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# Disciplining Health Regulations through the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures: Science and the Rule of Law

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## Abstract

The World Trade Organization's (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) disciplines WTO Members' health regulations to prevent their misuse for protectionist purposes. In doing so, its obligations reflect several elements of the rule of law, including legal certainty, non-arbitrariness and non-discrimination, as well as a recognition of the rights of individuals. Through its obligations of non-discrimination, transparency and scientific justification and the scope it leaves for Members to prioritise the protection of health over trade liberalisation, the SPS Agreement can be regarded as entailing a rule-of-law approach. However, cognisant of the limits to the rule of law when transposed to the international level, it is important to avoid an overly "judicialised" approach to the disciplines of the SPS Agreement, and in particular its reliance on scientific justification to prevent arbitrariness in sanitary and phytosanitary regulation. Otherwise, there is a risk of intruding too far into the regulatory autonomy of States, weakening the "compliance pull" of the agreement and thus inadvertently undermining the rule of law in this area. An approach that instead recognises the inherent subjectivity and uncertainty in science and respects Members' divergent priorities in health regulation would go further in engendering support for the rules-based system of international trade.

**Keywords:** Rule of law; sanitary and phytosanitary regulation; scientific basis

## I. Introduction

The legal governance of international trade has become increasingly important in promoting health by ensuring food safety and plant and animal health, as global supply chains for agri-food products have become more complex and interconnected. The production and distribution of agri-food products is increasingly dispersed, involving many countries and actors, reaching beyond the jurisdictional limits of a single State to regulate this complex system. National sanitary and phytosanitary (SPS) law, regulating traded agri-food products, has become an essential tool for the protection of health in the territories of trading nations by setting standards for food safety and to protect against health risks from pests and diseases of plants and animals.

However, national SPS regulations can also be misused by States, whether for protectionist purposes, under pressure from their domestic agri-food industries or for political reasons, using their market power to exert influence on their trading partners.

A glaring example of such misuse is China's imposition of barriers for obtaining customs clearance to enter its territory for agri-food products from Lithuania following Lithuania's decision to allow the opening of a Taiwanese representative office in its capital.<sup>1</sup>

International trade agreements bring discipline to national SPS regulation to prevent such misuse by binding States to agreed rules that promote legal certainty, non-arbitrariness and non-discrimination, subject to impartial adjudication. In doing so, they ensure that the rule of law prevails in the trade relationships between States instead of the "law of the jungle" in which economically powerful States can use their market power to impose their interests on their weaker trading partners. In contrast to the latter, the rule of law is based on the idea of equality before the law, regardless of economic power. The concept of the rule of law thus provides a framework for understanding the use of international trade agreements to regulate State action, including in the area of SPS regulation, establishing a rules-based rather than a power-based system.

This article explores the role of the rule of law in disciplining SPS measures through international trade agreements. It begins by defining the rule of law and its constituent elements and explaining its relevance and limits in the regulation of international trade. It then examines how the multilateral trade agreement that deals with SPS regulation incorporates elements of the rule of law in balancing the competing objectives of allowing States sufficient policy space to pursue their SPS objectives on the one hand and disciplining State action to avoid misuse of SPS regulation for political or economic objectives on the other. Its innovative use of science as the scale on which these competing interests are balanced is discussed in light of relevant elements of the rule of law. The limits to the rule-of-law approach to disciplining SPS regulations are then sketched. In conclusion, a nuanced approach to the rule of law in trade agreements that govern health regulation is proposed.

## II. The role of the rule of law in regulating international trade

Although the concept of the rule of law emerged at the national level, as a framework of elements to provide checks against arbitrariness and abuse of power by governments,<sup>2</sup> its growing relevance at the international level has been recognised. The United Nations General Assembly has affirmed that an international order based on the rule of law is an "indispensable foundation[] for a more peaceful, prosperous and just world".<sup>3</sup> In the area of trade and investment, it recognises the importance of fair, stable and predictable legal frameworks for generating inclusive, sustainable and equitable development, economic growth and employment, generating investment and facilitating entrepreneurship.<sup>4</sup> This reflects the evolving understanding of the concept of the rule of law, broadening its conception by recognising that it cannot be divorced from its normative context and in particular from the protection of the rights of individuals, who are affected by the distributive impacts of trade agreements.<sup>5</sup>

<sup>1</sup> These restrictions and others imposed by China on Lithuanian exports were challenged by the European Union, under inter alia Arts 2 and 8 and Annex C.1(a) of the SPS Agreement in the WTO dispute *China - Measures Concerning Trade in Goods*, WT/DS610, currently pending before a WTO panel.

<sup>2</sup> See Venice Commission, *Rule of Law Checklist*, adopted at the 106th Plenary Session of the Venice Commission, 11–12 March 2016. This checklist identifies the following core elements of the rule of law: (1) legality; (2) legal certainty, including transparency and accessibility of laws; (3) prohibition of arbitrariness and abuse of power; (4) access to justice before independent and impartial courts; (5) respect for human rights; and (6) non-discrimination and equality before the law.

<sup>3</sup> UN General Assembly, *Declaration of the High-level Meeting of the General Assembly on the Rule of Law at the National and International Levels*, A/67/L.1, 19 September 2012, para 1.1.

<sup>4</sup> *ibid.*, para 1.8.

<sup>5</sup> C Lopez, "WTO Reform and the Rule of Law" *Opinio Juris*, 7 February 2016.

The concept of the rule of law can be regarded as underpinning international trade agreements, in particular those of the World Trade Organization (WTO), as they lay down rules that require non-discrimination, legal certainty (transparency, predictability and stability), non-arbitrariness and due process in the trade relationships between States, recognising equality before the law.<sup>6</sup> They also ensure independent and fair resolution of trade disputes by judicial organs that clarify and apply the law according to legal principles. Such “judicialisation” of international law through international courts, including those of the WTO, has been argued to be “a development that is in line with fundamental principles of international law, such as the rule of law . . .” and which can “promote impartial decision-making, assist states in sending credible signals and resolve collective issues”.<sup>7</sup> Further, the recognition in WTO agreements of the limits of trade liberalisation, by providing room for States to protect other societal interests even when this has trade-restrictive effects, reflects the evolving conception of the rule of law by prioritising the interests of individuals and of society. As such, the rule-of-law approach to international trade has brought great benefits in creating an environment conducive to stable and peaceful trade relations between unequal trading partners and generating economic growth while cognisant of the rights of individuals.

However, it is acknowledged that the transposition of the concept of the rule of law from the national to the international level has its limits.<sup>8</sup> In the national context, the rule of law serves to ensure fairness and predictability in the relationship between the State and its citizens and can be safeguarded by an independent judicial authority that issues binding and enforceable rulings. By contrast, in the international context there is no single central governing authority whose exercise of power over its citizens must be constrained by law, but instead the rule of law in international trade agreements applies to the horizontal relationship between sovereign States.<sup>9</sup> Further, compliance with international trade rules, even those subject to a binding dispute settlement system, is largely reliant on the willingness of States to accept their constraints,<sup>10</sup> driven by their interests and the benefits they derive from participating in a rules-based international trading system.<sup>11</sup> However, where “judicialisation” is far-reaching, it may be perceived as diminishing the sovereign authority of States and intruding too far into their regulatory space by de facto taking control of policymaking from the hands of States.<sup>12</sup> Therefore, there may be situations in which political or economic considerations entice States away from their obligations under international trade agreements as elaborated by judicial organs and lead them to disregard dispute settlement rulings calling for compliance. The

<sup>6</sup> A Durkin, “Rule of law is the bedrock of trade agreements” (*Hinrich Foundation*, 24 January 2020) <<https://www.hinrichfoundation.com/research/tradevistas/sustainable/rule-of-law-trade/>> (last accessed 16 October 2023).

<sup>7</sup> E Acar, “Dejudicialisation of International Law and Future Trajectories” (2023) 10(1) *Groningen Journal of International Law* 2.

<sup>8</sup> See, eg, K Gorobets, “The International Rule of Law and the Idea of Normative Authority” (2020) 12 *Hague Journal on the Rule of Law* 227; S Chesterman, “An International Rule of Law?” (2008) 56 *American Journal of Comparative Law* 331.

<sup>9</sup> See further, in this special issue, H Culot, “The Concept of the Rule of Law and Global Governance: Theoretical Perspectives”.

<sup>10</sup> AW Wolff, “The Rule of Law in an Age of Conflict”, Keynote Address at the Closing Ceremony World Trade Institute Master Programmes (University of Bern 29 June 2018) 4 <[https://www.wti.org/media/filer\\_public/fd/08/fd087b42-ac5b-4df8-9e91-b76220c72953/bern\\_june\\_29\\_2018\\_final\\_july\\_1\\_corrected.pdf](https://www.wti.org/media/filer_public/fd/08/fd087b42-ac5b-4df8-9e91-b76220c72953/bern_june_29_2018_final_july_1_corrected.pdf)> (last accessed 16 October 2023).

<sup>11</sup> Such interests include the economic benefits of participating in a secure and predictable trading system and the political benefits of securing their reputation as trustworthy trading partners. See further B Zangl, “Judicialization Matters! A Comparison of Dispute Settlement under GATT and the WTO” (2008) 52 *International Studies Quarterly* 829.

<sup>12</sup> Acar, *supra*, note 7, 3.

increasing instances of economic nationalism and unilateralism that characterise the current trading environment as well as the recent dismantling of the WTO's highest judicial organ, the Appellate Body, evidence this reality.<sup>13</sup> These developments have led commentators to question whether the crisis in which the WTO now finds itself reflects an underlying dissatisfaction of its Members with its now-outdated trade rules<sup>14</sup> and with the increasingly "judicialised" interpretation and application of these rules by WTO dispute settlement organs,<sup>15</sup> which have sometimes been regarded as intruding too far into the sovereign policy sphere of its Members.<sup>16</sup> Van den Bossche even poses the question as to whether we are witnessing the end of a "glorious experiment with the rule of law in international economic relations".<sup>17</sup> The reliance on the concept of the rule of law at the international level must therefore be approached with caution, cognisant of its benefits but also of its limits.

It is now useful to explore the way in which the rules of the multilateral trade agreement dealing with SPS regulation reflect rule-of-law elements and to assess their effectiveness in appropriately disciplining SPS regulation by States whilst respecting the rights of individuals. Appropriate disciplines in this context refers to rules that weed out discriminatory, disguised or arbitrary trade restrictions whilst leaving sufficient room for States to fulfil their sovereign duty to protect health through regulatory measures in response to the needs of their national constituencies. This examination focuses on the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)<sup>18</sup> of the WTO.

### III. The rule of law in balancing trade and health in the SPS Agreement

The SPS Agreement was negotiated and adopted as part of the WTO legal framework in order to address the difficult and controversial issue of trade-restrictive measures adopted to protect health against risks from traded agri-food products. Negotiators recognised the inherent importance of respecting the right and duty of sovereign States to safeguard human, animal and plant health in their territories while facilitating trade in agri-food products, a sector subject to high levels of protectionism in many countries.<sup>19</sup> This delicate balance was regarded as necessitating a separate agreement, going beyond the rules contained in the General Agreement on Tariffs and Trade of 1994 (GATT 1994) and the Agreement on Technical Barriers to Trade (TBT Agreement). The SPS Agreement was therefore adopted, reaffirming in its preamble that "no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health".<sup>20</sup> It establishes a set of rules and obligations aimed at promoting, but not obliging,

<sup>13</sup> For an in-depth discussion, see V Hegde, J Wouters and A Raina, "The Demise of the Rules-Based International Economic Order?" Leuven Centre for Global Governance Studies Working Paper No. 224, November 2020 <<https://ghum.kuleuven.be/ggs/wp224-hegde-raina-wouters-vh-eds.pdf>> (last accessed 16 October 2023).

<sup>14</sup> Lopez, *supra*, note 5.

<sup>15</sup> Zangl, *supra*, note 11.

<sup>16</sup> Arcuri notes that there is a "shared view that states ought to maintain (or regain) political space". See A Arcuri, "International Economic Law and Disintegration: Beware the Schmittean Moment" (2020) 23(2) *Journal of International Economic Law* 327. She cites Rodrik's critique of hyper-globalisation as "pushing rule making onto supranational domains too far beyond the reach of political debate and control" (at 329).

<sup>17</sup> P Van den Bossche, "The Demise of the WTO Appellate Body: Lessons for Governance of International Adjudication?" WTI Working Paper No. 02/2021 <[https://www.wti.org/media/filer\\_public/c2/ef/c2efc2de-ce85-45c7-9512-9286e14fca47/wti\\_working\\_paper\\_02\\_2021.pdf?ref=genevapolicyoutlook.ch](https://www.wti.org/media/filer_public/c2/ef/c2efc2de-ce85-45c7-9512-9286e14fca47/wti_working_paper_02_2021.pdf?ref=genevapolicyoutlook.ch)> (last accessed 16 October 2023).

<sup>18</sup> Agreement on the Application of Sanitary and Phytosanitary Measures, 1867 U.N.T.S. 49, 15 April 1994.

<sup>19</sup> G Stanton, "Food Safety and the SPS Agreement" (Standards and Trade Development Facility, 2000) 1.

<sup>20</sup> First preambular recital to the SPS Agreement.

harmonisation of SPS regulations around internationally set standards and ensuring the transparent, non-discriminatory and science-based application of SPS measures by WTO Members. Its rules reflect elements of the rule of law, as they provide a legal framework equally applicable to all WTO Members that guides the formulation and implementation of their SPS measures, preventing non-transparent, arbitrary and discriminatory actions, and they are subject to enforcement through independent adjudication. Even Rodrik, a harsh critic of the neoliberal trading system, recognises that the SPS Agreement can improve national SPS decision-making through its obligations on “transparency, broad representation, accountability, and use of scientific/economic evidence”.<sup>21</sup>

More specifically, the obligation of non-discrimination,<sup>22</sup> which lies at the heart of the SPS Agreement, prohibits SPS measures that constitute arbitrary or unjustifiable discrimination.<sup>23</sup> Unlike the non-discrimination obligations in other WTO agreements,<sup>24</sup> those in the SPS Agreement do not seek to protect equal competitive opportunities between competing products but instead aim to ensure that similar health risks are treated in a consistent and coherent manner regardless of whether they are contained in competing or non-competing products.<sup>25</sup> Thus, this obligation goes beyond protecting competition in the market and promotes good regulatory practice by preventing arbitrary health regulations that could serve as disguised or inadvertent barriers to trade. However, in line with the evolving understanding of the concept of the rule of law, this obligation is cognisant of the effect of its disciplines on health protection and seeks to ensure that its operation does not undermine legitimate health regulation. Therefore, unlike the non-discrimination obligations in certain other WTO agreements, which prohibit all measures that have a detrimental impact on competitive opportunities regardless of their regulatory objective,<sup>26</sup> the SPS Agreement explicitly limits its prohibition to “arbitrary or unjustifiable” discrimination. A justification for different regulatory treatment of products (eg due to differences in conditions relevant to the specific health risk and the regulatory objective) would lead to a finding of non-violation of the non-discrimination obligations of the SPS Agreement.<sup>27</sup> As a result, the non-discrimination obligations in the SPS Agreement, as interpreted in the case law, avoid intruding too far into the sovereign sphere of WTO Members by leaving sufficient room for different treatment where the distinction serves legitimate regulatory purposes. This reflects the careful balance sought in the disciplines of the SPS Agreement between the competing objectives of liberalisation of agri-food trade and legitimate health regulation and the need to allow sufficient space for policy choices by Members in this sensitive area.

Transparency serves as a cornerstone of the rule of law in the SPS Agreement by enhancing legal certainty and preventing the abuse of power by regulating States.<sup>28</sup> Going further than the GATT 1994, which merely requires prompt publication of

<sup>21</sup> D Rodrik, *Straight Talk on Trade: Ideas for a Sane World Economy* (Princeton, NJ, Princeton University Press 2018) p 226.

<sup>22</sup> The Venice Commission (supra, note 2) identifies non-discrimination as a core element of the rule of law.

<sup>23</sup> Arts 2.3 and 5.5 of the SPS Agreement.

<sup>24</sup> Compare, eg, Art III:4 of the GATT 1994 and Art 2.1 of the TBT Agreement, both of which protect competitive opportunities between “like” products (ie products that are in a competitive relationship in the market of the importing Member).

<sup>25</sup> Panel Report, *Australia – Salmon (Art. 21.5 – Canada)*, para 7.112. See further D Prévost, “National Treatment in the SPS Agreement: A Sui Generis Obligation” in A Kamperman Sanders (ed.), *The Principle of National Treatment in International Economic Law* (Cheltenham, Edward Elgar 2014) pp 125–60.

<sup>26</sup> See, eg, Appellate Body Report, *Korea – Beef*, para 137.

<sup>27</sup> See, eg, Appellate Body Report, *Korea – Radionuclides*, para 5.54.

<sup>28</sup> The Venice Commission (supra, note 2) identifies legal certainty, including access to legislation and the prevention of abuse of powers, including the obligation to give adequate reasons for decisions, as core elements of the rule of law.

adopted measures that affect trade,<sup>29</sup> the SPS Agreement lays down a far-reaching set of transparency obligations.<sup>30</sup> These comprise, broadly speaking, four elements: the obligation to promptly publish all adopted SPS measures and to provide a reasonable period for exporters to adapt to their new requirements; the obligation to maintain a single Enquiry Point responsible for the provision of relevant documents and answers to all reasonable questions from interested Members; the obligation to notify, in advance, draft SPS regulations to the WTO and allow a period for comments from interested parties; and the obligation to provide, upon request, an explanation for the reasons behind an SPS measure. These extensive transparency obligations allow other Members to review new and existing SPS measures and assess their compliance with WTO rules as well as to provide comments during the drafting process for SPS measures and engage in discussion with other Members regarding any specific trade concerns that a measure may raise. This promotes legal certainty and predictability. It also enables Members to evaluate the legitimacy and potential impact of other Members' health regulations and have their input taken into account in the finalisation of the measures, and it permits traders to identify the SPS requirements that their products will face in their export markets and adjust their production processes accordingly. It thereby ensures that SPS measures are not implemented in an arbitrary manner but rather through an open, transparent and consultative process. Members can raise their trade concerns regarding the notified measures of other Members in the multilateral forum of the SPS Committee,<sup>31</sup> established under the Agreement, thereby facilitating the collaborative resolution of potential conflicts based on a shared understanding of the rules, without resort to formal dispute settlement proceedings.

Scientific justification constitutes a novel and vital aspect of the SPS Agreement and reflects the rule of law insofar as it provides safeguards against arbitrary or unfounded SPS regulation that could constitute disguised forms of protectionism.<sup>32</sup> The negotiators of the SPS Agreement saw science as a rational, objective and universal tool to depoliticise decisions on the legitimacy of SPS regulation, thereby rendering them acceptable to all Members. Understanding that SPS regulations go to the heart of concerns regarding State sovereignty and autonomy, they relied on science as the scale on which to balance the competing interests of health protection and trade liberalisation in the SPS Agreement and incorporated into the SPS Agreement a requirement that Members' SPS measures be based on scientific principles and supported by relevant scientific evidence.<sup>33</sup> The scientific foundation of SPS measures is further strengthened through the obligation of a scientific risk assessment as a basis for SPS measures.<sup>34</sup> As noted by Peel, "the very fact of having to take a risk assessment into account and respond to its findings could have the salutary effect of forcing national regulators 'to articulate objectives, to assess means, and to rationalize results', a substantial improvement for the regulatory processes of many nations".<sup>35</sup> This underscores the importance of scientific assessment in determining when and how to regulate to protect health whilst avoiding unjustified barriers to trade. Incorporating science into legal disciplines can therefore be seen as enhancing the

<sup>29</sup> Art X:1 of the GATT 1994.

<sup>30</sup> Art 7 and Annex B of the SPS Agreement.

<sup>31</sup> Art 12.2 of the SPS Agreement.

<sup>32</sup> The Venice Commission (*supra*, note 2) identifies the prohibition of arbitrariness and abuse of power as core elements of the rule of law.

<sup>33</sup> Art 2.2 of the SPS Agreement.

<sup>34</sup> Art 5.1 of the SPS Agreement.

<sup>35</sup> J Peel, "Risk Regulation under the WTO SPS Agreement: Science as an International Normative Yardstick?" (Jean Monnet Working Paper 02/04 NYU School of Law, June 2004) 57.



international rule of law by having science act as a proxy for the politically sensitive task of distinguishing health protection from disguised protectionism in order to result in neutral and universally acceptable outcomes and thereby engender a normative “compliance pull” in this politically charged area.

Lastly, the dispute settlement mechanism of the WTO served to reinforce the rule of law in the SPS Agreement, until 2019 when it was plunged into crisis by the demise of the Appellate Body.<sup>36</sup> The SPS Agreement provides that when a WTO Member believes that another Member’s SPS measures are inconsistent with the obligations of the SPS Agreement it can have recourse to the WTO dispute settlement mechanism.<sup>37</sup> The compulsory and impartial adjudication provided by WTO panels, and formerly also by the WTO Appellate Body, ensured that disputes were resolved based on legal principles to avoid tit-for-tat retaliation and escalating trade wars. The WTO dispute settlement system offered a rules-based mechanism for enforcing compliance with the SPS Agreement. This avenue aimed to discourage arbitrary actions, promote legal certainty for WTO Members and strengthen the rules-based system, and it has been seen as enhancing the international rule of law.<sup>38</sup> However, the lamentable breakdown of the WTO dispute settlement system has been ascribed by some to perceived excessive “judicialisation” of trade rules in dispute settlement rulings, with judicial interpretations that are out of step with current realities leading to politically unacceptable restrictions on the policy space of States.<sup>39</sup>

In conclusion, the rule of law assumes a pivotal role in the operation of the SPS Agreement. Through its obligations of non-discrimination, transparency and scientific justification, subject to impartial dispute settlement, the SPS Agreement seeks to provide a robust rules-based framework for health regulations, striking a delicate balance between safeguarding human, animal and plant health and facilitating international trade. However, the disciplines of the SPS Agreement must be interpreted and applied with care to avoid undermining Members’ confidence in the ability of this rules-based system to appropriately balance their interests at the politically sensitive interface between trade and health, thereby inadvertently weakening the rule of law in this area.

#### IV. The limits of science and the rule of law in disciplining SPS regulations

As seen above, the SPS Agreement aims to discipline SPS regulation through rules that reflect elements of the concept of the rule of law, going beyond the obligations applicable to regulation in other WTO agreements. The most innovative aspect of these disciplines is the use of legal obligations based on science to generate authoritative outcomes. This has

<sup>36</sup> The WTO Appellate Body is no longer operational due to the fact that since 2017 the USA has consistently blocked the consensus required for appointing Appellate Body members as the terms of existing members expired. In 2019, the number of Appellate Body members fell below three, the number needed to form a division to hear an appeal. Currently, there are no Appellate Body members left, and efforts of other Members to relaunch the appointment process have been unsuccessful. This not only eliminates the possibility for appeals to be heard but also allows a losing Member to prevent a panel report being adopted (and thus becoming binding) by appealing the report to a non-existent Appellate Body (known as appealing “into the void”). The USA justifies its actions with claims of judicial overreach by the Appellate Body. See United States Trade Representative, *Report on the Appellate Body of the World Trade Organization* (2020) <[https://ustr.gov/sites/default/files/Report\\_on\\_the\\_Appellate\\_Body\\_of\\_the\\_World\\_Trade\\_Organization.pdf](https://ustr.gov/sites/default/files/Report_on_the_Appellate_Body_of_the_World_Trade_Organization.pdf)> (last accessed 16 October 2023).

<sup>37</sup> Art 11 of the SPS Agreement.

<sup>38</sup> J Hillman, “An Emerging International Rule of Law – The WTO Dispute Settlement System’s Role in Its Evolution” (2010) 42(2) *Ottawa Law Review* 269.

<sup>39</sup> Judicialisation is defined as a “process in which courts and judges gradually take over policymaking and politics previously dominated by legislators and executives. As a result, judicialisation includes activities that might diminish the sovereignty and authority of states.” Acar, *supra*, note 7, 3.

been termed the “meta-legal” authority of science.<sup>40</sup> Currently, at the national level, scientific assessments of health risks are required in many countries to determine where regulatory action is necessary and how to regulate effectively.<sup>41</sup> This is seen as promoting regulatory rationality and preventing arbitrariness or private interest capture in the regulatory process. Similarly, at the international level, the reliance on science in legal rules as a neutral arbiter of regulatory choices has been taken over in the SPS Agreement, as discussed above.

However, the use of science in legal rules to prevent arbitrary or protectionist regulation, and thereby to promote the rule of law, has its limits. In reality, regulatory design is more than just a scientific discipline. Instead, regulations are drafted in a particular economic, social and political context and not only reflect the outcome of risk assessments but also incorporate societal preferences regarding acceptable levels of risk, economic cost/benefit analyses, political pressures brought to bear upon regulators by powerful lobby groups, consumer fears and other non-scientific factors. Science informs but does not determine SPS regulatory choices. The heavy reliance in the SPS Agreement on science as a “neutral arbiter” has been called into question, as it sits uncomfortably with the reality that health regulations are adopted in the face of divergent (and sometimes unfounded) consumer concerns, precautionary approaches and societal preferences rather than only scientifically proven health risks. This thorny issue, known as the “science versus democracy debate”, has come to the forefront of attention in the context of WTO disputes involving the SPS Agreement.<sup>42</sup>

In addition, a new understanding of the limitations of science has gradually replaced the initial view of its claims to objective validity. It is currently acknowledged that science does not provide absolute “truths” but is characterised by gaps in knowledge and uncertainties and that it is constantly evolving. Scientists deal with these realities by making use of basic assumptions, models, rules of thumb and extrapolations. This involves subjective judgment that is based on the values and dominant paradigms and ideologies of the scientific community of which the scientist is a part.<sup>43</sup> Therefore, more than one scientifically valid conclusion can be drawn from the same data. It is accordingly crucial to recognise that an element of subjectivity is present in scientific risk assessment. This understanding extends to the appreciation of the limits to the use of science in law as a tool to depoliticise decisions regarding the legitimacy of SPS regulation.

These limitations of science, however, do not imply that it is not still a useful tool in legal disciplines to promote greater rationality in SPS regulation, ensure effective protection of health and reduce the risks of arbitrariness and protectionism and thereby promote the rule of law.<sup>44</sup> Instead, they call for recognition of the limitations of the use of science in law by means of a realistic and nuanced approach to its justificatory capacity. If the WTO’s judicial organs take a too rigid or strict approach to the legal requirement of scientific justification of SPS measures in the SPS Agreement, reflecting excessive “judicialisation” by stepping into the shoes of regulatory authorities, they risk intruding

<sup>40</sup> C Joerges, “Scientific Expertise in Social Regulation and the European Court of Justice: Legal Frameworks for Denationalized Governance Structures” in C Joerges et al (eds), *Integrating Scientific Expertise into Regulatory Decision-Making: National Traditions and European Innovations* (Baden-Baden, Nomos 1997) p 320.

<sup>41</sup> J Atik, “Symposium: Institutions for International Economic Integration: Science and International Regulatory Convergence” (1997) 17 *Journal of International Law and Business* 736.

<sup>42</sup> See, eg, D Winickoff et al, “Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law” (2005) 30 *Yale Journal of International Law* 85.

<sup>43</sup> G Khachatourians, “How Well Understood Is the ‘Science’ of Food Safety?” in PWB Phillips and R Wolfe (eds), *Governing Food: Science, Safety and Trade* (Montreal, McGill-Queen’s University Press 2001) pp 13–23.

<sup>44</sup> A Green and T Epps, “The WTO, Science, and the Environment: Moving Towards Consistency” (2007) 10(2) *Journal of International Economic Law* 303.



too far into the regulatory sphere of States, thereby weakening the incentive for States to comply with its disciplines.

Although in early disputes under the SPS Agreement panels took a rather intrusive approach when applying the scientific disciplines, the Appellate Body has taken a more realistic view, interpreting the scientific obligations in a way that recognises that science is often contested and cannot provide objective and universally accepted answers regarding the existence and magnitude of a risk.<sup>45</sup> It has allowed for risks to be expressed either quantitatively or qualitatively in a risk assessment, has recognised the right of regulators to rely on divergent minority scientific opinions (provided that they are from respected and reputable sources) and has acknowledged that not only risks established under laboratory conditions but also risks arising from “real-world” factors (eg the difficulty of control and detection) may be considered as part of a risk assessment.<sup>46</sup>

Further, the Appellate Body has cautioned panels, when reviewing the risk assessments relied on by WTO Members, not to apply an intrusive standard of review (ie level of scrutiny) by substituting their own scientific judgment for that of the risk assessor.<sup>47</sup> This issue of the appropriate standard of review is crucial, as it governs the extent to which the WTO panels are entitled to interfere in Members’ regulatory determinations, thereby determining the allocation of authority to make policy choices balancing competing trade and health interests.<sup>48</sup> While a too deferential approach would create possibilities for circumvention of the scientific obligations, undermining the rule of law in disciplining SPS regulation, an intrusive or “de novo” review in which a panel acts as a risk assessor by evaluating the scientific basis for a regulation itself to determine whether it constitutes “sound science” would step too far into the regulatory space of WTO Members. The Appellate Body has set out a more balanced approach to the standard of review, holding that panels’ scrutiny of the underlying scientific basis of an SPS measure should be limited to reviewing whether it constitutes “legitimate science according to the standards of the relevant scientific community”, whereas their scrutiny of the reasoning of the risk assessor based upon such underlying science should be less deferential and should involve an “assessment of whether the reasoning of the risk assessor is objective and coherent, that is, whether the conclusions find sufficient support in the scientific evidence relied upon”.<sup>49</sup> Ensuring that panels stay within the bounds of the relevant standard of review not only respects the allocation of competences written into the SPS Agreement but also makes room for the diversity of priorities, consumer preferences, economic development and regulatory capacity between WTO Members to be reflected in the science-policy choices incorporated into national risk assessments.<sup>50</sup>

Nevertheless, the Appellate Body, in its interpretation of the science-based obligations in the SPS Agreement, has stopped short of acknowledging the role that public perceptions of risk that are not science-based can play in the regulatory process. Particularly in the face of consumer fears surrounding new agricultural or food technologies such as biotechnology, cloning, irradiation and nanotechnology, regulators may respond in

<sup>45</sup> See the discussion in S Jasanoff “The Practices of Objectivity in Regulatory Science” in C Camic, N Gross and M Lamont (eds), *Social Knowledge in the Making* (Chicago, IL, University of Chicago Press 2011) pp 307–37.

<sup>46</sup> Appellate Body Report, *EC – Hormones*, paras 186–87; Appellate Body Report, *US – Continued Suspension*, para 545.

<sup>47</sup> Appellate Body Report, *US – Continued Suspension*, para 590.

<sup>48</sup> G Shaffer, “Power, Governance, and the WTO: A Comparative Institutional Approach”, in M Barnett and R Duvall (eds), *Power in Global Governance* (Cambridge: Cambridge University Press 2005) p 159.

<sup>49</sup> Appellate Body Report, *Australia – Apples*, para 215.

<sup>50</sup> For a critical discussion of this issue, see A Alemanno, “The Dialogue between Judges & Experts in the EU and WTO” in F Fontanelli, G Martinico and P Carrozza (eds), *Shaping Rule of Law through Dialogue – International and Supranational Experiences* (Zutphen, Europa Law Publishing 2010) pp 345–73. Alemanno argues that “judges, being non-scientists, are not epistemically capable of discerning between ‘good science’ and ‘bad science’”.

trade-restrictive ways, without hidden protectionist objectives.<sup>51</sup> However, the way in which the obligation to base SPS measures on science has been interpreted in the case law means that only once a risk has been scientifically proven to exist may WTO Members give effect to consumer fears by choosing to pursue a high level of protection in their SPS regulation. This rigorous approach to the requirement of a scientific risk assessment aims to filter out disguised protectionist measures. However, it is insensitive to the reality that SPS regulation is often genuinely triggered by public perceptions of food safety risks that are not science based. It has been called a “bottleneck” to the recognition of the role of risk perception in SPS regulation in the SPS Agreement.<sup>52</sup>

As argued above, at the international level, the rule of law depends on States’ willingness to tie their own hands with legal rules, trusting that these rules reflect their common interests and appropriately balance competing priorities. An overly “judicialised” approach to the scientific disciplines in the SPS Agreement and/or a too intrusive standard of review, rather than strengthening the rule of law in disciplining SPS regulation, lead to politically unacceptable outcomes that States find difficult to comply with.<sup>53</sup> This may result in non-compliance with dispute settlement rulings or informal solutions and political accommodations between disputing parties, thereby undermining the disciplining effect of the SPS Agreement and weakening the international rule of law in this area.

## V. Conclusion

The regulation of international trade in agri-food products through SPS measures is of critical importance to safeguarding public health. However, the misuse of such regulations for protectionist or political purposes can undermine the elements of legal certainty, non-arbitrariness and non-discrimination that underpin the rule of law. To address these challenges, the SPS Agreement establishes a non-discriminatory, transparent and science-based framework, subject to impartial adjudication, for regulating SPS measures, embodying key elements of the rule of law.

However, the rule of law approach in international disciplines on SPS regulation also faces inherent limits, in particular that of ensuring that its outcomes are acceptable to States. The SPS Agreement’s heavy reliance on science as a neutral arbiter of regulatory choices to achieve this objective is misguided, as regulatory design involves multiple factors beyond scientific risk assessments, such as consumer risk perceptions, economic analyses and political pressures. Moreover, the subjectivity and uncertainties in scientific assessments necessitate a nuanced understanding of the justificatory capacity of science in law. Striking the right balance in the standard of review between deference and intrusion is crucial to maintaining States’ confidence in the rules-based system and avoiding political backlash. A realistic and balanced approach to scientific disciplines serves to ensure that the rule of law respects the diversity of priorities, consumer perceptions of risk and regulatory capacities amongst WTO Members. The Appellate Body’s case law has taken significant steps in this direction, but more is needed to avoid politically unacceptable intrusions into Members’ regulatory space. An overly “judicialised” approach to scientific disciplines allows the judicial bodies to take on the role of SPS regulator by assessing the “soundness” of the science on which measures are based and determining which non-science factors may be reflected in regulatory choices. This risks

<sup>51</sup> For a detailed discussion of this issue, see A Alemanno, “Public Perception of Risks under WTO Law: A Normative Perspective” in G Van Calster and D Prévost (eds), *Research Handbook on Environment, Health and the WTO* (Cheltenham, Edward Elgar 2012).

<sup>52</sup> *ibid.*

<sup>53</sup> Examples of SPS disputes in which compliance has been problematic, namely *EC – Biotech Products* and *EC – Hormones*, are precisely those in which the measures at issue reflected consumer fears rather than sound science.

undermining the effectiveness of the SPS Agreement, as it may lead to non-compliance, thus weakening the rule of law.

In conclusion, the rule of law as reflected in the SPS Agreement serves as a critical instrument in fostering stable and peaceful trade relations whilst safeguarding public health. Its emphasis on transparency, non-discrimination, non-arbitrariness through scientific justification and dispute settlement ensures fairness, legal certainty and accountability in SPS regulation. Although science plays a valuable role in promoting regulatory rationality and non-arbitrariness, its limitations necessitate a cautious approach to its justificatory capacity in law. A balanced application of the rule of law elements in the SPS Agreement by the judicial organs of the WTO, respecting Members' regulatory space and diverse priorities, is essential to ensuring that the SPS Agreement genuinely promotes both public health and economic growth. As the global food supply chain continues to become more complex and interconnected, upholding the evolving concept of the rule of law in SPS regulation will remain an ongoing challenge and an essential pillar in achieving a more peaceful, prosperous and just world.

**Competing interests.** The author declares none.