances has already been discussed, this can also be seen as a case where uncertainty resulting from a lack of consensus is dealt with differently by the parties. On the one hand, the German authorities base their position on a study which points towards potential risks for the monarch butterfly, thereby contradicting the original risk assessment's results that non-target organisms are safe. On the other hand, the SCP

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69 SCP (57).

70 Hansen and Obrycki (n68).



refuses to accept this research as a sufficient reason to reject the studies on which the original assessment was based. It is the authors' understanding that, at this point, the two parties interpret uncertainty as a lack of consensus in the scientific community differently. Germany apparently considers that contradicting scientific positions are a sufficient reason to take precautionary measures against the product, while the SCP still upholds the conclusions from the original assessment as correct.

In conclusion, the analysis of the risk assessment documents indicates that uncertainty, particularly as a result of a lack of consensus and system complexity, is interpreted differently by Member States and the scientific studies they refer to, on the one hand, and the EU expert bodies, on the other hand.

This conflict is however not a matter of 'who knows best', but rather of the two sides' clash on how to deal with these types of uncertainty. Member States seem overall more apt to acknowledge them. In the original risk assessments of the EU scientific bodies, they did not play a role, while in their response to the Member States' concerns uncertainties are mentioned but disregarded, leading to the conclusion that no new evidence has been submitted. As it will be demonstrated in the next part, this position, in conjunction with the WTO Panel's interpretation of the SPS agreement, eventually led to completely disregard the uncertainties presented in the Member States' documents.

## 5. Disciplining Risk Assessments at the WTO – The *EC-Biotech* case

The World Trade Organization (WTO) is significant in illustrating tensions among risk definitions as a result of the global aspect of manufactured risks. In theory, it allows Member States to set their own level of protection and, as such, does not conduct risk assessment but only disciplines those conducted by its Members. The WTO requires, through Article 5.1 of the SPS Agreement, that any trade-restrictive regulations be founded on a scientific basis. Such measure must not, in any case, be disguised discrimination or restriction on international trade.<sup>71</sup> However, when the relevant scientific evidence necessary to conduct an adequate risk assessment is insufficient, Article 5.7 allows Members to base their safeguard measures on available pertinent information. However,

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71 Article 5.5 SPS Agreement.

the requirements imposed on Members have presented several problems, especially when dealing with the interpretations of these two articles and the key inbuilt concepts thereof, as it will be demonstrated later in this paper.

As presented in the conceptual framework, the politicization of science can occur in different forms: two of which concerning the way risk is being naturalized and the way recognized scientific evidence is being reduced to the extent that Member States no longer have the possibility to freely set their own levels of protection. In this part, it will be demonstrated how the scientific evidence presented by Austria, Germany and Luxembourg in the case of Bt-176 maize is refused legal standing, and how the Panel's reasoning appears to be problematic when dealing with manufactured risk. In essence, scientific evidence can be accepted at the WTO level in three different manners for Member States to base their SPS measures on them. The first consists of being recognized as a 'risk assessment' under Annex A(4) and Article 5.1. The second is by incorporating the evidence presented by the Members to the original risk assessment (in this case: SCP, SCAN & SCF. The third consists of invoking Article 5.7 by proving the existence of the 'insufficiency of scientific evidence'. This part will review how the documents presented by the Member States failed to meet each of the requirements and were ultimately disregarded by the Panel.

### 5.1 Manufactured Risk

The WTO has developed a few measures which seem to apply within the context of manufactured risk. Even though the originators did not intend this effect, the introduction of Article 5.7 of the SPS Agreement allows the application of precautionary measures<sup>72</sup> in case of insufficiency of scientific evidence. As manufactured risks are speculative and uncertain, this appears to be an adequate provision to deal with them. Furthermore, since not only quantitative risk assessments but also qualitative ones<sup>73</sup> are allowed at the WTO level, it allows in theory a wider range of scientific evidence to be accepted. However, and as will be demonstrated later, these steps are not always sufficient in order to properly tackle manufactured risks.

### 5.2 Uncertainty

Uncertainty is a complex notion which comprises different aspects, among which four have been emphasized in relation to manufactured risks.<sup>74</sup> In this respect, it is important

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72 Appellate Body Report, *EC – Hormones*, para. 124.

73 Appellate Body Report, *Australia-Salmon*, para. 124.

74 See: Conceptual Framework.

to understand the general attitude of the WTO towards the role of science and the types of uncertainty it recognizes. In the *EC-Biotech* case, the SPS Agreement, and the Panel's interpretation thereof, allow for a narrow conception of uncertainty when dealing with the Bt-176 maize. As an ultimate consequence, its interpretation results in the restriction of the Member States' discretion to set their own levels of protection.

It is relevant to look at the way the Panel reacts to the EC's claim concerning the existence of scientific uncertainty in GM crops:

If scientific uncertainty concerning the risks of biotech plants had been as great as claimed by the European Communities, it is unlikely that any of these products would have successfully completed the regulatory process in any country.<sup>75</sup>

The Panel dismissed the concerns of the EC and its Member States regarding the potential risks of biotech plants on the basis that other countries did not face the alleged uncertainties to complete the regulatory process when approving those products. Such comparison undermines the concerns certain Members have regarding the highly speculative nature of manufactured risks and the potential long-term danger that biotech products have. It thus simplifies the complexity of products which are characterised by their high level of uncertainty.

The perceptions of uncertainty as well as the consequences of such understandings in the context of biotech products will be referred to in the analyses of the Panel's applications of Article 5.1 and 5.7 with regards to Bt-176 maize.

### 5.3 Risk assessment – Article 5.1 and Annex A(4) SPS Agreement

In this section, it will be demonstrated how the risk assessment requirements laid down in the SPS Agreement represent a narrow understanding of such assessment for manufactured risks, and triggers several issues. First, the current interpretation of risk assessment leads to the naturalization of risk due to its demand to positively assess the risk through inappropriate legal requirements. Second, these constraints reduce the array of possible outcomes for Member States to decide the risk management policies they deemed necessary.

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75 Panel Report, *EC-Biotech*, para 4.538

After declaring that the safeguard measures regarding Bt-176 maize adopted by the Members in question<sup>76</sup> qualified as SPS measures within the meaning of Annex A(1),<sup>77</sup> the Panel decided that it had to first check whether their safeguard measures were 'based on' a risk assessment according to Article 5.1 SPS Agreement. In order to do so, it had to assess whether the documents and scientific studies provided by the Members were actual risk assessments falling under the definition of Annex A(4).<sup>78</sup>

The Panel dismissed the documents and scientific studies provided by the Members because they did not demonstrate the *likelihood* of entry, establishment or spread of a pest or disease or the *potential* of adverse effects on human or animal health arising from the biotech product.<sup>79</sup> For instance, when assessing Germany's Reasons document, the Panel argued that the document provided for the '*possibility*' of risks but failed to evaluate the '*likelihood*' of those risks.<sup>80</sup> Additionally, the document explained that the potential for adverse effects on animal or human health due to the Bt-176 was very small. However, the Panel argued that no clear evaluation of the potential was provided.<sup>81</sup>

In other words, the Panel considered that the Members failed to qualitatively assess the risk. However, only a few paragraphs were dedicated to this dismissal and no concrete evidence of this lack of assessment was given. This blurry interpretation leaves Member States ignorant of the criteria applied by the Panel when the latter considered whether a risk is qualitatively assessed. There seems to be a lack of consistency in this interpretation where the evaluation of *potential* or *likelihood* rests on arbitrary or unclear requirements solely known by the Panel.

Furthermore, when the Panel assessed these documents, the way it used science may be subject to criticism. Firstly, such interpretation of the scientific studies seems to result in the naturalisation of science in the sense that the Panel conceived 'risk' as an objective notion that can, and must, be assessed positively through the use of scientific evidence. As shown above, merely pointing out the possibility and/or the existence of uncertainties

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76 Namely Austria, Germany and Luxembourg.

77 Panel Report, *EC-Biotech*, paras. 7.2655 (Austria); 7.2806 (Germany); 7.2915 (Luxembourg)

78 According to Annex A(4), a risk assessment can either be the "evaluation of the *likelihood* of entry, establishment or spread of a pest or disease within the territory of an importing Member" or the "evaluation of the *potential* for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs" (*emphasis added*).

79 Panel Report, *EC-Biotech*, paras. 7.3054 (Austria); 7.3152 (Germany); 7.3208 (Luxembourg)

80 E.g. "adverse effects *would* occur"; "unacceptable development of resistance *may* occur"; "possible effects of Bt-toxin on soil micro-organisms *cannot be excluded*"; etc. (Panel Report, *EC-Biotech*, para. 7.3145)

81 Panel Report, *EC-Biotech*, para. 7.3146.

cannot be considered as a risk assessment under Annex A(4). In these circumstances, the Panel articulates the belief that risk is a natural category that, if existing, must be positively definable through scientific means. Secondly, this view leads to a definition of risk assessment which relies on stringent legal conditions which are hard to fulfil when dealing with manufactured risks. Indeed, *likelihood* and *potential* may not fit the reality of products whose risks are highly speculative. Moreover, these requirements necessitate a positivist assessment of the risks. This means that, in order for the reports to be considered as 'risk assessments', the Members must demonstrate the existence of the risk - even though it is highly speculative. In the present case, since the studies aimed at pointing out uncertainties (which is what is *not* known instead of what *is* known), they were not regarded as risk assessments. Thirdly, by denying scientific evidence which does not assess the potential or likelihood, this restricted perception of what constitutes a 'proper' risk assessment may ultimately lead to a narrow scope of possible outcomes when deciding whether an SPS measure can be implemented in the context of this type of risk. Indeed, Members are left with a reduced capacity to decide by themselves which level of protection they wish to set, based on the available scientific evidence.

#### 5.4 'Based on' a Risk Assessment – Article 5.1 SPS Agreement

In the present section, several points will be made regarding the requirement for a SPS measure to be based on a risk assessment. First, the different types of uncertainty recognized by the Panel will be shown, and the implications of such recognition will be presented. Second, this part will explain the consequences of the Panel's decision that the Member States' divergent views must be explicitly included in the original risk assessment. Finally, the claim that the Members failed to explain how and why they assessed the risks in a different way than the EC agencies will be questioned.

The Panel, after establishing that the documents provided for by the Member States did not amount to 'risk assessments',<sup>82</sup> went on to see whether Austria's, Germany's and Luxembourg's safeguard measures were '*based on*' any risk assessments conducted by the EC scientific agencies. The Panel concluded that the safeguard measures could not be considered to be based on any risk assessments.<sup>83</sup>

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82 Within the meaning of Annex A(4) SPS Agreement.

83 Panel Report, *EC-Biotech* case, paras. 7.3086 (Austria); 7.3158 (Germany); 7.3212 (Luxembourg). The arguments presented in the case of Austria's safeguard measure on T25 maize applied *mutatis mutandis* to Austria's, Germany's and Luxembourg's safeguard measures on Bt-176 maize (Panel Report, *EC-Biotech* case, paras. 7.3085; 7.3157; 7.3211).

The EC argued that Members may use divergent scientific opinion based on new information rather than mainstream scientific opinion, and it was so in the present instance.<sup>84</sup> The Panel accepted this claim as it was already established in *EC-Hormones*, wherein the Appellate Body accepted that risk assessments could be based on prevailing/mainstream opinion but also based on diverging scientific views as long as they were from respected and qualified sources.<sup>85</sup> This has been accepted and allowed especially in situations of life-threatening risks constituting a “clear and imminent threat to public health and safety”.<sup>86</sup>

However, the Panel pointed out that this was applicable only in cases where the divergent opinion was part of the original risk assessment, which was not presently the case. Indeed, the Panel could not see any divergent views expressed in the agencies’ risk assessment.<sup>87</sup> Therefore, the Panel decided that the *EC-Hormones*’ decision – that risk assessments can be based on diverging scientific evidence – could not be applied to the current situation. In the Panel’s view, safeguard measures based on a divergent scientific opinion could not be based on a risk assessment that establishes a single opinion with no reference to the divergent view.

Previously, the Panel stated that when the Members face a situation where it is possible to conduct a risk assessment because of sufficient relevant scientific evidence, they may take into consideration the uncertainties present in the result and conclusion of the assessment to set their SPS measures. In this context, the risk assessment can support several outcomes and conclusions which may be the basis for different measures. The Panel defines these uncertainties as for example, “uncertainties linked to certain assumptions made in the course of the performance of a risk assessment”.<sup>88</sup> However, it seems they can only be relied on if they are explicitly mentioned in the risk assessment.

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84 Panel Report, *EC-Biotech* case, para. 7.3057.

85 “A risk assessment could set out both the prevailing view representing the ‘mainstream’ of scientific opinion, as well as the opinions of scientists taking a divergent view” (Appellate Body Report, *EC-Hormones*, para. 194).

86 Appellate Body Report, *EC-Hormones*, paras. 193-194.

87 Panel Report, *EC-Biotech* case, para. 7.3059.

88 Panel Report, *EC-Biotech*, para. 7.1525. (“[T]he mere fact that relevant scientific evidence is sufficient to perform a risk assessment does not mean that the result and conclusion of the risk assessment are free from uncertainties (e.g. uncertainties linked to certain assumptions made in the course of the performance of a risk assessment). Indeed, we consider that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken. In view of these uncertainties, a given risk assessment may well support a range of possible measures. Within this range, a Member is at liberty to choose the one which provides the best protection to human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen is reasonable supported by the risk assessment and not inconsistent with other applicable provisions of the SPS Agreement, such as Article 5.6.”)

Additionally, the Panel did not wish to imply that it is impossible to rely partly on a current risk assessment exposing a single opinion, to show divergent opinions. However, it stated that,

[...] to the extent they disagree with some or all of the conclusions contained in such an assessment, it would in our view be necessary for Members to explain, by reference to the existing assessment, how and why they assess the risks differently, and to provide their revised or supplemental assessment of the risks.<sup>89</sup>

According to the Panel, the Member States failed to do so.

The 'based on requirement' is the second means a Member may implement a safeguard measure at the WTO level. If it did not fulfil the first requirement of Article 5.1 – to have its scientific studies recognized as a 'risk assessment' – it can attempt to show that its SPS measure is 'based on' another existing and recognized assessment, in the present case, the EC original risk assessments.

The first point that can be raised regarding the Panel's decision is that it explicitly recognizes the uncertainty as the lack of scientific consensus<sup>90</sup> as well as "uncertainties linked to certain assumptions made in the course of the performance of a risk assessment".<sup>91</sup> It thus broadens the scope of recognized uncertainties to tackle manufactured risks in a more adequate manner. However, it has proven to be insufficient and profitless because of the stringency of the legal requirements in Annex A(4) – i.e. potential and likelihood – which render the possibility for Members' scientific reports to be recognized as 'risk

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89 Panel Report, *EC-Biotech*, para. 7:3062.

90 Appellate Body Report, *EC-Hormones*, para. 194.

91 Panel Report, *EC-Biotech*, para. 7:1525. ("[T]he mere fact that relevant scientific evidence is sufficient to perform a risk assessment does not mean that the result and conclusion of the risk assessment are free from uncertainties (e.g. uncertainties linked to certain assumptions made in the course of the performance of a risk assessment). Indeed, we consider that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken. In view of these uncertainties, a given risk assessment may well support a range of possible measures. Within this range, a Member is at liberty to choose the one which provides the best protection to human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen is reasonable supported by the risk assessment and not inconsistent with other applicable provisions of the SPS Agreement, such as Article 5.6.")

assessments' onerous. Thus, if the Members do not pass the first hurdle of proving the potential or likelihood of the risks, they are unable to take advantage of the other types of uncertainty acknowledged by the Panel.

Secondly, it is interesting to see that the Members' different interpretation of scientific evidence and their additional scientific information would only be recognized if they were *explicitly* included in the original risk assessment on which they wish to base their safeguard measures. Indeed, the Panel stressed the fact that diverging views and uncertainties regarding the result or conclusion of the risk assessment must be mentioned in the original assessment for them to rely on. However, since the scientific agencies did not recognize that the documents provided by the Members submitted for additional scientific information, even though they recognized its validity in itself, the measures were deemed not to be based on the original assessment but rather on their own modified and divergent assessment. The agencies did not include any divergent views which could have represented the Members' concerns regarding the potential risks linked to the marketing of Bt-176 maize. The issue with the requirement that the Members' scientific findings must be included in the original assessment for them to be recognized, is that it leaves a very slim possibility for Member States to have their evidence accepted since the agencies' risk assessments are politicized, as previously demonstrated.

Finally, the Panel stated that the Members should have explained how and why they assessed the risks differently compared to the way they were assessed by the EC agencies since they fundamentally disagreed with the original assessment. It is questionable whether they did not do so since they provided for documents and scientific studies that show the possibility of potential adverse effects Bt-176 maize has on human or animal health and the environment.<sup>92</sup> They attempted to show, based on scientific evidence from a divergent source, that the risk assessments conducted by the agencies were not free from any challenge. This is even more striking in the case of Luxembourg, where the Reasons document explicitly refers to scientific information provided by the EC scientific committees.<sup>93</sup> The EC committees acknowledged the fact that, when using Bt-176 maize, the risk that antibiotic resistance would develop because of the gene transfer to bacteria in the gut of humans or animals existed, though small. However, the EC scientific experts dismissed this potential adverse effect due to its low chance of manifestation whereas the Luxembourg authorities were concerned by its possible occurrence.<sup>94</sup>

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92 See: Risk Assessment – Article 5.1 and Annex A(4) SPS Agreement.

93 Panel Report, *EC-Biotech*, para. 7.3203.

94 Panel Report, *EC-Biotech*, para. 7.3203.



## 5.5 Insufficiency of Scientific Evidence – Article 5.7 SPS Agreement

In the following section, Article 5.7 and the Panel's interpretation thereof are analysed in the context of the Bt-176 maize. First, the Panel's decision to reject the Members' measures illustrates the fact that the Panel accepted the EC agencies' risk assessments as an authoritative source, even though they were already politicized at the EU level. Second, the only type of uncertainty, which can trigger the use of Article 5.7, is uncertainty as insufficiency of scientific evidence. This is a clear manifestation of uncertainty intolerance as other types of uncertainty are disregarded. This leads to an additional restriction of the number and types of scientific evidence allowed at the WTO level, which is provided by the Members. Finally, it will be shown how the Panel's interpretation and application of Article 5.7 ultimately leads to the restriction of the discretionary powers Member States should have when setting their own level of protection.

### *1. Uncertainty as insufficiency of scientific evidence*

After holding that the Members' measures regarding Bt-176 maize did not comply with Article 5.1, the Panel examined whether Article 5.7 could be triggered. The Panel found that the safeguard measures did not respect the first condition, which requires the measure to be imposed in respect of a situation where "relevant scientific information is insufficient".<sup>95</sup> Before analysing the Panel's interpretation, it is first important to refer to the definition given by the SPS Agreement regarding the only type of uncertainty which may trigger the use of precautionary measures. As stated in *Japan-Apples* by the Appellate Body, "the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but by the insufficiency of scientific evidence".<sup>96</sup> Thus, the SPS Agreement allows for the possibility to rely on uncertainty *as lack of data* to avoid the requirements for a risk assessment laid down in Article 5.1 and hence to use provisional measures under Article 5.7.

### *2. The Panel's definition of insufficiency of scientific evidence*

The Panel reviewed the arguments of the EC to see whether there was indeed a case of insufficient scientific evidence. The Members' measures, when submitted to the EC, were reviewed by the EC scientific agencies<sup>97</sup> in order to check whether, on the basis of the information provided by the Members, there was a risk for human health or to the

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95 Appellate Body Report, *Japan – Agricultural Products II*, paras. 89 and 176; Panel Report, *EC – Biotech*, para. 7.3218.

96 Appellate Body Report, *Japan – Apples*, para. 184.

97 Germany: SCP; Austria & Luxembourg: SCF, SCAN, SCP.

environment. However, the agencies did not consider that the information provided was ‘new scientific evidence’ that would overturn the risk assessment that had previously been conducted by the EC agencies.<sup>98</sup> The Panel deemed that the agencies had “effectively reviewed their original risk assessment in the light of the information presented”<sup>99</sup> by Germany and came to the conclusion that their risk assessments were still valid and were not altered in any way. The opinions by the EC scientific committees which were expressed for the EC approval procedures (i.e. the original assessments), as well as the opinions by the EC scientific committees which were delivered after the adoption of the Members’ SPS measures (i.e. the review assessments) were considered by the Panel as risk assessments within the meaning of Annex A(4) and Article 5.1. Therefore, in the Panel’s view, the EC did not prove that the safeguard measures were adopted due to a lack of scientific evidence since the review assessments and the original assessments of Bt-176 maize showed that, at the time the SPS measures were adopted, there was sufficient scientific evidence to conduct an adequate risk assessment within the meaning of Annex A(4) and Article 5.1.<sup>100</sup>

Some remarks can be made regarding the Panel’s decision. Firstly, the new evidence presented by the Members was solely assessed by the scientific agencies. The Panel did not take the active position of examining whether the evidence delivered by the Members could overturn the original risk assessments. It neither has the competence nor the scientific expertise to do so, and it is not argued here that it should be given such competence. However, by doing so the Panel accepts the scientific agencies’ risk assessments as authoritative sources, even though they disregarded the uncertainties mentioned in the Members’ Reasons documents, thus politicizing science and demonstrating a certain level of uncertainty intolerance at the EU level, as previously demonstrated.

Secondly, it is interesting to point out that only the insufficiency of scientific evidence can trigger the use of precautionary measures at the WTO level. Both uncertainty as lack of consensus and as inherent to scientific practice,<sup>101</sup> which are the epistemological categories intrinsic to the scientific practice, are disregarded and cannot be used to trigger the application of Article 5.7. On the other hand, it is worth noting that Article 5.1 recognizes uncertainty as lack of consensus as a sound basis for SPS measures.<sup>102</sup> By disregarding the

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98 Panel Report, *EC-Biotech*, paras. 7.3272 (Austria); 7.3326 (Germany); 7.3368 (Luxembourg).

99 Panel Report, *EC-Biotech*, para. 7.3326, emphasis added.

100 Panel Report, *EC-Biotech*, paras. 7.3272 (Austria); 7.3327 (Germany); 7.3369 (Luxembourg).

101 See: the *Conceptual Framework*.

102 “[a] risk assessment could set out both the prevailing view representing the ‘mainstream’ of scientific opinion, as well as the opinions of scientists taking a divergent view” (Appellate Body Report, *EC- Hormones*, para. 194).

other types of uncertainty, the Panel presents an 'uncertainty-intolerant' behaviour when dealing with these biotech products. Moreover, because other types of uncertainty are not allowed in Article 5.7, the SPS Agreement and the Panel's interpretation contribute to the continuing politicization of science and to the growing diminution of scientific evidence witnessed at all levels (EU and WTO).

Thirdly, the Panel rejected the EC's argument that the assessment of the risk of the Bt-176 maize was concluded in a situation with insufficient evidence. It argued that because the original assessments have successfully been conducted, it proves there was indeed enough scientific data to perform a risk assessment. In the case of Germany Bt-176 maize, the SCP, when reviewing the German Reasons document and other scientific reports, stated that the findings of Germany "do not invalidate the original risk assessment".<sup>103</sup> The Panel interpreted it as implying that no new scientific evidence was provided by Germany that could overturn the risk assessment conducted by the SCPE.<sup>104</sup> It thus confirmed the original risk assessment and demonstrated, in the Panel's view, that there was enough scientific evidence to conduct a proper risk assessment.<sup>105</sup> Therefore, on one hand, the SCP accepted the claim made by Germany but did not include it in the original risk assessment, and on the other hand, the Panel interpreted the SCP's remark that Germany's documents "do not invalidate the original risk assessment" as a proof of sufficiency of scientific evidence.<sup>106</sup> Thus, the agencies disregarded the Members' assessments while recognizing that their information was valid. This resulted in the fact that their scientific documents could neither be recognized through Article 5.1 when basing their SPS measure on the original risk assessment, nor through the application of Article 5.7 by proving insufficiency of scientific evidence. Hence, it appears that the Members' concerns that a low level of risk may materialize were dismissed solely because the EC's original assessment disregarded uncertainties, which it deemed immaterial.<sup>107</sup> This is a direct implication of the

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<sup>103</sup> SCP (n57).

<sup>104</sup> Panel Report, *EC-Biotech*, para. 7.3326.

<sup>105</sup> Panel Report, *EC-Biotech*, para. 7.3327.

<sup>106</sup> SCP (n57).

<sup>107</sup> "In the Reasons document, Luxembourg alleges that Bt-176 maize poses risks in relation to the development of antibiotic resistance and the development of insect resistance to Bt toxin. Regarding the development of antibiotic resistance, the Reasons document refers to scientific advice from EC scientific committees and other scientific experts. *Although Luxembourg acknowledges that these experts indicated that there was only a small risk that antibiotic resistance would develop due to gene transfer to bacteria in the gut of humans or animals, Luxembourg insists that a small risk exists, notably in situations where the maize in question is used as animal feed*, and argues that there is a need for further study regarding the mechanism of gene transfer." (Emphasis added). Panel Report, *EC-Biotech*, para. 7.3203.

politicization of the EC original risk assessments, which results in the dismissal of certain scientific evidence based on certain types of uncertainty, disregarded in the application of Article 5.7. It ultimately leads to the curtailment of scientific information and to the reduction of the discretionary scope Members should have when setting their own level of protection.

## 5.6 Final Remarks

The analysis of the *EC-Biotech* case attempted to demonstrate the general tendency of the SPS Agreement and the Panel to naturalize risk in the present case. One of the consequences of such form of politicization of science is the ever-continuing reduction of scientific data. Even though some types of uncertainty are explicitly recognized, the Panel did not allow the Member States' scientific evidence to be given legal standing at the WTO level. While uncertainty as lack of scientific consensus and general uncertainties found in scientific assumptions<sup>108</sup> are accepted when performing a risk assessment, it has been shown not to be useable when legal requirements are too harsh to be complied with. Additionally, these types of uncertainty, although acknowledged by the agencies as well, were disregarded when the scientific agencies stated that the Members' scientific studies did "not invalidate the original risk assessment"<sup>109</sup> and when the Panel interpreted such statement as meaning that diverging views were not expressed in the original risk assessments. Moreover, the application of Article 5.7 can only be triggered by the insufficiency of scientific evidence, which thus disregards the other types of uncertainty. Compartmentalizing the different forms of uncertainty in the application of the different articles and rejecting others denies the possibility of acknowledging the complexity Members and other actors may face when dealing with manufactured risks. Therefore, the legal existence of the certain types of evidence is not recognized due to the restrictive bases on which scientific evidence can be accepted at the WTO level, and due to the restrictive acknowledgment of the different forms of uncertainty.

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<sup>108</sup> Panel Report, *EC-Biotech*, para. 7.1525. ("[T]he mere fact that relevant scientific evidence is sufficient to perform a risk assessment does not mean that the result and conclusion of the risk assessment are free from uncertainties (e.g. uncertainties linked to certain assumptions made in the course of the performance of a risk assessment). Indeed, we consider that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken. In view of these uncertainties, a given risk assessment may well support a range of possible measures. Within this range, a Member is at liberty to choose the one which provides the best protection to human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen is reasonable supported by the risk assessment and not inconsistent with other applicable provisions of the SPS Agreement, such as Article 5.6.").

<sup>109</sup> SCP (n57).

The reduction of scientific evidence from one level (EU) to the other (WTO) has two main consequences: first, it leads to a scientification of politics in the sense that it impedes Member States to exercise their discretionary powers by setting the level of protection they deem appropriate. Second, it fails to properly respond to the challenges of manufactured risks, characterized by their global effects, their uncertainties and the speculative nature of their risks.

## 6. Conclusion

In this paper, we have investigated how science has been politicised in the risk assessment of the EC scientific agencies and in the *EC-Biotech* case concerning the regulation of the Bt-176 maize. In particular, the authors have identified two main forms of politicisation that highly contributed to the regulatory outcomes.

First, the risk of the genetically modified products considered in the *EC-Biotech* case was politically framed by the Panel as a natural category which could be defined on the sole basis of scientific knowledge. This is particularly visible in the requirements expressed in Article 5.1 and Annex A(4) of the SPS Agreement and the Panel's interpretation thereof, which require the SPS measures to be appropriately based on an assessment of risk, and that, such risk assessment must be grounded on scientific evidence that evaluate the potential and likelihood of the risk. In this respect, not only is risk being naturalised, but, in addition, it is considered that an appropriate definition of risk can be positively expressed.

Secondly, we have demonstrated that science is being politically used with the expectations that it could provide for a single authoritative answer. This process takes place at the EC scientific agencies in a risk assessment that does not display the uncertainties that the experts are being faced with,<sup>110</sup> and through the scientists' normative interpretations of the outcomes of their research.<sup>111</sup> At the WTO level, the apparent authoritative power of scientific evidence is the result of the limited amount of evidence<sup>112</sup> that is recognised by the Panel. The process of discounting scientific evidence

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110 Particularly visible in the way system complexity is not being mentioned by the EC Scientific agencies while being raised in the Member States reason documents.

111 This is for instance visible when the experts from the SCAN claimed that “[...]a natural transformation is *unlikely* [...]” in their assessment while concluding “that horizontal gene transfer from plant to prokaryotic organisms can be *excluded* on present scientific evidence” (emphasis added). See: SCAN (n55).

112 As well as to the fact that this evidence, namely the EC scientific agencies' risk assessments, has previously been politicised.

is particularly visible through the way most types of uncertainty are being disregarded in the SPS agreement and their interpretation by the Panel. In this regard, in order to adequately evaluate the way science is being politicised, it is relevant to consider which types of uncertainty are being recognised, and in which context.

	EC scientific agencies		WTO, <i>EC-Biotech</i>		
	Explicitly present in the risk assessments carried out by the European scientific agencies	Recognised by the EC-Agencies in the responses to the Member States opinion <sup>1</sup>	Definition of risk assessment according to article 5.1 & Annex A(4)	Available to be used to base member state's safeguard measures on the original EC- risk assessment (Article 5.1)	Can trigger Article 5.7
Lack of data	No	No	Directly triggers Article 5.7	Directly triggers Article 5.7	Yes
Lack of consensus	No	Yes	Yes	Yes	No <sup>1</sup>
System complexity	No	Yes	∅	∅	∅
Inherent uncertainty	∅	∅	∅	∅ <sup>1</sup>	No

**Table 1** Types of Uncertainty in the EC scientific agencies risk assessment and in the *EC-Biotech* case.

At the level of the EC scientific agencies, it is relevant to notice that no reference to ‘lack of data’ could be identified. However, this is hardly surprising considering that lack of data, as understood by the WTO Panel, amounts to the impossibility to conduct a risk assessment based on the available information. Since the experts concluded their risk assessments, and responded to the Member State’s documents, this form of uncertainty is effectively ‘dispelled’. On the other hand, ‘lack of consensus’ was acknowledged by the SCP when assessing the evidence provided by Member States. However, by claiming that this evidence “do[es] not invalidate the original risk assessments”,<sup>113</sup> the uncertainty is, in fact, not integrated in

<sup>113</sup> SCP (n57).

the risk assessment. With regard to uncertainty as ‘system complexity’, Austria pointed out that a ‘highly unlikely’ risk under laboratory research has to be considered in contrast to the complexity of the natural environment in which it will evolve, and that, in such settings, the uncertainty remain unknown.<sup>114</sup> Whereas the risk assessment conducted by SCAN did not, to our knowledge, respond or refer to the existence of such uncertainty.<sup>115</sup> Finally, none of the documents explicitly referred to a type of ‘inherent uncertainty’, however, this is, not surprising considering that this form of uncertainty cannot really be problematized by scientists (as it consist of additional scientific evidence).

At the WTO level, it could be observed in the analysis of the *EC-Biotech* case that the ‘lack of data’ is the only type of uncertainty that may trigger the use of Article 5.7. This is the reason why such form of uncertainty is excluded when deciding whether an SPS measure is based on a risk assessment within the meaning of Article 5.1 and Annex A(4). Whereas ‘system complexity’ is never mentioned in the Panel Report, uncertainty as an “inherent part of science” is explicitly rejected in the application of Article 5.7. Indeed, in *Japan-Apples*, the Appellate Body stated that “the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but by the insufficiency of scientific evidence”.<sup>116</sup> Regarding uncertainty as “lack of scientific consensus”, it is interesting to see that even though it was accepted in the performance of a risk assessment,<sup>117</sup> it could not be applied in the present case. The Panel decided that the Member States’ safeguard measures could not be based on the original risk assessment conducted by the EC scientific agencies because the scientific views on which they rely to base their safeguard measures were not expressed in the original assessments. Indeed, the Panel interpreted the agencies’ statement that the evidence provided by the Members did “not invalidate their risk assessment”<sup>118</sup> as meaning that there was no lack of consensus or diverging views in the original assessments. Through this interpretation, the Member States were deprived of the possibility to rely on minority views to base their safeguard measures.

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114 Specifically the Austrian authorities claimed that: “the highly unlikely risks have to be compared to the fact that high amounts of plant material containing the relevant gene will be given to humans and animals for a long time after an admission of the product to the market”. Bundesministerium für Gesundheit und Frauen (n56)

115 SCAN instead claimed that “Even under optimal experimental in vitro conditions, a successful transformation has not been achieved.” See: SCAN (n55).

116 Appellate Body Report, *Japan – Apples*, para. 184.

117 Appellate Body Report, *EC-Hormones*, para. 194. .

118 SCP (n57)

In conclusion, the politicisation of science, as described above, ultimately resulted in the scientification of politics, i.e. in the reduction, due to the authoritative use of science, of the discretionary power of Member States to set their levels of protection. Although in the *EC- Hormones* case the Appellate Body clearly stated that Members have the right to set their own levels of sanitary protection,<sup>119</sup> it has been demonstrated in the analysis of the *EC-Biotech* case that the Member States were confronted with a narrow scope of possible solutions. The dismissal of the scientific evidence presented in their documents as well as the interpretation thereof by minority views disabled the application of Articles 5.1 or 5.7 of the SPS Agreement.

Through the narrow interpretation of 'risk assessment' and the way certain types of uncertainty are being discarded, one can see how the Panel's understanding of the SPS Agreement is inappropriate to adequately deal with manufactured risks. It is important to point out that the provisions of the SPS Agreement do provide for more room than what can be expected from the Panel's Report. Indeed, Article 5.1 requires the performance of a risk assessment *appropriate to the circumstances*. This argument has been put forward by the EC which claimed that the Member States' safeguard measures were based on an assessment which was appropriate to the present circumstances.<sup>120</sup> However, the Panel rejected this argument<sup>121</sup> and thus furthered the politicisation of science. Overall, even though some leeway is left for improvements in the interpretation of the SPS Agreement, the way risk is being naturalised and positively defined, as well as the rejection of most types of uncertainty, do not seem to allow the WTO to appropriately deal with manufactured risk. Therefore, it seems necessary to reconsider how existing guidelines can be accommodated to risks bearing the characteristics of manufactured risk.

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119 Appellate Body Report, *EC-Hormones* case, para. 124.

120 Panel Report, *EC-Biotech* case, para. 7:3052.

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