Risk Management Policies Under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures

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ABSTRACT

The globalization of the national food markets raises a number of difficult legal and political problems. In response, national governments have adopted a wide range of regulatory measures which are not only aimed at the protection of the environment and human health and safety but may also constitute attractive vehicles for protectionism. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) was therefore specifically designed to regulate possible abuses of sanitary and phytosanitary (SPS) regulations. Although, the most important part of the SPS Agreement relates to risk assessment disciplines, this article argues that it is legitimate to speak about risk management dimension of the Agreement. The substantive analysis of the SPS Agreement shows that these disciplines can be identified while their recognition helps to link the text of the Agreement with the practice
of national regulators and documents of international standard setting bodies. The article begins from the discussion of basic principles of risk analysis, including risk assessment, risk management and risk communication. In order to background the following discussion, it examines relevant passages from EC – Hormones, case which materially shaped the understanding of risk management disciplines of the SPS Agreement. Then the author analyzes the relevant provisions of the Agreement, including concept of an appropriate level of protection as well as specific risk management disciplines, finding some developments of the case law disappointing. On that basis, the author attempts to draw overall conclusions on the risk management dimension of the SPS Agreement, noting that the overall assessment of the SPS Agreement as far as risk management is concerned will only be possible after they are addressed in the case law.

**KEYWORDS:** SPS Agreement, risk management, WTO, international risk regulation, trade and health, ALOP

**I. INTRODUCTION**

The world is getting smaller and smaller. The introduction of new technologies, liberalization of the international trading system, lower costs of transport and logistics, as well as the free flow of capital truly shape the world of today. This process also includes the globalization of the national food markets. As a result of this, consumers from different countries benefit from access to cheaper food and can select from a wider variety of different agricultural products in any season of the year.

However, the down side of this is that the globalization process as it relates to food raises a number of difficult legal and political problems. For example, people are increasingly concerned with the quality and safety of food. Disputes over the use of hormones for bovine growth and milk promotion purposes, the problem of “mad cow disease” (BSE), and the marketing of food from genetically modified organisms are central issues in many political agendas and the subject of intense public discussion. Simultaneously, the issues of invasive species (both weeds and pests) which can be imported together with foreign agricultural products raise a
separate set of public concerns. In response to these fears, national governments have adopted a wide range of regulatory measures aimed at the protection of the environment and human health and safety. What is at issue here is that these measures are also attractive vehicles for protectionism and often take the place that has traditionally been occupied by the tariff barriers.

Law of the World Trade Organization attempts to address these problems with the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), specifically designed to regulate possible abuses of sanitary and phytosanitary (SPS) regulations. The central point of the SPS Agreement is an obligation on rational decision-making, as it requires scientific basis for SPS decisions. Simultaneously, the Agreement promotes the harmonization of diverse national SPS rules by establishing a presumption of conformity for those measures which align with international standards.

The SPS Agreement is not, however, limited to the above issues. It also contains provisions disciplining the risk management policies in the SPS field. This part of the SPS Agreement has received less attention of scholars as compared to risk assessment disciplines. The article intends to restore the balance in the scholar discussion.

The article proceeds as follows. The first part presents a brief overview of the basic principles of risk analysis, the paradigm which is commonly used in the process of national and international risk regulation. That includes a discussion on risk assessment, risk management and risk communication. The aim of this is to place the issue of risk management, as embodied in the SPS Agreement, in a broader context. The second part examines relevant passages from EC – Hormones, the case that shaped the understanding of risk management disciplines under the SPS Agreement. That part concludes that it is legitimate to speak about the risk management dimension of the SPS Agreement. The third part analyzes the relevant provisions of the Agreement, including concept of an appropriate level of protection as well as specific risk management disciplines (options evaluation, implementation and application of SPS decisions, their monitoring and review). The article does not address the issue of

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1 Sanitary and phytosanitary measures are understood under the SPS Agreement as those measures, which relate to protection of human, animal and plant life and health from specific SPS risks. See Agreement on the Application of Sanitary and Phytosanitary Measures, Annex A, ¶ 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter SPS Agreement].

2 Important exceptions include: Thomas Cottier, Risk Management Experience in WTO Dispute Settlement, in GLOBALIZATION AND THE ENVIRONMENT – RISK ASSESSMENT AND THE WTO 41 (David Robertson & Aynsley Kellow eds., 2001); Marion Wooldridge, Risk Assessment and Risk Management in Policy Making, in id. at 81; David Wilson & Digby Gascoine, National Risk Management and the SPS Agreement, in id. at 155.
provisional measures (Article 5.7). Although that provision may be seen as an element of risk management, the size of the article does not allow further discussion on the subject. Moreover, Article 5.7 has already been elaborated on in the literature. The last part of the article attempts to draw overall conclusions on the risk management dimension of the SPS Agreement.

II. REGULATION, RISK ASSESSMENT AND RISK MANAGEMENT

In the majority of modern societies, the problem of SPS risks is addressed through governmental regulation. State intervention is generally justified by the need to minimize the level of SPS risk exposure and to distribute the costs of risk in socially acceptable ways. National risk regulation is predominantly based on a paradigm of risk analysis. That concept can be defined as a systematic process of identifying hazards, and the subsequent collection and evaluation of information leading to actions (or inactions) of risk managers. The process is informed by continuous information exchange between different actors (i.e. scientists, risk managers, interest groups and the general public). In other words, risk analysis can be seen as a structuralized regulatory response to risks, consisting of three components: risk assessment, risk management and risk communication.

Risk assessment may be defined as a process of a probabilistic estimation of the potential adverse health or environmental effects of a

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3 For the same reasons, this article does not discuss Article 10.1 of the SPS Agreement. That article provides that “[i]n the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members”; SPS Agreement art. 10.1 (emphasis added). This clearly requires WTO Members to apply their risk management policies in a flexible manner. However, the article has not yet been interpreted either by a panel or the Appellate Body. Thus, the extent of the special treatment of developing countries with respect to risk management provisions of the SPS Agreement is unclear.


5 DANIEL M. BYRD III & C. RICHARD COTHERN, INTRODUCTION TO RISK ANALYSIS: A SYSTEMATIC APPROACH TO SCIENCE-BASED DECISION MAKING 6 (2000).

substance, process, action or event, determined according to scientifically plausible methods. The goal of risk assessment is to provide risk managers with the information necessary for rational decision-making.\footnote{See, e.g., NRC/NAS COMMITTEE ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT 18 (1983).} Risk assessment is initiated by risk managers who preliminary indicate a potential problem. This constitutes a triggering factor for subsequent steps of the whole risk analysis process.\footnote{Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, supra note 6, at 104 (identifying this initial step as a part of risk management); International Standards for Phytosanitary Measures – Guidelines for Pest Risk Analysis, ISPM No. 2 (Secretariat of the Int’l Plant Protection Convention (IPPC) Food and Agric. Org., U.N., 1996) [hereinafter Guidelines for Pest Risk Analysis] (identifying this step as separate from both risk management and risk assessment).} The assessment as such is conceptualized as consisting four distinctive steps. These are: identification of hazard (any source of potential damage, harm or other adverse effects), hazard characterization (quantitative and/or qualitative evaluation of the nature of the identified adverse effects caused by an agent), exposure assessment (quantitative and/or qualitative evaluation of exposure by relevant group to the agent) and risk characterization (qualitative and/or quantitative estimation of the probability of occurrence and severity of known or potential adverse effects in a given group).\footnote{See, e.g., Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, supra note 6, at 103.}

Risk management is defined as “a process of identifying, evaluating, selecting and implementing actions to reduce risk”\footnote{Presidential/Congressional Commission on Risk Assessment and Risk Management, 1 Framework for Environmental Health Risk Management – Final Report (1997).} and reflects the preferences of a particular society for an acceptable level of risk exposure. Similar language is contained in the documents of international standard setting bodies, which are recognized by the SPS Agreement (Codex Alimentarius Commission (Codex), International Office of Epizootics (IOE) and Secretariat of the International Plant Protection Convention (IPPC)).\footnote{The International Office of Epizootics has changed its name to the World Organization for Animal Health, while the function of the IPPC Secretariat is performed by the FAO’s Secretariat of the International Plant Protection Convention.} The Codex definition provides that risk management is a process “distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.”\footnote{Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, supra note 6, at 47.} Risk management is also recognized as an integral part of pest risk analysis.\footnote{Guidelines for Pest Risk Analysis, supra note 8, at 5.} IPPC defines risk management as “an evaluation and
selection of options to reduce the risk of introduction and spread of a pest.”

Finally, according to the OIE Terrestrial Animal Health Code, risk management is a “process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.” Again, management is considered as an indispensable part of risk analysis. Despite different wording, all international standard setting bodies recognize that risk management is a distinctive process from risk assessment and is comprised of the regulatory decisions on how to deal with particular risk (evaluation of alternatives and subsequent selection of a measure). The aim of this functional separation between risk assessment and management is to protect the scientific integrity of the risk assessment by distinguishing scientific findings from value judgments. The panel in EC – Hormones captured that essence of risk management when it said that “once the risks have been assessed, i.e., once the risks and their probability of occurrence identified, a Member will need to decide [what SPS measures to adopt], on the basis of its own value judgments.”

Of course, the above does not mean that risk assessment is absolutely free from value judgments. Due to uncertainty inherited in the scientific research, scientists are frequently forced to adopt nonscientific assumptions in the process of risk assessment. What weight should be assigned to positive and negative studies? What is the statistical significance? Can uncertainties be addressed through conservative assumptions/safety factors or rather through additional research? These may not have absolute answers and non-scientific judgments need to enter the process. Thus, the separation between risk assessment and risk management should be seen as a quest for minimizing the role of value judgments in risk assessment rather than an attempt to establish strict distinction.

15 World Organization for Animal Health, supra note 6, § 1.1.1.1.
16 Id.
17 Id. § 1.3.2.1; Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, supra note 6, at 102; Guidelines for Pest Risk Analysis, supra note 8, at 5.
18 Panel Report, European Communities – Measures Concerning Meat and Meat Products (Hormones) (Complaint by the United States), ¶ 8.160, WT/DS26/R/USA (Aug. 18, 1997) [hereinafter EC-Hormones (U.S.) Panel Report], modified by Appellate Body Report, European Communities – Measures Concerning Meat and Meat Products (Hormones), WT/DS26, 48/AB/R (Jan. 16, 1998) [hereinafter EC-Hormones Appellate Body Report]. Note, however, that the panel’s statement is imprecise as the notion of risk under the SPS Agreement encompasses already probability or possibility (Annex A(4) of the SPS Agreement); thus, the panel should have rather used the notion of hazard (source of potential damage, harm or other adverse effects which together with probability of occurrence constitutes risk) than risk.
20 There are some authors who argue against distinction between risk assessment and management, claiming that it is “neither feasible nor appropriate to separate science policymaking into a purely technical phase and a political phase,” David Winickoff et al., Adjudicating the GM Food Wars:
Risk management is composed of four elements or phases: risk evaluation, options evaluation, implementation of decision, and monitoring and review. The first phase consists of an evolution of risk assessment results in the light of appropriate level of protection (ALOP). Establishing ALOP is a part of risk management as it reflects societal values and preferences towards particular risk. ALOP may be pre-existing (if already decided with respect to same or similar risk) or determined on this stage. The risk evaluation phase determines whether any regulatory action is required or not (i.e. identified risk is above or below particular ALOP). If the answer is positive, during the second phase, available risk management options are identified (e.g. sale prohibition of particular product, establishing tolerable level of a particular substance in a product, requiring appropriate label) and evaluated with regard to their efficacy and feasibility. This phase usually requires involvement of risk assessors who provide data on technical aspects of available options, including information on the extent to which a particular alternative reduces likelihood and magnitude of identified risks. The task of risk managers is to compare those different alternatives, confronting their efficacy with potential societal, operational and economic costs and benefits (that may include assessment of social, commercial and environmental impact of proposed measures). ALOP may be modified during this phase due to the costs or other problems related to regulatory action. On that basis risk managers decide on further actions, which may result in implementation of an SPS measure (phase 3). The last phase can be described as the ongoing process of monitoring and reviewing of a measure. The aim is to adapt a measure to changing circumstances and to improve its operability.

Finally, risk communication is understood as the two-way “flow of information and risk evaluation . . . between academic experts, regulatory practitioners, interests groups, and the general public.” In the context of the SPS Agreement, that also includes trading partners which may be

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21 World Organization for Animal Health, supra note 6, § 1.3.2.6.; Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, supra note 6, at 107; Guidelines for Pest Risk Analysis, supra note 8, at 10-12 (identifying three steps of risk management – option evaluation, selection, monitoring and evaluation, while risk evaluation is included in the phase of option evaluation).

22 For a very interesting discussion on complexities involved in the interactions between different actors in the process of risk analysis, see Winickoff et al., supra note 20, at 96-104.

23 William Leiss, Three Phases in the Evolution of Risk Communication Practice, 545 ANNALS 85, 86 (1996). Note that there are also one-way definitions of risk communication where information flew only from risk assessors to risk managers, see Baruch Fischhoff, Risk Perception and Communication Unplugged: Twenty Years of Process, in THE EARTHSNAP READER IN RISK AND MODERN SOCIETY 133-45 (Ragnar Löfstedt & Lynn Frewer eds., 1998).
affected by particular national SPS decision. Risk communication has an objective dimension (information on facts) and subjective one (information of judgments and decisions). The aims of risk communication are multiple.

It enables provision of the initial information on potential hazards from general public and risk managers to risk assessors, information exchange between scientists, transmission of the information on the outcomes of risk assessment (both to general public and governmental authorities) as well as the information on the results of the applied risk management policies (again to general public and risk assessors). Risk communication is helpful in increasing the trust and support of the general public for regulatory decisions in the particular area of risk, along with improving the quality and legitimacy of risk decisions. Finally, it may assist in avoiding defects in agenda setting (selecting those risks which should be addressed, and establishing their priority according to different criteria such as public preferences for risk exposure, potential seriousness of risks etc.).

The table below presents a diagram of risk analysis process.

### Table 1

<table>
<thead>
<tr>
<th>Risk Analysis Process</th>
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<tr>
<td><strong>Initiation of the Risk Analysis Process</strong> (by risk managers)</td>
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<tr>
<td><strong>Risk Assessment Phase:</strong></td>
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<tr>
<td>- hazard identification</td>
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<td>- hazard characterization</td>
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<td><strong>Risk Management Phase:</strong></td>
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<td>- risk evaluation</td>
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<td>- options evaluation</td>
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<td>- implementation</td>
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<tr>
<td>- monitoring and review</td>
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<tr>
<td><strong>Risk Communication - ongoing exchange of information between scientists, risk managers, interest groups and general public</strong></td>
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The SPS Agreement explains risk assessment disciplines extensively, defining assessment as an “evaluation of the likelihood of entry,

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24 The notion of risk communication is not used in the SPS Agreement; nevertheless such provisions are easily identifiable. See, e.g., SPS Agreement art. 7, Annex B & Annex C.
25 Winickoff, et al., supra note 20, at 101 (“[S]cientific risk assessment necessarily involves the prior selection of the objects of analytic attention, reflecting what is collectively valued and thus worthy of possible protection.”).
establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures, which might be applied, and of the associated potential biological and economic consequences” (quarantine risks) or as 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” (food-borne risks). The SPS Agreement stipulates that unless the measures conform to international standards, the scientific justification (Article 3.3) presumably in the form of a formal risk assessment is required (Article 5.1). The SPS agreement also enumerates the elements, which need to be included in the risk assessment process (Article 5.2-5.3). In case of insufficient scientific data, SPS measures may be taken provisionally on the basis of available pertinent information (Article 5.7).

As opposed to risk assessment, the SPS Agreement does not explicitly refer to the notion of risk management and risk communication. Nevertheless, the substantive analysis of its content reveals that there are numerous provisions, which discipline national risk management activities, as well as the process of risk communication vis-à-vis other WTO Members. As far as risk communication is concerned, Article 7 (obligation to notify changes in national SPS regulations) and Annex B (transparency of SPS regulations – both in the process of their adoption and implementation) may serve as good examples. The risk management disciplines of the SPS Agreement are presented in the subsequent parts of this article.

III. WHAT THE APPELLATE BODY SAID AND DID NOT SAY IN EC-HORMONES

The distinction between risk assessment and risk management appeared in the SPS case law for the first time in the EC-Hormones panel report. As noted by the panel, Article 5 of SPS Agreement addresses two aspects of the national decision-making process. The first one is risk assessment – “a process of assessment of potential adverse effects (if any) related to a specific substance . . . together with the probability of occurrence of any such effects,” the second one provides disciplines with respect to risk management. That aspect relates to the determination by a

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26 SPS Agreement Annex A ¶ 4.
27 Id.
WTO Member of appropriate level of SPS protection and subsequent implementation of SPS decision. The panel characterized risk management as a non-scientific process, which involves social value judgments.\(^{30}\) According to the panel “once the risks have been assessed, . . . a Member will need to decide, on the basis of its own value judgments, whether it can accept these risks. In so doing a Member sets its ‘appropriate level of sanitary protection’.”\(^{31}\) The obligations, which are particularly relevant in this respect, are those included in Articles 2.2-2.3 and 5.4-5.6 of the SPS Agreement.\(^{32}\) These provisions impose legal obligations as to how a WTO Member may react to risks identified by risk assessment, establishing limits on the possible responses to those risks.

The Appellate Body, when addressing the above findings of the panel, used somewhat unfortunate language. It rejected the distinction between risk assessment and risk management, finding no textual basis in the Agreement. It is worth citing the finding of the Appellate Body in full:

> the Panel observed that an assessment of risk is, at least with respect to risks to human life and health, a “scientific” examination of data and factual studies; it is not, in the view of the Panel, a “policy” exercise involving social value judgments made by political bodies. The Panel describes the latter as “non-scientific” and as pertaining to “risk management” rather than to “risk assessment”. We must stress, in this connection, that Article 5 and Annex A of the SPS Agreement speak of “risk assessment” only and that the term “risk management” is not to be found either in Article 5 or in any other provision of the SPS Agreement. Thus, the Panel's distinction, which it apparently employs to achieve or support what appears to be a restrictive notion of risk assessment, has no textual basis. The fundamental rule of treaty interpretation requires a treaty interpreter to read and interpret the words actually used by the agreement under examination, and not words which the interpreter may feel should have been used.\(^{33}\)

Did the Appellate Body really remove the concept of risk management from the SPS Agreement? This article argues that despite the above findings, it is legitimate to use this notion within the SPS Agreement. First, note that the interpretation of the Appellate Body did not really reject the

\(^{30}\) _Id._ ¶ 8.160.

\(^{31}\) _Id._

\(^{32}\) _Id._ ¶ 8.96.

distinction under the SPS Agreement. Secondly, even if this is not true, the current practice in international and national risk regulation justifies such conceptualization of the SPS Agreement. This argument is particularly relevant due to the fact that all the standard-setting bodies, which are explicitly referred to in the SPS Agreement, recognize risk management as fundamental element of international risk regulation.

As far as the first argument is concerned, note that the Appellate Body rejected the distinction between risk assessment and management because it resulted, under the panel’s analysis, in restrictive formulation of risk assessment, excluding “all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences.” According to the Appellate Body “the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effect on human health in the real world where people live and work and die.” The practical effect of the panel approach was the exclusion from risk assessment, the evaluation of risks which were related to possible abuse of hormones in agricultural practice (non-observance of good veterinary practices). The panel believed that these risks were to be taken into account in the risk management phase. Moreover, the panel disregarded certain reports of the European Parliament, finding that they only evaluated other scientific reports and, consequently, constituted a part of risk management considerations. These reports also analyzed the problem of abusive administration of hormones in the American agriculture sector.

It is not difficult to agree with the findings of the Appellate Body that the definition of risk assessment under the SPS Agreement is sufficiently broad to cover assessment of risks resulting from the non-observance of good veterinary practice. In fact, that can be done only in the risk assessment process (either as a separate assessment or as an element of the

34 Contra Winickoff et al., supra note 20, at 98 (arguing that the refusal to distinguish risk management and risk assessment was a deliberate decision of the Appellate Body). The author, for the reasons discussed in this section of the article, cannot agree with such an interpretation.


36 Id.


39 Interestingly, the Appellate Body found that those reports did constitute neither scientific evidence nor risk assessment, and in consequence could not constitute a basis for an SPS measure, see EC-Hormones Appellate Body Report, supra note 18, ¶ 207.

40 Article 5.2 provides that risk assessment shall take into account “scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest - or disease - free areas; relevant ecological and environmental conditions; and quarantine or other treatment.”
original risk assessment). The risks resulting from the abuse of hormones in agricultural practice are the same as other types of risks and need to be first assessed in the risk assessment process. The risk management phase would only address the questions of whether and how to deal with such identified risks. Thus, the finding of the Appellate Body on the scope of risk assessment is correct. The reservations made by the Appellate Body with respect to risk management should be seen in this context. In consequence, The statement of the Appellate Body is not a rejection of the concept of risk management under the SPS Agreement, but rather a dismissal of restrictive (and in fact incorrect) formulation of risk assessment by the panel. In short, what the Appellate Body did not like was a restrictive notion of risk assessment and not the distinction itself.

There are some additional arguments, which support recognition of the risk management disciplines under the SPS Agreement. First, it facilitates to reconcile the text of the Agreement with the documents of the international standard-setting bodies. As discussed above, all the standard-setting bodies identified in the SPS Agreement rely in their work on the risk analysis paradigm, a paradigm that recognizes risk management as an indispensable part of regulatory actions. Second, the distinction between risk assessment and risk management also helps to better understand the disciplines of the SPS Agreement, as it reflects the common practice in the area of risk regulation.41 Third, the substantive analysis of the SPS Agreement, as presented below, shows that risk management disciplines can be easily identified in the Agreement. These provisions establish a number of requirements with respect to risk and options evaluation, implementation of risk decision, monitoring and review, the elements that are commonly identified as risk management. Note also that introduction of the concept of risk management to the SPS Agreement is neutral for WTO Members. It does not change the balance between the rights and obligations, but rather it helps to conceptualize SPS disciplines in a clear and consistent manner. Finally, the current scholar discussion seems to concentrate on risk assessment (Article 5.1 – 5.3), while the rest of the analysis under the SPS Agreement does not receive proper consideration. This is also reflected in case law where the focus has been mainly, though not exclusively, on Article 5.1-5.3. Thus, reintroducing a distinction between risk assessment and risk management may also be helpful in highlighting the importance of other provisions of the SPS Agreement.42

41 See, e.g., Molak, supra note 6; Presidential/Congressional Commission on Risk Assessment and Risk Management, supra note 10, at 1.
42 Thanks to Prof. Scott for drawing my attention to this aspect.
IV. THE SPS AGREEMENT AND RISK MANAGEMENT DISCIPLINES

Different provisions of the SPS Agreement set requirements with respect to national risk management decisions. First, the SPS Agreement confirms the right of WTO Members to set level of SPS protection, which they deem appropriate. That right is not absolute as Members shall “avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.” Members should also “take into account [when establishing ALOP] the objective of minimizing negative trade effects.” Second, in the case of quarantine risks there is a need, before the adoption of the final measure, to evaluate the efficacy of different SPS alternatives. Simultaneously, Members are obliged to supply both the WTO Secretariat and their trading partners with the information on contemplated measure, engage in the discussion and take into account comments and observations of other WTO Members. Third, a final SPS measure needs to be rationally related to the outcome of risk assessment and scientific evidence as well as applied only to the extent that is necessary to protect human, animal, or plant life or health. It cannot be “more trade-restrictive than required to achieve . . . appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.” Fourth, a WTO Member needs to guarantee that no SPS measure is maintained without sufficient scientific evidence. That requires review of a measure in case of new scientific evidence.

When one confronts the above provisions with the definitions of risk management, it is clear that the SPS Agreement introduces certain obligations on national regulatory responses that fall into the risk management phase. It sets disciplines on the establishment of ALOP, option evaluation, implementation of the risk-reducing actions and potential review of SPS measures. As noted above, all those elements can be identified as risk management actions. The analysis below attempts to systematize those SPS provisions and corresponding case law.

A. Establishing the Appropriate Level of Protection

An ALOP is defined in the Annex A of the SPS Agreement as the level of protection deemed appropriate by a WTO Member introducing an SPS measure to protect human, animal or plant life or health within its territory. An ALOP determines how much risk is acceptable for a particular Member.

43 SPS Agreement arts. 3.3, 4.1, 5.4, 5.5, 5.6 & Annex A ¶ 5.
44 SPS Agreement art. 5.5.
45 SPS Agreement art. 5.4.
46 SPS Agreement art. 5.6.
It can therefore be understood as the highest level of risk that a country is prepared to tolerate. In its preamble the SPS Agreement explicitly states that this right is a prerogative of WTO Members. In the same line, the language in the Annex A of the SPS Agreement (specifically the phrase “deemed appropriate by the Member”) confirms that it is an independent right of Members. Other provisions of the SPS Agreement aspire to the same goal. This explicit language of the Agreement is also reflected in the case law. The Appellate Body has confirmed on several occasions that a Member has considerable discretion in setting its level of SPS protection. This implies that WTO Members may “trade off health values from other social values (including economic welfare).” On the other hand, it is not clear whether the above statement is true with respect to risks to animal or plant life and health (quarantine risks). Note that Article 5.3, which is applicable to these types of risk, requires WTO Members to take into account economic factors when determining SPS measures to be applied for achieving their ALOPs. This may imply proportionality between identified risks and SPS measures and restrict the freedom of WTO Members to establish level of protection which they deem appropriate. Although the case law has not yet addressed the issue, there are clues, which suggest that this may not be necessary a case. Note that Article 5.3 use soft language of “taking into account” rather than stronger expression “to base on”. As observed by the Appellate Body, “taking into account” may be understood as referring “to some subjectivity which, at some time, may be present in particular individuals but that, in the end, may be totally rejected by those individuals.” Thus, Article 5.3 can be understood not as requiring proportionality but rather as an obligation of more informed decision where different factors (including economic considerations) are evaluated by risk managers. This interpretation will be also compatible

47 Sixth paragraph of the preamble of the SPS Agreement provides that “[d]esiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards . . . without requiring Members to change their appropriate level of protection of human, animal or plant life or health” (emphasis added).

48 See, e.g., SPS Agreement art. 3.3 (allowing WTO Members to introduce and maintain measures that result in a higher level of SPS protection than would be achieved if based on the international standards); see also id. arts. 4.1, 5.4, 5.5, 5.6 & Annex B ¶ 3.


51 Article 5.3 specifically provides that “in assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks”.

52 EC-Hormones Appellate Body Report, supra note 18, ¶ 189.
with the general approach of the case law, which grants considerable discretion to WTO Members in this respect. In consequence, it may be legitimately argued that the SPS Agreement provides significant freedom to WTO Members in defining the level of risk (including quarantine risks), which is acceptable for them.

The SPS Agreement implicitly obliges WTO Members to positively determine their ALOP.\(^{53}\) Positive determination does not mean that an ALOP needs to be determined in quantitative terms (e.g. 1:1,000), since qualitative determination is also possible (e.g. low, moderate, high, conservative).\(^{54}\) The case law adopted rather liberal approach with respect to that obligation. First, a mere statement of a WTO Member in a panel proceeding seems to satisfy the requirement of positive determination.\(^{55}\) However, as discussed below, this leads to peculiar consequences for the application of Article 5.6. Second, lack of (or imprecision in) determination does not constitute a violation of the SPS Agreement. The only consequence is possibility of performing such determination by a panel. In the words of the Appellate Body, “in cases where a Member does not determine its appropriate level of protection, or does so with insufficient precision, the appropriate level of protection may be established by panels on the basis of the level of protection reflected in the SPS measure actually applied.”\(^{56}\)

This approach is plausible as it allows the panel to perform an examination of a measure under those provisions of the SPS Agreement, which require pre-assessment of an ALOP.

1. ALOP and an SPS Measure. — A distinction needs to be made between an ALOP and an SPS measure. The former is an objective, while the latter is an instrument used to attain or implement that objective. As noted by the Appellate Body, “determination by a Member of the ‘appropriate level of protection’ logically precedes the establishment or decision on maintenance of an SPS measure.”\(^{57}\) Thus, under the SPS Agreement, ALOP is a benchmark that is external to an SPS measure. The measure itself also reflects a certain level of protection (e.g. import ban reflects zero-risk level). In the majority of cases these two levels are the same, meaning that an SPS measure reflects ALOP. However, that does not necessarily need to be the case. As noted by the Appellate Body “to imply the appropriate level of protection from the existing SPS measure would be to assume that the measure always achieves the appropriate level of protection determined by the Member. That clearly cannot be the case.”\(^{58}\)

\(^{53}\) Australia-Salmon Appellate Body Report, \textit{supra} note 49, ¶ 206.

\(^{54}\) \textit{Id.}

\(^{55}\) \textit{Id.} ¶ 197.

\(^{56}\) \textit{Id.} ¶ 207.

\(^{57}\) \textit{Id.} ¶¶ 200-01.

\(^{58}\) \textit{Id.} ¶ 203.
As a result, the level reflected in an SPS measure can be lower than the ALOP. According to the Appellate Body the opposite situation, when a level of protection reflected in a measure is higher than ALOP, is also possible. That was a case in Australia – Salmon, where the ALOP was described by Australia as conservative while the SPS measure under examination adopted zero-risk level. Although the Appellate Body did not find such situation to be incompatible with the provisions of the SPS Agreement, arguably it will be easier for a complainant to establish in such circumstances prima facie case of violation of Article 2.2 and 5.6. This results from the fact that under both provisions the relevant benchmark for assessment of SPS measures is ALOP (in other words, the questions is whether alternatives to a measure achieve ALOP and not a level of protection reflected in a measure). Finally, note that ALOP will be the same as the level of protection reflected in a measure in all these situations when a Member does not determine an ALOP, or does not do so with sufficient precision. In such cases, an ALOP is established by a panel on the basis of the level of protection reflected in an SPS measure.

The conceptualization of ALOP as something external to an SPS measure, while accepting that a simple statement of a WTO Member in a panel proceeding on its ALOP is sufficient, leads, however, to a strange outcome. Note that such interpretation encourages a defendant to claim existence of higher ALOP than the one which is reflected in a measure, as it makes it more difficult for a claimant to establish a violation of Article 5.6. This results from the fact that Article 5.6 refers to ALOP and not to the level of protection reflected in a measure. The consequences of this are completely illogical. The complainant may identify a reasonably available and significantly less restrictive alternative that reflects the same level of protection as a contested measure, and still fail the test because such an alternative does not achieve a Member’s ALOP. The possible solution would be to assume that a level of protection reflected in a measure is at least as high as ALOP. This, however, was explicitly rejected by the Appellate Body.

2. Minimizing Negative Trade Effects (Article 5.4). — Article 5.4 provides that WTO Members should, when determining an ALOP, take into account the objective of minimizing negative trade effects. On the textual level, Article 5.4 may be interpreted in different ways. One may, for example, argue that it provides for a procedural obligation, requiring WTO Members to consider the impact of the SPS measure on international trade, when determining their ALOPs. The notion “take into account” indicates

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59 *Id.* ¶ 197.
60 *Id.*
61 Article 5.4 has received very little attention in the case law. Complainants, probably discouraged by the findings of the panel in *EC–Hormones* never after argued the violation of Article 5.4.
that such an objective only needs to be considered, and that it does not need to be reflected in the final level of protection. Such understanding seems to be advisable. It does not require Members to compromise its health goals with the economic costs, and at the same time guarantee more informed decision, where the trade impact is also taken into account. Nevertheless, when examining Article 5.4 in the first SPS dispute, the panel decided to adopt a more lenient interpretation. It applied an over-textual interpretation and stated that “guided by the wording of Article 5.4, in particular the words ‘should’ (not ‘shall’) and ‘objective’, we consider that this provision of the SPS Agreement does not impose an obligation.”62 The panel added that the objective prescribed by Article 5.4 could only be taken into account as part of the analysis under other SPS provisions. It is not, however, clear which provisions the panel meant. The determination of an ALOP is not mitigated under the SPS Agreement by any economic considerations. Consequently, whether a WTO Member actually took into account the objective of minimizing negative trade effects is irrelevant and the panel’s statement seems to have no legal implications. Note also that the interpretation adopted by the panel seems to be incompatible with the principle of effective treaty interpretation, already recognized in the previous WTO case law.63 This principle requires that meaning should be given to every provision of the agreement. A reading of Article 5.4, which deprives it of any legal relevance, can be hardly seen as reaching that standard.


3. *Weak Consistency (Article 5.5).* — The right to establish ALOP is not absolute as Article 5.5 requires WTO Members to address similar or same risks in a consistent manner. An inconsistent approach is still possible, however, only if it is not arbitrary or there is justification for such inconsistency. In consequence, Article 5.5 does not impose what is sometimes incorrectly referred to as the requirement of full consistency. It is a goal to be achieved in the future rather than an actual legal obligation on WTO Members. As noted by the Appellate Body, “governments establish their appropriate levels of protection frequently on an *ad hoc* basis and over time, as different risks present themselves at different times, it is difficult to require a full consistency.”\(^{64}\) Thus, the requirement of Article 5.5 is more modest, as it only prohibits arbitrary and unjustifiable inconsistencies.\(^{65}\) If the difference of ALOPs in two situations is not arbitrary or can be justified there will not be violation of Article 5.5. In its second part, Article 5.5 requires WTO Members to cooperate in the SPS Committee for the purpose of developing guidelines for the practical implementation of the consistency requirement. On that basis, the SPS Committee adopted the Guidelines to Further the Practical Implementation of Article 5.5 (Guidelines).\(^{66}\) The document is discussed briefly in the next Section.

The Appellate Body interpreted Article 5.5 as providing for three elements that need to be demonstrated in order to establish its violation. As noted by the Appellate Body, the test under Article 5.5 has a cumulative character, meaning that all the elements need to be proved by the complainant. These are: (i) different ALOPs in different, but comparable, situations, (ii) these differences are arbitrary or unjustifiable, and (iii) they result in discrimination or in a disguised restriction on international trade.\(^{67}\) The analysis below discusses each element in more detail.

The task, under the first element, is twofold. First, it is necessary to select a comparator (a “different situation”) against which the comparison will be made. Secondly, an ALOP in a situation under the examination and a situation that is compared needs to be ascertained. The different situations were understood as situations with some common element(s). As observed by the Appellate Body, such understanding was required by the logic since “if the situations proposed to be examined are *totally* different from one another, they would not be rationally comparable and the differences in levels of protection cannot be examined for arbitrariness.”\(^{68}\) The case law

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\(^{64}\) EC-Hormones Appellate Body Report, *supra* note 18, ¶ 213.

\(^{65}\) *Id.*

\(^{66}\) Committee on Sanitary and Phytosanitary Measures, *Guidelines to Further the Practical Implementation of Article 5.5*, G/SPS/15 (July 18, 2000) [hereinafter Guidelines].

\(^{67}\) EC-Hormones Appellate Body Report, *supra* note 18, ¶ 214.

\(^{68}\) *Id.* ¶ 217.
refrained, however, from stating in general terms what makes two situations comparable. Both, panels and the Appellate Body, instead preferred a case-by-case approach. To date, the following elements have been considered as making different situations comparable: (i) presence of the same substance, (ii) presence of the same adverse health effect (e.g. carcinogenicity),69 (iii) risk of entry, establishment or spread of the same or a similar disease, (iv) the same or similar associated potential biological and economic consequences.70 Given the case-by-case approach, the above list is in no way exhaustive and there are other factors which make two situations comparable.71 What also follows from the above is that different products can be compared as long as there is an element which makes them comparable.72 On the other hand, it is not clear whether the scope of points (i) and (ii) was deliberately limited by the panel. The Appellate Body in Australia – Salmon referred both to sameness and similarity while the panel in EC – Hormones limited its observation to the same substance and same adverse health effect. The SPS Agreement does not give the grounds for such limitation. A second part of the analysis requires identification of ALOPs with respect to situations that are compared. It seems that the same rules, as explained above, apply here. Thus, it is for each WTO Member to determine its ALOP – both with respect to the original situation as well as the situation that is used for comparison. The intervention of the panel is only justified if such ALOP has not been determined or it has been established without sufficient precision.

In this context, it is interesting to ask whether man-made risks and naturally occurring risks can be considered as comparable situations. Note that neither ordinary people nor regulatory practice treats these two types of risk as comparable. As discussed below, lay people tend to consider man-made risks as more dangerous, while regulators, responding to differences in risk perception, frequently adopt different regimes for these two types of risk. Despite this, the case law adopted a broad understanding of what is suitable for comparison.73 This confirms strong reliance of the WTO

70 Australia-Salmon Appellate Body Report, supra note 49, ¶ 146.
71 It was also argued that the comparison may be made only between affirmative measures, or in other words “occasions where the member has actively regulated,” Atik, supra note 50, at 485.
72 Different panels compared the levels of protection in the following situations: natural hormones used as growth promoters as opposed to the same hormones when used for therapeutic or zootecchnical purposes, natural hormones for growth promotion as opposed to the same hormones occurring endogenously in meat and other foods, natural and synthetic hormones for growth promotion as opposed to carbadox and olaquindox (EC-Hormones), the salmon products as opposed to uncooked Pacific herring, cod, haddock, Japanese eel and plaice for human consumption, salmon products as opposed to uncooked Pacific herring, Atlantic and Pacific cod, haddock and European eel for human consumption, salmon products as opposed to herring in whole, frozen form for use as bait and salmon products as opposed to live ornamental finfish (Australia – Salmon).
73 E.g., EC-Hormones Appellate Body Report, supra note 18, ¶¶ 216-18.
adjudicating bodies on the technical paradigm, as what is important under this paradigm is the probability of harm resulting from exposure to the substance, and is not the source of hazard. The Guidelines also take a similar position by stating that “categorizing risks as ‘similar’ must include a comparison of both the relevant likelihoods and the corresponding consequence,” without indicating source as a relevant factor. Note, however, that the popular perception of risk (including the distinction between man-made and naturally occurring risks) can be taken into account under the second condition of Article 5.5.

The second element requires that differences in levels of protection in the comparable situations are arbitrary or unjustifiable. The case law does not distinguish between two parts of the alternative and both elements are considered together. Note also that the SPS case law provides neither clear criteria for the evaluation of arbitrariness nor lack of justification. As observed by Hurst, the Appellate Body’s analysis in EC – Hormones shows that “the inquiry into whether differences are arbitrary or unjustifiable is purely subjective; the result will turn entirely on the body making the evaluation.” The same unprincipled approach was also taken in Australia – Salmon. This is not surprising, since the case law under GATT 1994 has also failed to establish clear criteria, preferring a case-by-case approach. The most general observation which can be made is that a WTO Member needs “to be able to ‘defend’ or convincingly explain the rationale for any discrimination.”

Closer examination of the case law reveals that making a prima facie case with respect to the second element is not very demanding task, since a statement by a claimant supported by limited evidence seems to fulfill the requirement. Consequently, a defendant should be prepared to present evidence that the differences are not arbitrary or that there is a justification for them. What, then, serves as a possible justification for the distinction? According to the case law, the extent of regulatory action is relevant. That

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75 Guidelines, supra note 66, ¶ A.4.
78 Panel Report, Brazil – Measures Affecting Imports of Retreaded Tyres, ¶ 7.260, WT/DS332/R (June 12, 2007) [hereinafter Brazil-Tyres Panel Report]; of course under the SPS Agreement the burden of proof shifts to defendant only after the claimant establish prima facie case of inconsistency.
80 EC-Hormones Appellate Body Report, supra note 18, ¶ 221 (finding that to require prohibition of the production and consumption of food containing naturally occurring hormones or to limit
is, the more governmental intervention is required, the lesser chance that differences in levels of protection in the comparable situations will be arbitrary or unjustifiable. Another factor, which is important is higher risk from the products in question as opposed to products being compared.  

An interesting issue in this context is whether public perceptions of particular risks (including differences between man-made risks and naturally occurring risks) may serve as a justification. The European Communities raised this argument in EC – Hormones, but the Appellate Body did not address the issue. As indicated by the different sociological and psychological studies, human perception of risk may differ from the assessment of technical experts. Risks that are highly ranked by experts can be disregarded by laypersons. The opposite is also true; risks which, according to the experts are unlike, can generate great public concern. The risk science identified a number of factors that influence the assessment of risk by laypersons. That availability is heuristic, which can be defined as the ease with which an instance is brought to mind. Events that can be easy recalled by a person (e.g. due to personal experience, media coverage) are considered to be more likely than those that are harder to recall. Similarly, the source of risk plays an important role in man-made risk (e.g. environmental pollution) and is considered to be more serious than naturally occurring risk (e.g. floods). Yet another factor is controllability – risks that are viewed as controllable (e.g. driving a car) are perceived as less serious and less likely to materialize into harm than risk with respect to which there is no perceived control (e.g. risks from genetic modifications). As many of those factors are culturally related, it is not surprising to see differences in the risk perception between different nations. Thus, Europeans seem to be more concerned with the potential consumption of such foods “entails such a comprehensive and massive governmental intervention in nature and in the ordinary lives of people as to reduce the comparison itself to an absurdity”).

81 But see Atik, supra note 50, at 485 (arguing that those two situations are not comparable rather than arbitrary and without justification). Note, however, that the Appellate Body finding was made in the context of the second element of Article 5.5 and not the first one.


83 EC-Hormones Appellate Body Report, supra note 18, ¶ 33.


risks connected with genetic modifications while Americans tend to overestimate cancer risks.  

Without deciding whether perception of risk by laypersons is a psychological deficiency or rather a rival rationality to scientific discourse, it seems advisable to accept it as a justification for a distinction in ALOPs. As perceived risk needs to be genuine (otherwise it would fail the test of a scientific basis as provided in Article 2.2 and 5.1), there are no compelling reasons against such approach. Note also that an ALOP itself reflects the preferences of a particular society for the level of risk exposure and the differences in these preferences should be relevant in the context of the SPS Agreement. Moreover, the SPS Agreement explicitly recognizes that risk to which people voluntarily expose themselves should be treated differently. It is not clear whether the SPS Agreement considers such situations as unsuitable for comparison or rather as justified divergence. The text of Guidelines may suggest that the second understanding is to be preferred. According to the Guidelines, WTO Members should identify those situations which justify their acceptance of the lower level of protection. Similarly, the Guidelines speak about “reasons for a significant difference in . . . accepted level of protection.” These terms indicate that any difference needs to be justified, rather than exclude the possibility of comparison. The Guidelines, elaborating on this issue, enumerate certain such risks (i.e. “consumption of alcoholic beverages, or substantial consumption of some traditional foods such as smoked fish, or of varieties of fish known to be toxic). That clearly indicates that perception of risk finds its recognition under the SPS Agreement. Finally, acceptance of cultural differences in risk perception as possible justification may also serve as a legitimizing factor of the WTO dispute settlement system. As noted in the literature, disregard of the popular perception of the risk may “endanger public support for the trade regime” in general. 

Nevertheless, it is difficult to predict the future case law on this issue. On the one hand, the conceptualization of risk assessment, which excludes cultural factors as legitimate grounds for SPS measures, may suggest that they will also be irrelevant in the justification of the distinction. On the other hand, the language of Article 5.5 seems to be open for broader interpretation than in the case of Article 5.1, while there are strong

89 The relevant part of Article 5.5 provides that “[t]he guidelines are designed to take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.”
90 Guidelines, supra note 66, ¶ A8.
92 SCOTT, supra note 82, at 101; Gruszczynski, supra note 28, at 384.
arguments for such inclusion. It remains to be seen which way will be chosen by the Appellate Body.

The third element of the test under Article 5.5 requires that the distinction needs to result in discrimination or a disguised restriction on international trade. According to the Appellate Body, the third condition refers “to the measure embodying or implementing a particular level of protection . . . resulting, in its application, in discrimination or a disguised restriction on international trade.”93 In other words, it is an application of a particular SPS measure, which needs to result in discrimination or a disguised restriction on international trade. On the textual level, the third condition has two distinctive dimensions. On the one hand, the examination of disguised restriction arguably involves the question of intent of the party imposing the measure. On the other hand, an examination whether a distinction in levels of protection results in discrimination, involves an objective test. As correctly noted by Hurst, “while one can objectively assess whether a measure creates a ‘restriction on international trade,’ whether or not such a restriction was ‘disguised’ is a matter of intent.”94

Does the case law reflect this textual interpretation? The answer is not an easy one. In EC – Hormones the Appellate Body considered both requirements of the third element in one analysis without distinguishing its objective and subjective dimension. Nevertheless, both elements were present.95 In the subsequent case (Australia – Salmon), the panel and Appellate Body concentrated only on the notion of “disguised restriction” and did not address the issue of discrimination per se. At the same time, the analysis was based on so-called warning signals and additional factors. This system, as described below, predominantly relates to the detection of objective discrimination than inquiry into the intent of a party (except from the third warning signal). Thus, it seems that the panels and the Appellate Body disregarded the subjective dimension inherited in the notion of disguised restriction. To complicate the issue further, all the complaining parties in EC – Biotech Products argued, by reference to warning signals and additional factors, the existence of both elements (discrimination and a disguised restriction on international trade), without making any distinction

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93 EC-Hormones Appellate Body Report, supra note 18, ¶ 214. The Appellate Body also characterized that element as the most important one within the test provided by Article 5.5, however, that finding is questionable as the test under Article 5.5 is cumulative one and all elements are equally important, id., ¶ 240.
94 Hurst, supra note 76, at 26.
95 The Appellate Body addressed the question of intent through an analysis of the rationales standing behind the EC measure (protection of EC population health and safety, the necessity for harmonizing internal regulations and the reduction of any beef surplus) and the objective dimension through analysis (very limited) of the structure of the EC directive; EC-Hormones Appellate Body Report, supra note 18, ¶¶ 236–46.
between them.\textsuperscript{96} Thus, it is far from clear how those concepts should be understood under Article 5.5 and whether the provision has indeed the mixed objective-subjective character. The case law decided under Article XX may be helpful in this context: it recognizes that discrimination and disguised restriction are distinct, although related concepts.\textsuperscript{97} The examination of the discrimination consists of the assessment of the treatment of: (i) domestic products as compared to imported ones or (ii) products from different exporting members. On the other hand, there is no uniform interpretation of disguised restriction. In some cases, the analysis under Article XX was based on objective factors\textsuperscript{98} while in others the intent of the party was also examined (together with other factors).\textsuperscript{99} In one of the recent rulings, the panel applied in the examination of disguised restriction the aim and effects test. According to the panel, the examination of disguised restriction includes inquiry into the intent of a Member (whether a measure is, in fact, only a disguise to conceal the pursuit of trade-restrictive objectives)\textsuperscript{100} as well as into the effects of a measure. Nevertheless, the panel was more concerned with the effects of the measure (to what extent the operation of the measure undermines the achievement of the stated objective) than the intent, as it was found a disguised restriction without establishing the intent of the party at all.

Although the general case law is not without ambiguity, it suggests two things for the SPS Agreement. First, discrimination and disguised restriction are distinct concepts having legal meaning. That requires, for the purpose of clarity, the performance of a separate analysis with respect to each of them. Second, the recent developments in the case law (i.e. Brazil – Tyres case) indicate that the intent of the WTO Member is a relevant factor in the examination of the notion of disguised restriction. This, however, does not mean that reconstruction of the intent is necessary for finding a violation. It is rather a helpful element in the analysis of disguised restriction.

As it was mentioned above, the case law, in examination of disguised restriction and discrimination, relies on the system of so-called warning

\textsuperscript{97} US-Gasoline Appellate Body Report, \textit{supra} note 63, at 25 (interrelated obligations, disguised restriction defined as very broad concept); US-Shrimp Appellate Body Report, \textit{supra} note 77, ¶ 184.  
\textsuperscript{98} US-Gasoline Appellate Body Report, \textit{supra} note 63, at 29 (finding disguised restriction without any discussion on the intent of the party).  
\textsuperscript{100} Brazil-Tyres Panel Report, \textit{supra} note 78, ¶ 7.330.
signals and additional factors. In the words of the Appellate Body, the warning signals operate as indirect proof that “a Member may actually be applying an SPS measure in a manner that discriminates between Members or constitutes a disguised restriction on international trade.”\textsuperscript{101} The additional factors perform the same function but they relate to specific circumstances of the case and cannot be easily generalized. The concept warning signals seems to be of general applicability as, having been introduced in \textit{EC – Hormones}, it was also employed in \textit{Australia – Salmon}. It is also important to stress that none of the warning signals (or additional factors) has a decisive character and must be considered cumulatively.\textsuperscript{102} Similarly, not all of the warning signals need to be present in order to establish a violation of the third element of Article 5.5, since in particular circumstances some of them may be more important than the others. Note that, the Appellate Body only stated that warning signals needed to be considered cumulatively and not that they had a cumulative character (in contrast to the analysis of Article 5.5 as whole). It is not clear whether the catalogue of warning signals constitutes a closed list. Arguably, this is not the case. Neither the panel nor the Appellate Body ever used language to indicate the exclusion of other factors as potential warning signals.\textsuperscript{103} Nevertheless, complainants in the subsequent disputes tended to present new factors as additional ones, rather than as other warning signals.\textsuperscript{104}

The first warning signal is “the arbitrary or unjustifiable character of the differences in levels of protection considered by a Member as appropriate in differing situations.”\textsuperscript{105} Note that this warning signal is also the first element of the Article 5.5 test. The Appellate Body, while accepting this factor as relevant, also refused to follow the approach of the panel, which called for the deduction of the discrimination or a disguised restriction on international trade from the difference in levels of protection (the first element) and the arbitrariness (the second element) alone.\textsuperscript{106} According to the Appellate Body, such an inference is not justified by the language of Article 5.5.

The second warning signal is a degree of difference between ALOPs in situations identified for the purpose of the first warning signal. According to the case law, the difference needs to be “rather substantial”,\textsuperscript{107} which

\textsuperscript{101} EC-Hormones Appellate Body Report, \textit{supra} note 18, ¶ 240.
\textsuperscript{102} \textit{Id.}; Australia-Salmon Appellate Body Report, \textit{supra} note 49, ¶ 177.
\textsuperscript{103} The Appellate Body supplemented in \textit{Australia – Salmon} two warning signals, identified in \textit{EC – Hormones}, with additional one; Australia-Salmon Appellate Body Report, \textit{supra} note 49, ¶ 166.
\textsuperscript{104} See, \textit{e.g.}, First Submission in EC-Biotech (Can.), \textit{supra} note 96, ¶ 219.
\textsuperscript{105} EC-Hormones Appellate Body Report, \textit{supra} note 18, ¶ 215.
\textsuperscript{106} \textit{Id.} ¶¶ 238-39.
\textsuperscript{107} Australia-Salmon Panel Report, \textit{supra} note 79, ¶ 8.150. \textit{See also} Australia-Salmon Appellate Body Report, \textit{supra} note 49, ¶ 164.
excludes *de minimis* situations. Note also that this qualified form of difference (“substantial”) is strengthened even further by the word “rather”. Arguably, this provides for a higher threshold than one that is purely “substantial”. Apart from this observation, it is not clear to what extent of the discrepancy in ALOPs is required to meet the threshold. Note that the case law dealt with rather easy cases of total prohibition *versus* tolerance.

The third warning signal is whether an SPS measure at issue is based on a risk assessment as provided by Article 5.1 and whether it is compatible with Article 2.2 of the SPS Agreement. The rationale behind this warning signal is clear. A lack of risk assessment (no risk assessment, insufficient assessment or no rational relationship between such assessment and an SPS measure) may indicate that a measure is not really concerned with the protection of the life and health of human, animals and plants but “is instead a trade-restrictive measure taken in the guise of an SPS measure.” Note also that this warning signal is close to the notion of disguised restriction understood as having a subjective dimension (the intent of the party).

Apart from three warning signals, there are several other factors which, according to the case law, are helpful in establishing discrimination and disguised restriction (so called “additional factors”). Although these are to be identified in the specific circumstances of the case brought before a panel, they may presumably be generalized. Thus substantial but unexplained change in the conclusions of risk assessments in the absence of new relevant scientific evidence (arguably only if the subsequent conclusions are more stringent) is relevant. Similarly, a difference between the measures applied internally (absence of internal control) as compared to measures applied to the imported products (prohibition) may indicate that the distinction results in violation of the third element of Article 5.5. It has also been argued that a disproportionate effect of the SPS measure on the producers located on the territory of complainant as compared to the producers of the defendant might serve as an additional factor. The panel did not address this argument.

Article 5.5 has had rather surprising effects on trade liberalization. In the compliance proceeding of *Australia – Salmon*, the panel found the new Australian measure to be consistent with the requirements of the SPS Agreement. However, what Australia did, as far as Article 5.5 is concerned,
was to strengthen the requirements with respect to other fish products (the comparators in the original dispute). Thus, as noted by Atik, “the challenge of one SPS measure under Article 5.5 may lead to the imposition of new restrictions on the other imported products – an unexpected result for the free trade regime.”

4. Guidelines to Further the Practical Implementation of Article 5.5. — As it was mentioned above, the SPS Committee, following the disposition of the second part of Article 5.5, adopted the guidelines on practical implementation of the article. The Guidelines, formulated in very general terms, are built upon the existing SPS case law and provide some guidance as to the implementation of Article 5.5. The Guidelines expressly state that they do not affect or modify the existing rights and obligations of the Members under WTO law (including the SPS Agreement). The Guidelines use rather soft language (should and may instead of shall), indicating its non-binding character. Moreover, they are not to be understood as providing any binding interpretation of the SPS Agreement, the task, which according to Article IX:2 of the Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement), is reserved for the Ministerial Conference and the General Council. The above does not mean that the Guidelines do not have any relevance, as acts of the WTO organs such as the SPS Committee are also a source of WTO law and “must be taken into account by panels and the Appellate Body.” Moreover, as they reflect the existing case law, this gives them additional persuasive power.

The Guidelines address two issues, first the consistency between the ALOPs and second, the obligation to avoid arbitrary or unjustifiable distinctions in the levels considered appropriate if such distinctions result in discrimination or a disguised restriction on international trade. As far as the ALOP is concerned, the Guidelines prescribe that levels of protection should be stated in a clear manner, either in quantitative or qualitative terms. However, due to convenience for the purpose of comparison, the Guidelines express a preference for the quantitative approach as well as the employment of common terms or units across different SPS measures.

According to the Guidelines, countries, when setting ALOP (either in a specific situation or as an overall policy objective), should consider and compare this with the existing levels as reflected in other SPS measures. If necessary, the new level should be adjusted or, alternatively, already

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113 Atik, supra note 50, at 483.
114 However, it may be argued that the Guidelines are to be considered as an instrument, which was made by one or more parties in connection with the conclusion of the treaty and, in accordance with the Vienna Convention on the Law of Treaties, bearing the relevance in the interpretation of Article 5.5.
existing levels of protection should be re-evaluated and modified.\textsuperscript{117} In line with the three-prong test adopted by the Appellate Body in \textit{EC – Hormones} and \textit{Australia – Salmon}, when establishing ALOP, countries should consider whether there is a difference between such level of protection and levels already determined in different situations and, if so, whether this difference is arbitrary or unjustifiable and whether it may result in discrimination or in a disguised restriction on international trade.\textsuperscript{118} WTO Members should also identify those situations where they accept a lower level of protection for human health, particularly those risks to which people expose themselves voluntarily.\textsuperscript{119}

The Guidelines also prescribe a number of technical issues relating to the process of determining an ALOP, selection and implementation of SPS measures. Thus, countries should establish proper (“clear and effective”) communication between the competent authorities responsible for determining and implementing ALOP.\textsuperscript{120} The Guidelines advocate establishing “common approaches” or “consistent procedures” for assessing risks and evaluating SPS measures. According to the Guidelines, a common approach should be developed with respect to particular categories of risk, namely risks affecting human life or health, risks to animal life or health, and risks to plant life or health.\textsuperscript{121} Finally, the Guidelines also recommend considering, when determining an ALOP or implementing an SPS measure, the relevant international standards, guidelines or recommendations and measures applied by other WTO Members facing similar risks and situations.\textsuperscript{122}

\textbf{B. Options Evaluation}

The SPS Agreement contains very limited obligations with respect to this phase of risk management. This is not surprising as the Agreement is more concerned with the final outcome of the decision-making process rather than with the process itself. The first thing to be noted is that the SPS Agreement does not impose any general and direct obligation of evaluation of different risk management options. The obligation which exists is more concerned with risk assessment than management and applies only to quarantine risks. The SPS Agreement provides that assessment of quarantine risks needs to “evaluate the likelihood of entry, establishment or spread of these diseases (or pests – LG) according to the SPS measures.

\textsuperscript{117} Id.\textsuperscript{118} Id. ¶ A.2.\textsuperscript{119} Id. ¶ A.8.\textsuperscript{120} Id. ¶ B.1.\textsuperscript{121} Id. ¶ B.2.\textsuperscript{122} Id. ¶ B.5 & B.6.
which might be applied.” 123 The case law adopted rather broad interpretation and demands not only an evaluation for a measure actually applied, but also for other measures that might be potentially applied.124 This means that risk managers need to be supplied with the information on the efficacy of different measures.125 The process of selection between those alternatives is left entirely to WTO Members as the SPS Agreement does not contain any provisions in this respect. Of course, other parts of the SPS Agreement require WTO Members to adopt a measure that is necessary (Article 2.2) and which is the least trade restrictive alternative (Article 5.6). However, these obligations relate to the final measure and not the process of its selection.

The SPS Agreement also requires, with respect to both types of risks, to inform other Members and the WTO Secretariat about proposed regulation. The relevant notice needs to be published at an early stage in such a manner as to enable other countries to become acquainted with the proposal.126 Moreover, WTO Members are obliged to provide the WTO Secretariat with the information on the product coverage, objective and rationale of the proposed regulation.127 The other WTO Members may present their comments and discuss the contemplated measure with the relevant Member who needs to take into account the outcome of these discussions and the comments.128 Although, these obligations fall into category of risk communication, they also have a risk management dimension. First, they create procedural requirements for the evaluation of risk management options by requiring WTO Members to furnish the information to their trading partners and to engage in discussion. Second, the comments and the outcome of discussions can influence the type and the structure of the final measure. Although, the SPS Agreement uses rather soft wording (“take into account”), which indicates that a final SPS measure does not need to reflect the positions of other WTO Members, in practice the concerns of the trading partners frequently find their way in the national regulatory process. In consequence, they may influence the content of a final measure.

123 Id.
125 Surprisingly, there is no equivalent obligation in respect to the assessment of food and feedstuff risks. It is difficult to find any reasons for this, and probably this was just a simple mistake in the drafting process of the SPS Agreement.
126 SPS Agreement Annex B(5a).
127 SPS Agreement Annex B(5b).
128 SPS Agreement Annex B(5d). Note that in case of emergency all these obligations can be waived by WTO Members.
C. Implementation of SPS Decision

Article 2.2 and 5.1 are core risk assessment provisions of the SPS Agreement. Nevertheless, both provisions also consist of a risk management dimension. That particularly refers to: (i) necessity of an SPS measure, (ii) a required relationship between risk assessment/scientific evidence and a measure, and (iii) a permissible basis for an SPS regulation (i.e. which situation can be regulated). Article 2.2 also plays an important role in the last phase of risk management (monitoring and review) by requiring not to maintain an SPS measure without sufficient scientific evidence. Simultaneously, Article 2.3 establishes a general requirement of non-discrimination between different WTO Members (subject to identical or similar conditions) and forbids application of SPS measures in a manner which would constitute a disguised restriction on international trade. Finally, Article 5.6 introduces the least trade-restrictive alternative requirement. All these standards set the limits of risk managers’ discretion in the implementation and the maintenance of risk decisions.

1. Necessity (Article 2.2). — Article 2.2 in its first part requires WTO Members to “ensure that any SPS measure is applied only to the extent that is necessary to protect human, animal or plant life or health” (emphasis added). The SPS case law has not yet addressed this part of Article 2.2. However, the case law decided under Article XX(b) of GATT 1994 can arguably provide useful guidelines in the interpretation. Its relevance is justified by two factors: (i) similar wording of these two provisions and, (ii) the nature of the SPS Agreement, which is explicitly pronounced in its 8th preambular paragraph.

The expression “applied to” suggests that Article 2.2 is more concerned with the application of a measure than the measure itself. The Appellate Body in US – Gasoline, when examining this notion under the chapeau of Article XX, found that the chapeau “by its express terms addresses, not so much the questioned measure or its specific contents as such, but rather the manner in which that measure is applied.” Thus, from the textual point of view, the analysis under the first part of Article 2.2 should be limited to the application of a measure. This would

129 See generally Gruszczynski, supra note 28, at 378-89.
130 But see SCOTT, supra note 82, at 160 (pointing out numerous problems with the use of the case law decided under Article XX of GATT 1994 in the interpretation of Article 2.2 due to systemic differences between these two provisions).
131 The relevant passage provides that one of the aims of the SPS Agreement is “to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).”
132 Note, however, that it may be argued that those terms are different as the SPS Agreement uses the expression “applied only to the extent” while the GATT 1994 refers to “applied in a manner”.
differentiate the scope of application of Article 2.2 from that of Article 5.6, as the latter refers to a single measure alone.\textsuperscript{134} Consequently, these two provisions could be viewed as complementary: that is, Article 2.2 covers the application of a measure, while Article 5.6 applies to a measure as such. Despite this explicit language, the panel in Japan – Agriculture Products II found Article 5.6 to be a more specific formulation of Article 2.2.\textsuperscript{135} The same approach was adopted in EC – Biotech Products, where the panel stated that “Article 5.6 is a specific application of the first obligation provided for in Article 2.2.”\textsuperscript{136} This would imply that Article 2.2 covers both a measure as such as well as its application. There is also a systemic argument, which suggests that both articles are not of a complementary nature. Note that Article 2.2 is included in the provision titled “Basic Rights and Obligations”. That suggests its general nature. On the other hand different subparagraphs of Article 5 were referred to in the case law as specific obligations of WTO Members. It would be natural to follow the same approach in the case of Article 5.6.

According to the GATT 1994 case law, the examination of necessity is a process of weighting and balancing a series of factors.\textsuperscript{137} The case law identified the following: (i) the relative importance of the values furthered by the challenged measure, (ii) the contribution of this measure to the realization of the ends pursued by it, (iii) the restrictive impact of the measure on international commerce.\textsuperscript{138} Obviously, the more important values at stake, the higher contribution of the measure to attaining objectives, and the lesser impact on international trade, make it easier to find the necessity. The second step of the analysis consists in the comparison of a challenged measure with possible alternatives. The aim is to determine whether “a WTO-consistent alternative measure, or a less WTO-inconsistent measure, which the Member concerned could reasonably be expected to employ, is available.”\textsuperscript{139} The three factors identified above also play a role in this determination. Moreover, alternatives that are merely theoretical or impose an undue burden on a

\textsuperscript{134} For detailed discussion on disciplines of Article 5.6, see infra Part IV.A.4.
\textsuperscript{135} Panel Report, Japan – Measures Affecting Agricultural Products, ¶ 8.71, WT/DS76/R (Oct. 27, 1998); Appellate Body Report, Japan – Measures Affecting Agricultural Products, WT/DS76/AB/R (Feb. 22, 1999) [hereinafter Japan-Agriculture II Appellate Body Report] (saying that the more specific language of Article 5.6 should be read in light of the more general language in Article 2.2).
\textsuperscript{139} Brazil-Tyres Panel Report, supra note 78, ¶ 7.104.
Member (prohibitive costs or substantial technical difficulties) are not considered to be reasonably available.\textsuperscript{140}

Does the notion of necessity under Article 2.2 require the examination of all of these factors? It seems that this is not a case. Note that, as far as the first element is concerned, the protection of human life or health is recognized in the case law as vital and important in the highest degree.\textsuperscript{141} Similar high value is assigned to animal or plant life and health.\textsuperscript{142} Thus SPS measures are considered as serving important values and there is no need to further assess that importance under Article 2.2. The examination of the contribution of the challenged measure to the realization of the pursued end (mitigation of risk) also seems to be excluded here as it is already established within the analysis of sufficiency of scientific evidence (second part of Article 2.2 of the SPS Agreement). According to the GATT 1994 case law, that element is demanding as a measure’s contribution needs to be significantly closer to the pole of ‘indispensable’ than to the opposite pole of simply ‘making a contribution to’ the end.\textsuperscript{143} Note that this closely corresponds with rational relationship required from scientific evidence and an SPS measure.\textsuperscript{144} A measure, which does not mitigate a risk (either because there is no risk or a measure is not related to the risk), will fail the rational relationship test. Finally, the restrictive impact of the measure on international commerce, at least in theory, seems to have a limited importance as the SPS Agreement “assumes that there is no compromising of authentic health values under the SPS Agreement.”\textsuperscript{145} In practice, however, the SPS case law seems to engage in some kind of proportionality analysis, which confronts the restrictiveness of the measure with the risks at stake. As it is discussed below, if a measure is disproportionate to identified risk, no rational relationship between a measure and scientific evidence will be found.

This article argues that the necessity test, as provided by Article 2.2, should be limited only to examination of whether a WTO-compatible or less restrictive alternative exists. Taking into account the specificity of the SPS Agreement (right of WTO Members to establish a level of protection they deemed to be appropriate), such an alternative should achieve the same ALOP. Thus the restrictiveness cannot be relevant if an alternative

\begin{footnotesize}

\textsuperscript{141} Id. ¶ 172.

\textsuperscript{142} Brazil-Tyres Panel Report, \textit{supra} note 78, ¶ 7.112.

\textsuperscript{143} US-Gambling Appellate Body Report, \textit{supra} note 138, ¶ 310.

\textsuperscript{144} See \textit{infra} Part IV.A.2 for the more detailed discussion.

\end{footnotesize}
does not reach a level of protection reflected in the measure under the examination. This would also closely correspond with Article 5.6 which provides for a similar test and explicitly requires from alternative to achieve a Member’s ALOP.

2. Rational Relationship (Article 2.2 and 5.1). — Pursuant to the SPS Agreement, an SPS measure should be based on the risk assessment (Article 5.1) and not be maintained without sufficient scientific evidence (Article 2.2). Those obligations were interpreted as requiring a rational relationship between risk assessment/scientific evidence and an SPS measure. According to the Appellate Body, the relationship between risk assessment and an SPS measure should be perceived “an objective situation that persists and is observable between an SPS measure and a risk assessment.”

146 The very same language was used under Article 2.2 where “adequate relationship between two elements . . . between the SPS measures and scientific evidence” was required. The adequate relationship was understood as a “rational or objective one.” The examination of an objective relationship should consist in a comparison of the scientific conclusions reached in the risk assessment (or on the basis of scientific evidence) with the conclusions embedded in the SPS measure. Those conclusions do not need to conform with each other, but rather the scientific conclusions of the risk assessment must reasonably support the SPS measure under the examination. In consequence, risk management decision cannot be isolated from the findings of risk assessment (or scientific evidence) and selected SPS measure needs to have a rational justification in the risk assessment. The case law, however, does not provide any specific test and the existence of a rational relationship is evaluated on the case-by-case basis.

A rational relationship was also interpreted in the case law as an encompassing proportionality test. According to the panel in Japan - Apples, disproportion between the risk identified by the scientific evidence and the SPS measure implies that there is no rational or objective relationship. In the same line the panel also introduced the notion of “negligible risk” - risk whose probability of occurrence is very low. If an adopted SPS measure is strict (presumably aiming at zero risk level), while

146 EC-Hormones Appellate Body Report, supra note 18, ¶ 189.
148 Id.
149 Id.
150 Id. ¶ 194; see also Japan-Agriculture II Appellate Body Report, supra note 135, ¶ 79 (characterizing in a similar way the relationship existing between the scientific information and the SPS measure under Article 3.3 of the SPS Agreement).
152 The negligible risk was defined by one of the experts in Japan – Apples as the “likelihood of between zero and one in a million,” Japan-Apples Panel Report, supra note 124, Annex 3 ¶ 332.
the risk is negligible (which does not mean that it does not exists) no rational or objective relationship between the measure and the relevant scientific evidence will be found. Lack of such a relationship indicates that a measure is maintained “without sufficient scientific evidence” and violates Article 2.2 of the SPS Agreement. The panel approach is clearly incorrect. Both concepts - proportionality and negligible risks, reflect the political considerations, which belong to the risk management phase and are reserved to WTO Members. Under the SPS Agreement, WTO Members may regulate any kind of risk, including risk that was characterized by the panel as negligible. It is in the discretion of the Member to decide whether or not to react to particular risk. Similarly, the Appellate Body recognized that there is no threshold level of risk for the purpose of Article 5.1 (i.e. 1:1,00,000)\(^{153}\) Consequently, if a country is entitled to establish its ALOP with respect to any kind of identifiable risk, the panel may not classify risks as negligible.\(^{154}\) Moreover, the concept of proportionality introduced by the panel effectively violates a WTO Member’s right to establish its ALOP. As noted above in Section IV.A, WTO Members have a right to establish a level of protection which they deem appropriate. That right also includes an option of zero risk policy. However, if in the case of a very low level of risk, a Member is precluded from taking strict measures (aiming at zero risk objective), this Member will be automatically prohibited from establishing its ALOP with respect to these risks.

The case law decided under Article 2.2 and 5.1 also clarifies what may constitute the basis for further risk management actions. The risk, which is evaluated in the risk assessment, needs to be ascertainable, as “theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed.”\(^{155}\) The theoretical uncertainty was defined as the kind of uncertainty that is “inherent in the scientific method and which stems from the intrinsic limits of experiments, methodologies, or instruments deployed by scientists to explain a given phenomenon.”\(^{156}\) Thus, ascertainability of risk serves as a bottom line for the definition of risk under the SPS Agreement. In consequence, risk managers are precluded from regulating the hypothetical risks.\(^{157}\) Note, however that this situation is different from


\(^{154}\) But see Japan-Apples Panel Report, supra note 124, ¶ 4.64 (“[The U.S. observed that] in describing the risk of transmission as ‘negligible’ rather than ‘zero’, the scientific reports merely reflected ‘the uncertainty that theoretically always remains [that an event may occur] since science can never provide absolute certainty’ that an event may never occur.”).

\(^{155}\) EC-Hormones Appellate Body Report, supra note 18, ¶ 186.

\(^{156}\) Japan-Apples Appellate Body Report, supra note 124, ¶ 241.

\(^{157}\) To some extent those risks can be addressed under Article 5.7, however in such case there needs to be insufficient scientific evidence for the performance of risk assessment and, what seems to be more problematic, an SPS measure needs to be based on the pertinent information. In case of theoretical risks that requirement could constitute too high threshold.
the case of negligible risk. Ascertainability is an objective concept (either it can be ascertain or not), while the phrase "negligible" denotes subjective judgment over the risk. Thus ascertainability seems to fall into the risk assessment phase whereas negligibility, as a non-scientific judgment, into risk management.

Risk managers may base their risk management decisions on both the majority of scientific opinions as well as those opinions of scientists taking a divergent view.\textsuperscript{158} The SPS case law introduces, however, a certain quality standard with respect to minority opinions. According to the Appellate Body, the minority scientific opinion needs to come from "qualified and respected sources."\textsuperscript{159} That may be interpreted as requiring a divergent opinion with a sound basis in science. Presumably, not every divergent view may amount to scientific opinion. Such approach to minority opinions is subject to legitimate criticism. It is submitted that requirement of specificity may result in the practical exclusion of some divergent opinions, as those opinions are usually "based in the kind of suggestive but not definite scientific evidence."\textsuperscript{160} On the other hand it should be stressed that acceptance of any kind of divergent view, irrespective of its quality, is not advisable. Unlimited reliance on the scientific minority view will transform the risk assessment requirement into mere formality, as it will be always possible to find an expert with a dissenting scientific opinion. A certain balance between accepting minority opinions and requiring from them scientific quality needs to be maintained. Nevertheless, establishing a clear borderline of what is acceptable without referring to the specific circumstances of a particular case seems to be impossible.

3. Non-discrimination (Article 2.3). — Article 2.3 contains two separate obligations. The first sentence deals with qualified form of discrimination and provides that Members shall ensure that their SPS measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail (including between their own territory and that of other Members). The second part of Article 2.3 stipulates that SPS measures shall not be applied in a manner which would constitute a disguised restriction on international trade. The rational of the provision is two-fold. First, it helps to eliminate those measures, which serve the protectionist purposed rather than genuine health concerns (in theory if there are similar or identical conditions in two countries there are no reasons to establish different SPS status). Second, it introduces an element

\textsuperscript{158} EC-Hormones Appellate Body Report, supra note 18, ¶ 194.

\textsuperscript{159} Id.

of technocratic rationality in the national risk regulation, as WTO Members need to respond to the same (or similar) risk in a consistent fashion.

Article 2.3 may be seen as a counterpart of Article I and III of GATT 1994, a variation on the National Treatment and the Most Favored Nation principles (i.e. Article I:1 and III:4 of the GATT 1994), supplemented by the part of the chapeau of Article XX. Of course, due to specificity of the SPS Agreement, these principles are conceptualized differently than under the GATT 1994. Article 2.3 of the SPS Agreement does not refer to a “product”. In consequence, like products analysis is excluded here\textsuperscript{161} as “discrimination in the sense of Article 2.3, first sentence, may also include discrimination between different products.”\textsuperscript{162} Instead, it prohibits discrimination between Members where identical or similar conditions prevail (external dimension) and between a Member's own territory and that of other WTO Members (internal dimension). In this respect, the scope of Article 2.3 is wider than that of Article I:1 and III:4 of the GATT 1994. As noted by one scholar, “the aim of this broader prohibition on discrimination is to take into account the fact that different products can pose the same or similar health risk.”\textsuperscript{163} Unlike Article I and III of GATT 1994, Article 2.3 addresses a qualified form of discrimination - only arbitrary or unjustifiable discrimination is prohibited therein. In this respect, the scope of Article 2.3 is narrower than that provided by GATT 1994. This approach is understandable when we consider the nature of the SPS measures, since they may discriminate between countries on the basis of a country's pest or disease status. Note also that under GATT 1994, discrimination may be justified under Article XX. The SPS Agreement does not contain the equivalent provision, and therefore it was necessary to supplement the obligation of non-discrimination with a certain threshold.

The case law with respect to Article 2.3 is very limited. It only identified, in very general terms, three elements which are required for violation of Article 2.3 first sentence. These are: (i) the SPS measure needs to discriminate either between the WTO Members or alternatively between an importing Member's own territory and that of other WTO Members, (ii) the discrimination needs to be arbitrary or unjustifiable, and (iii) identical or similar conditions need to prevail in the territory of the Members

\textsuperscript{161} For details concerning like product analysis under GATT 1994, see generally Donald H. Regan, Regulatory Purpose and “Like Products” in Article III:4 of the GATT (With Additional Remarks on Article III:2), 36 J. WORLD TRADE 443 (2002); Robert E. Hudec, “Like Product”: The Differences in Meaning in GATT Articles I and III, in REGULATORY BARRIERS AND THE PRINCIPLE OF NON-DISCRIMINATION IN WORLD TRADE LAW (Thomas Cottier & Petros Mavroidis eds., 2000).

\textsuperscript{162} Panel Report, Australia – Measures Affecting Importation of Salmon – Recourse to Article 21.5 of the DSU by Canada, ¶ 7.112, WT/DS18/RW (Feb. 18, 2000) [hereinafter Australia-Salmon (Article 21.5 by Canada)].

\textsuperscript{163} MACRORY ET AL., supra note 4, at 265 (giving as an example different fruits, which transmit the same disease).
compared.\textsuperscript{164} It is still to be decided how the above notions should be understood. Questions remain as to what is considered discrimination under Article 2.3, what may serve as possible justification and how wide is the concept of similar conditions. Bearing in mind similarities between Article 2.3 and 5.5, case law decided under the latter is probably relevant here. Presumably, the arbitrary and unjustifiable character of discrimination will be considered in one analysis on a case-by-case basis. Justification of discrimination will probably be the same as under Article 5.5. Thus, the extent of regulatory action may be relevant and the presence of higher risk resulting from the products imported from one country as opposed to products coming from the other country.\textsuperscript{165} Note also that Article 2.3 provokes the same questions as Article 5.5 with regard to risk perception as a justifying factor.

Similar conditions under Article 2.3 refer to the SPS status of a particular country. That condition arguably includes existence of the same or similar hazard (i.e. pest or disease) on the territory of that country, the level of SPS enforcement (e.g. observance of good veterinary practice). Note also that Article 2.3 refers to the territory of country as whole. Nevertheless, it seems that the obligation of Article 6 of the SPS Agreement, which requires WTO Members to recognize the concepts of pest- or disease-free areas, is also applicable here. This means that the territory of a country cannot be treated as monolith and similarity of the conditions should be established only after consideration is given to the status of a particular region within a country. Moreover, while under Article 5.5 the comparison concerns the appropriate levels of protection, under Article 2.3 it is the treatment of products (both similar and different) that is compared. In practice, it seems that both comparisons lead to the same result.

The second part of Article 2.3 requires that SPS measures are not applied in a manner which constitutes a disguised restriction on international trade. This obligation was not addressed by the case law. The Appellate Body only noted that the second sentence of Article 2.3 closely corresponds to the third element of the test under Article 5.5.\textsuperscript{166} The observation of the Appellate Body would indicate that the case law decided under Article 5.5 is relevant for the interpretation of the notion of “disguised restriction on international trade.” This, however, is not an easy task. Note that under Article 5.5 the examination of disguised restriction is performed together with the assessment of discrimination. The wording of Article 2.3 is different and presumably requires separate analysis of the

\textsuperscript{164} Australia-Salmon (Article 21.5 by Canada), \textit{supra} note 162, ¶ 7.111.

\textsuperscript{165} EC-Hormones Appellate Body Report, \textit{supra} note 18, ¶ 221; Australia-Salmon Panel Report, \textit{supra} note 79, ¶ 8.143.

\textsuperscript{166} EC-Hormones Appellate Body Report, \textit{supra} note 18, ¶ 238.
disguised restriction. The relevance of the intent of the party applying a measure is also an open question here. The general WTO case law indicates that this element has a rather limited value. Following the logic of the panel in Brazil–Tyres, it is more important to examine the effects of the application of an SPS measure. In other words, the question will be to what extent the operation of the measure undermines the achievement of the stated objective (reduction or elimination of a particular risk) rather than what is intent of the party behind a measure.

As far as the general relationship between Article 2.3 and 5.5 is concerned, both articles are closely related. The Appellate Body noted that “Article 5.5 may be seen to be marking out and elaborating a particular route leading to the same destination set out in Article 2.3.” The case law has also introduced a presumption of a violation of Article 2.3 for those measures which are incompatible with Article 5.5. The nature of that presumption is, however, problematic. The language used by the Appellate Body may indicate that the presumption can be rebutted (presumed instead of deemed or considered); however, in practice it may appear that it operates as an irrebuttable one. Finding that a measure does not arbitrarily or unjustifiably discriminate even if it fails to meet the requirements of Article 5.5 seems to be impossible. Given the more general character of Article 2.3, the positive presumption is, of course, not available, as Article 5.5 does not exhaust the whole meaning of Article 2.3. In consequence, an additional examination of the measure under Article 2.3 is not excluded, even if such a measure is found to be consistent with Article 5.5.\footnote{Id. ¶ 212.} \footnote{Australia-Salmon Panel Report, supra note 79, ¶ 8.109.} \footnote{Id.}
4. Least Trade Restrictive Alternative (Article 5.6). — As it was already mentioned, Article 5.6 introduces the least trade-restrictive alternative requirement. It specifically provides that WTO Members, when establishing or maintaining SPS measures to achieve the appropriate level of SPS protection, are obliged to ensure that such measures are not more trade-restrictive than required, in order to achieve their appropriate level of SPS protection, taking into account technical and economic feasibility. The text of Article 5.6 is supplemented by the footnote, which clarifies the meaning of “not more trade-restrictive than required.”

The case law adopted on this basis (both the text of Article itself and accompanying footnote) a three-prong test prescribing the elements which need to be established by the complainant to find a violation of Article 5.6. There needs to be an SPS measure which: (i) is reasonably available taking into account technical and economic feasibility, (ii) achieves the Member’s appropriate level of SPS protection, and (iii) is significantly less restrictive to trade than the contested SPS measure. The Appellate Body stressed that, as in Article 5.5, the test has a cumulative character, meaning that all the elements need to be demonstrated in order to find any inconsistency with Article 5.6.

Again existing case law is very limited. Neither reasonable availability nor technical and economic feasibility were defined. Note, however, that this language closely corresponds with the case law decided under Article XX of GATT 1994. Thus, alternatives that are merely theoretical or impose an undue burden on a Member (prohibitive costs or substantial technical difficulties) are not considered to be reasonably available. One may ask whether there is any threshold when an alternative becomes reasonably unavailable. Probably no generalization is possible and each situation needs to be assessed on the case-by-case basis. The GATT 1994 case law only indicates (it speaks about prohibitive costs and substantial difficulties) that small additional costs do not make an alternative unavailable. This is most likely also true under the SPS Agreement.

As far as the second element is concerned, the question is not whether any alternative meets the level of protection currently achieved by the measure under examination, but the ALOP as determined by the Member

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170 Cf. SCOTT, supra note 82, at 157 (describing that provision as a ‘weak proportionality requirement’ as it only concerns means and not balancing the value of the objective being pursued against the trade-restrictive effects of the measure).
171 The footnote to Article 5.6 reads: “[f]or purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.”
172 Australia-Salmon Panel Report, supra note 79, ¶ 8.167. See also Australia-Salmon Appellate Body Report, supra note 49, ¶ 194.
174 EC-Asbestos Appellate Body Report, supra note 140, ¶ 308.
concerned. This examination includes the following elements: (i) what is a Member’s ALOP and (ii) what level of protection could be achieved by each of alternative SPS measures. As it is discussed in Section IV.A of this article such formulation results in strange consequences. The complainant may identify an alternative that is reasonably available, significantly less restrictive to trade and reflects the same level of protection as a contested measure. Nevertheless, the complainant will fail if such an alternative does not reach an ALOP, irrespectively from the fact that the level of protection reflected in a contested measure also is lower. As it was already suggested, the possible solution would be to assume that a level of protection reflected in a measure is at least as high as ALOP. Alternatively, the analysis under Article 5.6 should be limited to a level of protection reflected in a contested measure. This would allow to escape from the above mentioned difficulties.

Under the third element, an alternative measure needs to be less restrictive than the contested SPS measure. That condition is, however, qualified as the difference in restrictiveness needs to be significant. Therefore, a de minimis difference is not sufficient for establishing a violation of Article 5.6. Again it seems that it is not possible (and advisable) to establish an abstract threshold. Possible SPS measures are so diverse that a case-by-case approach is definitively a better solution.

As already noted, Article 5.6 is closely related to Article 2.2. The panel specifically observed that “Article 5.6 must be read in context . . . [a]n important part of the context of Article 5 is Article 2. We consider that Article 5.6 should, in particular, be read in light of Article 2.2,”175 which provides that SPS measures are to be applied only to the extent necessary to protect human, animal or plant life or health. Recall that the panel in EC – Biotech Products found that Article 5.6 constitutes a specific application of the requirement in Article 2.2.176 In consequence, a breach of Article 5.6, presumes the violation of Article 2.2. However, as discussed in the Section IV.C (1) both Articles may be also seen as having a complementary character. Obviously, in such a case no presumption would be available. Moreover, if we accept the complementary character between these two provisions, the analysis under the first part of Article 2.2 should be supplemented with an additional element. Thus, in line with Article 5.6, in order to find a violation of Article 2.2, an alternative SPS measure should be significantly less restrictive to trade than the contested measure. If these two provisions are of a complementary nature, there is no reason to provide a more rigorous regime in case of application of measures. That postulate is also valid, even if we reject the complementary character of Articles 2.2 and 5.6. Note that under Article 2.2 any difference in restrictiveness between a measure and alternatives would constitute a violation of the

175 Australia-Salmon Panel Report, supra note 79, ¶ 8.165.
provision, while under Article 5.6 only a significant difference is relevant. In consequence, a broad reading of Article 2.2, which condemns any kind of difference, would deprive Article 5.6 of any legal meaning.

**D. Monitoring and Review**

As it was mentioned above, the SPS Agreement requires that SPS measures be based on risk assessment (Article 5.1) and not to maintain them without sufficient scientific evidence (Article 2.2). The word “to maintain” clearly indicates that the obligation of Article 2.2 has dynamic and continuous character. Thus, Article 2.2 is concerned not so much with the adoption of a measure but rather with its maintenance. Once the scientific evidence fails to justify the existence of a measure, such a measure will not stand the scrutiny of Article 2.2, irrespectively from the fact that there was sufficient scientific evidence at the time of its adoption. Such formulation has important implications. First, it requires WTO Members to track the latest scientific developments which are relevant for assessment of particular risk. Secondly, it forces risk managers to review a measure in order to guarantee that there is continuously sufficient scientific basis for a measure. As an effect of such a review, risk managers may be obliged to withdraw a measure (if the latest scientific research invalidates the previous evidence), to modify it (softening and tightening of its requirements) or to introduce a new measure(s).

Different wording of Article 5.1 may suggest a different scope of application of this article. Note that Article 5.1 only speaks about the obligation to base a measure on risk assessment and not to maintain it with assessment. This could suggest that Article 5.1 is not concerned with the maintenance of a measure but with its adoption. Thus, the panel examination under Article 5.1 would be limited to the existence of risk assessment as of the time of the adoption of a measure. The case law went, however, in a different direction. The panel in *EC – Biotech Products* interpreted the phrase “based on” broadly and found that Article 5.1 requires WTO Members to have updated risk assessment that corresponds to the latest scientific developments.\(^{177}\) In consequence, a date that is relevant for the examination of the existence of risk assessment is a date of establishment of a panel. Although, such interpretation may be disputable from the textual point of view, nevertheless it seems to be correct.\(^{178}\) Note that Article 5.1 is a “specific application of the basic obligations contained in Article 2.2,”\(^{179}\) and “may be seen to be marking out and elaborating a

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\(^{177}\) *Id.* ¶ 7.3034.

\(^{178}\) *Contra* SCOTT, *supra* note 82, at 125.

\(^{179}\) Japan-Agriculture II Appellate Body Report, *supra* note 135, ¶ 82.
particular route leading to the same destination set out in Article 2.2.\textsuperscript{180} A reading that limits the obligation of Article 5.1 only to the moment of adoption of a measure will hardly fit into that description.

V. CONCLUSIONS

This article argues that it is legitimate to speak about risk management under the SPS Agreement. The finding of the Appellate Body in EC – Hormones should be seen not as a rejection of that concept under the SPS Agreement but rather as dismissal of certain conclusions reached by the panel. Moreover, the analysis of the SPS Agreement clearly shows that this element of the risk analysis can be identified in the Agreement. The article also argues that the recognition of risk management disciplines of the SPS Agreement helps to reconcile its text with the documents of the international standard setting bodies (i.e. Codex, OIE, and IPPC) and to better understand the disciplines introduced by the SPS Agreement. Finally, it submits that reintroducing to the SPS Agreement a distinction between risk assessment and risk management may also help in highlighting the importance of these provisions that are not concerned with the process of risk assessment.

The case law has clarified the very general and rather enigmatic language of the SPS Agreement - the concepts of an ALOP, non-discrimination, rational relationship, consistency and the least trade-restrictive alternative were given real meaning. Some of the developments, however, seem to be disappointing. The requirement of proportionality between identified risk and an SPS measure and the concept of negligible risks under Article 2.2 seem to violate the right of the WTO Members to establish the ALOP. The same is true with respect to the requirement of ascertainability of risk as a precondition for valid risk assessment. The reading of Article 5.4, which reduces it to an expression of the objective without any real legal meaning, is also unsatisfactory. The article argues that such interpretation is incompatible with the principle of effective treaty interpretation. Instead, the article proposes to construe Article 5.4 as providing procedural obligation, which requires WTO Members to consider the impact of the SPS measure on international trade when determining their ALOPs. The article notes that the Appellate Body failed to establish any clear criteria for the evaluation of arbitrariness and a lack of justification under Article 5.5. The case law preferred an unprincipled approach, which makes the regime of the SPS Agreement less predictable. The article also recognizes that conceptualization of ALOP as an external benchmark, while accepting the statement of the defendant on its ALOP as

\textsuperscript{180} Australia-Salmon Panel Report, \textit{supra} note 79, ¶ 8.52.
sufficient, has a serious implication for the operation of Article 5.6. The article proposes as a solution to assume that a level of protection reflected in a measure is at least as high as ALOP or, alternatively, to limit the analysis of Article 5.6 to the level of protection reflected in contested measure. Finally, the relationship between Article 2.2 and 5.6 requires further elaboration. Are these two provisions complementary in nature or is the latter a specific application of the former? In this context the article notes that although the interpretation adopted by the panel seems to be unsatisfactory from the textual point of view, the systemic interpretation speaks against the complementary character of the provisions. Finally, the article points out that due to the wording of Article 5.6 the necessity test of Article 2.2 must be construed as including a certain threshold (significant difference in restrictiveness between contested measure and alternatives).

This article also identifies those risk management provisions of the SPS Agreement which have not yet been addressed. This refers particularly to Article 2.2 (necessity requirement), Article 2.3 the second sentence (application of the measure in a manner which constitutes a disguised restriction on international trade), Article 5.5 (the relevance of differences in the public’s perception of risk for the purpose of justifying the measure) and disciplines of Article 5.6. The article proposes possible interpretation of those provisions, noting, however, that the overall assessment of the SPS Agreement as far as risk management is concerned will only be possible after they are addressed in the case law.
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