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The Impact of WTO SPS Law on EU Food Regulations

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Chris Downes
European Consulting Company (ECCO)
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About the Author

Dr. Chris Downes has 15 years of experience working as a consultant on issues related to EU food law. He is currently Manager, International Trade & Regulatory Affairs at The European Consulting Company (ECCO), a Brussels-based consultancy specialising in food and trade policy. He is a guest lecturer on international economic law at the University of Kent, teaching at their Brussels campus.

Abbreviations

AB	Appellate Body
ADI	Acceptable Daily Intakes
AJIL	American Journal of International Law
ALOP	Appropriate Level of Protection
ASEAN	Association of South East Asian Nations
CAC	Codex Alimentarius Commission
CCFA	Codex Committee on Food Additives
CCFAC	Codex Committee on Food Additives and Contaminants
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CML Rev	Common Market Law Review
CNFR	Current Novel Food Regulation
DG Sanco	European Commission, Directorate General for Health & Consumers
ECJ	European Court of Justice
EJIL	European Journal of International Law
EL Rev	European Law Review
Envtl L	Environmental Law
EP	European Parliament
EU	European Union
FAO	Food and Agriculture Organisation
FVO	Food and Veterinary Office (European Commission)
GAIN	Global Agriculture Information Network
GATT	General Agreement on Tariffs and Trade
GM	Genetically Modified
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
GSFA	General Standard on Food Additives
HACCP	Hazard Analysis Critical Control Point
INS	International Numbering System
IPPC	International Plant Protection Convention
IR	International Relations

JCMS	Journal of Common Market Studies
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JWT	Journal of World Trade
KFDA	Korean Food and Drug Administration
LL	Liberty Link
MEP	Member of the European Parliament
Mercosur	Mercado Común del Sur (Southern Common Market)
MLR	Modern Law Review
MRA	Mutual Recognition Agreements
NA & EP	Notification Authority & Enquiry Point
NAFTA	North American Free Trade Agreement
NNFR	New Novel Food Regulation
PPM	Process and Production Method
RDI	Reference Daily Intakes
SPS	Sanitary and Phytosanitary
SPS Agreement	World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures
TBT	Technical Barriers to Trade
UK FSA	UK Food Standards Agency
US FDA	US Food and Drug Administration
USDA	US Department of Agriculture
VCLT	Vienna Convention on the Law of Treaties
VJIL	Virginia Journal of International Law
VMS	Vitamin and Mineral Food Supplements
WHO	World Health Organisation
WTO	World Trade Organisation

Chapter 1
Introduction

Abstract This introductory chapter explains the anomaly in assessments of the SPS Agreement that prompted further investigation into its impact on EU food regulations: the view of legal commentators that the regime significantly intrudes on domestic policy-making and the common understanding of EU officials that its influence is marginal. The chapter provides context for the analysis that follows, briefly introducing the Agreement, its origins, provisions and key implications for national regulators and outlining the legal and political context in which European food regulators operate. It then familiarises the reader with two important international venues for the development of food norms: the WTO Committee on Sanitary and Phytosanitary Measures and Codex Alimentarius. It concludes with an outline of the structure of the book and provides some guidance to readers.

1.1 Why Another Book About the WTO SPS Agreement?

A vast amount has already been written about the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the primary WTO text governing domestic food regulation.[1] Too much, perhaps. Reviewing a recent addition to the literature on the subject, Jacqueline Peel notes (barely suppressing a sigh, one suspects) that 'one might reasonably question the utility of another book devoted to the topic'.[2] My sense that this well-trodden ground merited further investigation stemmed from an incident in spring 2005.

Academic study of the Agreement at that time drew confident conclusions from early SPS-related case law that national regulators would henceforth face considerable constraints in developing new regulatory measures. With this in mind, I visited Rue Breydel in Brussels—home to the European Commission's service responsible for consumer protection and health (DG Sanco)—to represent the views of an industry group on a food law proposal under discussion. Well armed, I felt, with a convincing set of arguments drawn from SPS law, I contested the WTO compatibility of the new regulation. Somewhat bemused, the official concerned informed me

[1] Agreement on the Application of Sanitary and Phytosanitary Measures, opened for signature 15 April 1994, 1867 UNTS 493 (entered into force 1 January 1995) (SPS Agreement).

[2] J Peel, 'Review: *Regulating Health and Environmental Risks under WTO Law: A Critical Analysis of the SPS Agreement*. By Lukasz Gruszczynski' (2011) 23 *Journal of Environmental Law* 157.

C. Downes, *The Impact of WTO SPS Law on EU Food Regulations,* Studies in European Economic Law and Regulation 2, DOI 10.1007/978-3-319-04373-9_1,

that his limited knowledge of the SPS Agreement left him in no position to judge the case presented, and the discussion moved swiftly on. This rather dismissive attitude is not unusual. In the course of researching this book, I have pressed numerous officials dealing with different aspects of European food law for their views about the influence of the SPS Agreement on their work. Grappling with highly political and emotive food issues, the demands of domestic economic interests, the irreconcilability of diverging national cultural preferences, as well as dodging inter-institutional skirmishes, international legal obligations are consistently reported to be marginal to their everyday concerns.

In one sense, such responses are not surprising. One would not realistically expect all European Union (EU) officials to be well versed in international law, nor the presumptions of academics to be perfectly reproduced in the day-to-day realities of policy-making. Nevertheless, the disparity between academic and administrative perceptions of the SPS Agreement's significance raised questions in my mind about the validity and relevance of much scholarly work on this topic. What, if anything, has been the real impact of the SPS Agreement? Do international lawyers simply overestimate the influence that multinational agreements place upon domestic actors? Or does international law constrain the European decision-making process in a way that is not immediately obvious even to those directly involved? This book attempts to offer some answers to these questions.

A not unreasonable consideration at this point is whether it is worth dwelling too extensively on how scholars perceive the operation of an international treaty. In other words, why should we care how lawyers choose to characterise the SPS Agreement?

There are three ways in which academic work on the SPS Agreement may have broader ramifications. A first consideration is legal commentators' contribution to wider public acceptance of the WTO. Academic criticism of the SPS Agreement helps sustain the commonly held perception of an organisation that, in pursuit of free trade, silences valid public concerns. The resulting public frustration can spill over in a dramatic fashion as in Seattle in 1999, where the WTO's approach to growth hormones in beef was a prominently cited grievance in the violent street protests.[3] Regardless of one's views on the issue in question, it would be perverse if public anger was the product of an entirely erroneous understanding of the body's influence. Secondly, an overblown conception of the invasiveness of the SPS Agreement in national policy-making may galvanise legal reform.[4] If the evaluation that propels a call to rewrite the SPS Agreement is inaccurate, the remedies proposed are unlikely to be suitable. Any changes to the legal framework, and the efforts required to negotiate them, may then prove unnecessary or even harmful. If we wish to improve the system, we first have to understand its real impact. Finally, there is the behaviour of policy-makers themselves. If national administrators are encouraged to believe that their policy options will be unduly constrained by international law,

[3] J Madeley, 'There's a Food Fight in Seattle' *New Statesman* (22 November 1999) www.newstatesman.com/node/136187.

[4] For examples of proposals for revising the SPS Agreement, see n 78 in Chap. 3 below.

this may change the way they interact with other countries in international bodies, such as Codex Alimentarius, aimed at facilitating and managing the global food trade.[5] However, should international rules be shown not unduly to impinge upon national policy-making, potentially beneficial cooperation and compromise within these bodies need not be eschewed. The question of how we represent the power and influence of a legal regime is therefore not of purely academic interest.

More recently, particularly following the *US—Continued Suspension* dispute, scholars have tended to downplay the potential intrusiveness of the SPS Agreement.[6] In one way, this dilutes the anomaly that initially prompted this research. Yet, if anything, this latter trend towards a less negative appraisal of the SPS Agreement only accentuates the rather curious relationship between lawyers, law and social reality. How can a single dispute transform our appreciation of a treaty and the role it plays in international society? Does the revised view of the SPS Agreement imply that its significance has been wrongly understood over the preceding decade? Will the outcome of subsequent dispute settlement cases once more reverse the swing of the scholarly pendulum? More than ever, we need to understand the actual impact of the SPS Agreement.[7]

As indicated by Peel, the SPS Agreement has been extensively treated elsewhere. Nevertheless, for the benefit of readers not so familiar with the role of the Agreement, the remainder of this Introduction aims to situate the analysis that will follow. Section 1.2 briefly introduces the Agreement, its origins, provisions and key implications for national regulators. Section 1.3 describes how legal commentators have customarily characterised the SPS Agreement and its impact on domestic policy-making, the intriguing demonisation of the regime that initially provoked this study. As the focus of this book is largely on the Agreement's impact on the EU food

[5] There is some evidence of this, for example, in Codex Alimentarius meetings on food additives, in which EU representatives have recently started to adopt norms with a caveat (known as 'note 161') that accepts international standards only 'subject to national legislation'. See Codex Alimentarius Commission Document ALINORM 10/33/12, para 70–75. For a detailed discussion, see C Downes, 'Only a Footnote? The Curious Codex Battle for Control of Additive Regulations' (2012) 7 *European Food and Feed Law Review* 232.

[6] See, e.g. L Gruszczynski, *Regulating Health and Environmental Risks under WTO Law: A Critical Analysis of the SPS Agreement* (Oxford, OUP, 2010) 273 (concluding that 'the SPS Agreement is actually able to provide a workable mechanism that seriously takes into account the complex nature of science and scientific risk assessment and does not compromise the legitimate regulatory choices of WTO members'); B Mercurio and D Shao, 'A Precautionary Approach to Decision Making: The Evolving Jurisprudence on Article 5.7 of the SPS Agreement' (2010) 2 *Trade Law and Development* 195, 223 (noting that the Agreement 'is capable of being flexibly interpreted so as to both protect policy space and national regulations and at the same time protect against creeping protectionism'); S Cho, 'International Decisions, *United States—Continued Suspension of Obligations in the EC—Hormones*' (2009) 103 AJIL 299, 302 (pointing to the Appellate Body's (AB) 'ostensible effort to broaden a regulating member's policy space'). Others remain doubtful. See, e.g. J Peel, 'Of Apples and Oranges (and Hormones in Beef): Science and the Standard of Review in WTO Disputes under the SPS Agreement' (2012) 61 ICLQ 47 (pointing to the intrusive nature of the AB's approach in *Australia—Apples* subsequent to the *US—Continued Suspension* dispute).

[7] See Gruszczynski (n 6) 274 (noting that 'the impact of the SPS Agreement on the practice of WTO Members definitely merits a separate and detailed study').

policy, Sect. 1.4 will then provide a short scene-setting introduction to the legal and political context in which European regulators operate. Section 1.5 familiarises the reader with two important international venues for the development of food norms—the WTO Committee on Sanitary and Phytosanitary Measures (SPS Committee) and Codex Alimentarius—on which Part III of this book will focus. The Introduction concludes with an outline of the structure of the book and provides some guidance to readers (Sect. 1.6).

1.2 What Is the SPS Agreement?

1.2.1 Background

Concerns about the safety of imported food and suspicions of protectionism have been recurring features of trade in agricultural products for almost 150 years.[8] Before the Uruguay Round came into effect in 1995, all technical regulations fell within the scope of the General Agreement on Tariffs and Trade (GATT) Standards Code, which sought to outlaw technical standards that unnecessarily obstructed international trade.[9] However, the Code failed to provide an adequate framework for distinguishing necessary from unnecessary measures.[10] This ambiguity, combined with deficient enforcement, rendered the GATT largely ineffective at disciplining non-tariff measures.[11] From the outset of the Uruguay Round of negotiations launched to reform the GATT, technical regulations in the context of agricultural trade were singled out for attention.[12] Although there was no explicit mandate to do so, the Working Group charged with the task of addressing this issue quickly concluded that a separate code specific to agricultural measures was required.[13] Consequently, the Uruguay Round replaced the Standards Code with two separate agree-

[8] See T Epps, *International Trade and Health Protection* (Cheltenham, Edward Elgar, 2008) 17 (providing an interesting history of some of these disputes).

[9] Agreement on Technical Barriers to Trade, 12 April 1979, 1186 UNTS 276, GATT, BISD, 26th Supp 8 (1980).

[10] SJ Rothberg, 'From Beer to BST: Circumventing the GATT Standards Codes Prohibition on Unnecessary Obstacles to Trade' (1990) 75 *Minnesota Law Review* 505, 516–517.

[11] DG Victor, 'The Sanitary and Phytosanitary Agreement of the World Trade Organisation: An Assessment After Five Years' (2000) 32 *New York University Journal of International Law and Politics* 865, 874.

[12] GATT, Ministerial Declaration of Uruguay Round (GATT Doc MINDEC 20 September 1986), s D, Agriculture, iii (setting the aim of 'minimizing the adverse effects that sanitary and phytosanitary regulations and barriers can have on trade in agriculture, taking into account the relevant international agreements').

[13] GATT Doc MTN.GNG/NT5/WGSP/2 (14 November 1988) para 12. The prominent differences in European and US thinking on the use of growth hormones in meat were undoubtedly a factor in this decision. See DA Wirth, 'The Role of Science in the Uruguay Round and NAFTA Trade Disciplines' (1994) 27 *Cornell International Law Journal* 817, 823–824.

ments, one oriented towards sanitary and phytosanitary measures (SPS Agreement), and a further one aimed at regulating non-sanitary measures (Technical Barriers to Trade or TBT Agreement[14]).

In the context of the hard-fought liberalisation of agricultural trade, the SPS dimension of the Uruguay Round negotiations was relatively straightforward. There were limited changes between the draft text adopted in late 1990 and the final text adopted some 18 months later, once the deadlock on market access issues had been broken.[15] In the light of post-agreement conflicts, one popular narrative of the negotiations is that the EU[16] did not hold its ground in negotiations, culminating in a text that leaned manifestly towards the US regulatory philosophy.[17] However, in practice, all the major agricultural exporters, the EU included, were important players in discussions from the outset.[18] The EU had not only major defensive interests relating to the ongoing dispute on growth hormones in meat, but frustrated ambitions concerning the exports of wine.[19] The greatest resistance to the proposed text in the latter stages in fact came from the US delegation,[20] largely due to public fears of a drop in US food standards.[21] This issue was ultimately addressed by allowing individual Members to introduce measures more stringent than required by international standards. The one matter that was not conclusively resolved in the final text was the legitimacy of non-scientific concerns as a basis for setting sanitary

[14] Agreement on Technical Barriers to Trade, opened for signature 15 April 1994, 1868 UNTS 120 (entered into force 1 January 1995).

[15] TP Stewart, *The GATT Uruguay Round: A Negotiating History (1986–1994)* (The Hague, Kluwer Law International, 1999) 41. See also J Croome, *Reshaping the World Trading System: A History of the Uruguay Round* (Geneva, WTO Secretariat, 1995) 235–237.

[16] For simplicity, and at the risk of anachronism, the name 'European Union' (abbreviated to 'EU') will be used throughout this book, although until December 2009, and the entry into force of the Lisbon Treaty, the European Communities (EC) was the formal Member of the WTO. The same approach will be adopted when discussing regulatory developments predating the existence of the European Union.

[17] Drezner, for example, claims that 'the SPS Agreement was a low-priority issue for the European Union during the Uruguay round' and 'was not a major player in the SPS negotiations'. DW Drezner, *All Politics Is Global: Explaining International Regulatory Regimes* (Princeton, Princeton University Press, 2008) 162–163.

[18] See MTN.GNG/NT5/WGSP/1 (28 October 1988).

[19] At a key moment in discussions, the EU was facing restrictions on exports of wine to the US due to the presence of the pesticide procymidone. As Codex was in the process of adopting a residue limit for the pesticide, the EU keenly understood the potential benefits of reinforcing the role of international standards in the new agreement. See D Prévost and P van den Bossche, 'The Agreement on the Application of Sanitary and Phytosanitary Measures' in PFJ Macrory, AE Appleton and MG Plummer (eds), *The World Trade Organization: Legal, Economic and Political Analysis* (Berlin, Springer, 2005) 243.

[20] Stewart (n 15) 42.

[21] See H Rowen, 'Are Food Imports Safe?' *Washington Post* (31 May 1990).

measures,[22] an ambiguity that today remains one of the most significant challenges for policy-makers.[23]

1.2.2 Key Disciplines

The Agreement's core principles and aims are relatively simple. The SPS Agreement affirms the basic right of WTO Members to take measures to protect 'human, animal or plant life or health' (Article 2.1).[24] It also reiterates the obligations established in the GATT Agreement not to 'arbitrarily or unjustifiably discriminate' between Members, and prohibits applying measures in a manner that constitutes 'a disguised restriction on international trade' (Article 2.3). A distinguishing prerequisite for SPS measures is that they must generally be based on scientific principles and adequate scientific evidence (Article 2.2). To ensure that this is the case, a particular emphasis is placed upon substantiation through appropriate risk assessment (Article 5). This requirement is not absolute. Where there is insufficient scientific evidence to maintain a measure in this way, Members may provisionally act on the basis of 'available pertinent information' (Article 5.7).

Science has an obvious prominence throughout the SPS Agreement, but is not the only relevant factor in developing measures. In assessing the risk of determining the appropriate measure, Members must (under Article 5.3) also take into account economic factors (including, for example, 'the relative cost-effectiveness of alternative approaches') and strive to minimise negative trade effects (Article 5.4). There is also a more complex requirement to ensure consistency in the level of protection offered across SPS measures (Article 2.5). A further overarching obligation for WTO Members is to advance international harmonisation, both by basing domestic measures on international standards (Article 3.1) and through active involvement in international organisations (Article 3.4). While striving for harmonisation, the SPS Agreement does not necessarily require homogeneity of measures. Members must also accept the measures of other Members, regardless of their particular regulatory form, provided that they meet the level of protection deemed acceptable to the importing Member. The SPS Agreement hereby opens up the opportunity for inter-Member scrutiny and discussion of respective policies (Article 4).

As well as bringing discipline to WTO Members' development of sanitary measures, the SPS Agreement seeks to illuminate this process by introducing a commitment to transparency (Article 7 and Annex B). The latter includes a requirement for each Member to notify any new measures under consideration and ensure publication of all measures in force. A large number of SPS measures involve the control, inspection and approval of food. Article 8 and Annex C seek to improve

[22] See Epps (n 8) 27.

[23] See discussion in Chaps. 4 and 5 below.

[24] As the focus in this study is on food policy, provisions specifically oriented towards plant or animal health (such as SPS Agreement Art 6 relating to pest- or disease-free areas) are not considered.

the operation of these procedures: for example, by ensuring that they are no more burdensome in timing and information requirements than is absolutely necessary. In order to manage the operation of the SPS Agreement and advance its objectives, the Agreement establishes a Sanitary and Phytosanitary Committee made up of WTO Members. The Committee is charged to undertake activities required to advance the objectives of the Agreement, such as liaising with international organisations, monitoring harmonisation and facilitating communication between Members (Article 12). So that it can deal with the different levels of development of country Members, a commitment is made to provide technical assistance to other Members (Article 9) and to offer special and differential treatment to cater for the special needs of developing-country Members (Article 10).

1.2.3 What Are the Implications for Domestic Policymakers?

What do these disciplines actually mean for the national management of food policy? When trying to apply the basic principles outlined above to scientifically contentious and politically divisive areas of food policy, the vagueness of many of the SPS provisions soon becomes apparent.[25] Nevertheless, the dispute-settlement cases that have been brought before the WTO over the last 15 years, although limited in number, have brought clarity to a number of articles in a way that provides policy-makers with some idea of the scope of the requirements imposed. These have been dealt with expertly and comprehensively elsewhere.[26] As an introduction to the types of dilemma that the SPS Agreement creates for national administrations, a number of examples are given below of questions that have been explored by dispute-settlement bodies:

Does the SPS Agreement Allow a WTO Member to Choose What Risk Is Acceptable?

It remains the 'prerogative'[27] of WTO Members to establish what they consider to be an appropriate level of protection for their own citizens. This may be set as high as the Member chooses—potentially at 'zero risk'[28]—even in cases where the subject of the measure has already been treated in an internationally agreed

[25] The AB has vented its frustration about the difficulties in interpreting some aspects of the Agreement. See *EC—Measures concerning Meat and Meat Products* (*Hormones*), Appellate Body Report (adopted 16 January 1998) WT/DS26/AB/R, WT/DS48/AB/R, para 175 (in which the AB noted that 'Article 3.3 is evidently not a model of clarity in drafting and communication').

[26] For the fullest and most up-to-date analysis at the time of writing, see Gruszczynski (n 6).

[27] *Australia—Measures Affecting Importation of Salmon (Australia—Salmon),* Appellate Body Report (adopted 20 October 1998) WT/DS18/AB/R, para 199.

[28] *Australia—Salmon,* Appellate Body Report, para 125.

standard.[29] However, freedom is circumscribed somewhat by an 'implicit obligation' clearly to determine the level of protection, although not necessarily in quantitative terms.[30] A Member's chosen level of protection is paramount even where different to the actual level of protection provided by the applied measure.[31] This distinction is particularly important in a situation where other Members are seeking to demonstrate inconsistency between Members' measures under Article 5.5 and to suggest adequate and less trade-restrictive alternatives. The level of protection to be met in this instance is that determined by the Member and not that which may be inferred from the chosen measure.[32]

How Closely Does a WTO Member's Measure Have to Relate to the Available Science?

A greater constraint on national regulatory freedom arises from the obligation that measures be 'based on' risk assessment. To meet the demands of the SPS Agreement, there must be 'a rational relationship between the measure and the risk assessment'.[33] Rationality does not imply the need to adhere to mainstream scientific thinking. A minority scientific view can be considered a valid basis for a measure, provided 'the divergent opinion [is] coming from qualified and respected sources'.[34] Nevertheless, evidence pointing to potential general risk is not adequate. In order for a Member to draw upon the available science, it must be 'sufficiently specific to the case at hand'.[35] The adequacy of the scientific basis would have to be judged on a case-by-case basis.[36]

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[29] *Hormones*, Appellate Body Report, para 172.

[30] *Australia—Salmon,* Appellate Body Report, para 205.

[31] *Australia—Salmon,* Appellate Body Report, para 197 (in which Australia characterised its appropriate level of protection as 'very conservative', whereas the prohibition in place ensured 'zero risk').

[32] *Australia—Salmon,* Appellate Body Report, para 203. However, if the Member has failed to sufficiently determine its level of protection, this may be inferred from the measure actually applied. See paras 206–207.

[33] *Hormones*, Appellate Body Report, para 193.

[34] *Hormones*, Appellate Body Report, para 194.

[35] *Hormones*, Appellate Body Report, para 200 (in which the general studies demonstrating an overall risk of cancer associated with hormones were not found to be an adequate basis for the EU's restrictions) and *Japan—Apples*, Appellate Body Report, para 202 (finding the 'general discussion' of fire blight in Japan's risk assessment not to constitute risk assessment within the meaning of Art 5.1).

[36] *Japan—Measures Affecting Agricultural Products*, Appellate Body Report (adopted 22 February 1999) WT/DS76/AB/R, para 84.

What Can WTO Members Consider an Appropriate Risk Assessment?

The requirement to draw on risk assessment, in turn, places under scrutiny the adequacy of the scientific evaluation used by a Member to justify measures. Risk assessment has been defined as 'a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions'.[37] A Member does not have to undertake its own assessment, but can rely on an evaluation carried out by another Member or international body.[38] Article 5.2 provides a list of elements that can be taken into account in risk assessment, but this is not exhaustive. Factors 'not susceptible to quantitative analysis' can be equally relevant to a risk assessment.[39] Members are obliged to take into account risk assessment techniques developed by relevant international organisations, but are not compelled to replicate a particular form of risk assessment, which may be shaped in part by the level of protection chosen by the individual Member.[40] The risk that a Member seeks to analyse cannot be purely theoretical,[41] and the assessment again has to be adequately focused on that specific risk.[42]

When Can the WTO Member Take Provisional Measures?

In many cases, regulators find that scientific evidence is inconclusive, or that new research may bring into question previous understandings of risk. The Agreement creates the thankless task for a WTO Member or adjudicator of determining whether evidence is sufficient to be assessed in the normal way (under Article 2.2 and 5.1) or insufficient to permit the use of provisional measures (not based on risk assessment). The quantity of evidence, in itself, is not deemed to be determinant as 'a lot of scientific research has been carried out on a particular issue, without yielding reliable evidence'.[43] Nor is the fact that the science is controversial.[44] Furthermore, the existence of either an international standard or a broad scientific consensus does not mean *per se* that 'sufficient' scientific evidence is available within the mean-

[37] *Hormones,* Appellate Body Report, para 187.

[38] *Hormones,* Appellate Body Report, para 190.

[39] *Hormones,* Appellate Body Report, para 187.

[40] *United States/Canada—Continued Suspension of Obligations in the EC—Hormones Dispute (US—Continued Suspension),* Appellate Body Report (adopted 31 March 2008) WT/DS320/R, WT/DS321/R, paras 534 and 685.

[41] *Hormones*, Appellate Body Report, para 186.

[42] It is not sufficient, under Art 5.1, to undertake just *some* evaluation of the likelihood of the spread of disease, as Australian quarantine authorities were considered to have done in *Australia—Salmon*, if this evaluation leads only to 'general and vague statements'. *Australia—Salmon,* Appellate Body Report, para 129.

[43] *Japan—Measures Affecting the Importation of Apples*, Appellate Body Report (adopted 26 November 2003) WT/DS245/AB/R, para 185.

[44] *US—Continued Suspension*, Appellate Body Report, para 677.

ing of Article 5.7.[45] The finely determined requirement for recourse to Article 5.7 in cases of scientific controversy is that 'a qualified and respected scientific view … puts into question the relationship between the relevant scientific evidence and the conclusions in relation to risk thereby not permitting the performance of a sufficiently objective assessment of risk'.[46]

How Far Can a Member Deviate from International Standards?

Where a Member's measure 'conforms to' international standards, there is a (rebuttable) presumption of SPS consistency (Article 3.2).[47] However, a Member can choose either to 'base' a measure on international standards—incorporating some elements of the standard, but not others[48]—or to introduce an entirely unrelated measure which provides a higher level of protection than would be provided by the international standard. Where it does so, however, it must be supported by adequate risk assessment.[49] It is not entirely clear whether a measure providing a higher level of protection may nevertheless be considered to be based on an international standard, a claim that would potentially strengthen a Member's defence against a complainant.[50] A Member has an incentive to conform to international standards, but a failure to do so does not imply that the burden of proof is upon that Member to justify its deviation from the standard.[51]

As these examples indicate, the Agreement establishes a fundamental tension between, on the one hand, the national regulator's freedom to choose the measures deemed appropriate, and on the other, a notable scientific evidentiary burden. This book will explore the extent that this tension, so evident in abstraction, has in practice coloured the domestic regulatory process.

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[45] *US—Continued Suspension*, Appellate Body Report, paras 695–696. In this case, the Panel had held that there is a need for a Member to bring forward a 'critical mass' of scientific evidence in order to demonstrate that previously sufficient scientific information is now insufficient. However, the AB ruled (at para 705) that the threshold implied, equivalent to a 'paradigm shift', was far too 'inflexible'.

[46] *US—Continued Suspension*, Appellate Body Report, para 677.

[47] A conforming measure is one that 'would embody an international standard completely and, for practical purposes, converts it into a municipal standard'. *Hormones*, Appellate Body Report, para 170.

[48] *Hormones,* Appellate Body Report, para 163.

[49] *Hormones*, Appellate Body Report, para 177.

[50] For a detailed discussion, see Gruszczynski (n 6) 96–100.

[51] *Hormones*, Appellate Body Report, para 102.

1.3 How the SPS Agreement's Influence Is Generally Portrayed

The particular focus of this book on the SPS Agreement's impact on domestic policy-making brings with it a danger of overstating the importance of this dimension in the research to date. Many analysts, it should be noted from the start, are not predominantly concerned with the question of 'impact'. In some cases, commentators primarily aim to explain the content and functioning of SPS law.[52] Such analysis does not endeavour to draw far-reaching conclusions about the effect of the Agreement.[53] Other studies focus on the detail of a single WTO dispute, not necessarily exploring its wider implications for domestic regulations.[54] Alternatively, the author's primary interest may lie in a specific area of food policy,[55] the overall operation of the WTO[56] or an aspect of the policy-making process.[57] In each case, the SPS Agreement forms a significant factor of the analysis undertaken, but the impact of law on domestic policy falls beyond the scope of these studies.

While clearly not all writers choose to reflect on the significance of the Agreement for national regulators, it is nevertheless a regularly recurring theme. Some commentators are hesitant about positing a direct link between international legal

[52] Pauwelyn's assessment of the SPS regime is exemplary in this respect, highlighting the significant aspects of the text, describing dispute-settlement findings and explaining the implications of the latter for an understanding of the Agreement's provisions. J Pauwelyn, 'The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures As Applied in the First Three SPS Disputes' (1999) 2 JIEL 641. For this type of evaluation of Codex Alimentarius, see TP Stewart and DS Johanson, 'The SPS Agreement of the World Trade Organisation and International Organisations: The Roles of the Codex Alimentarius Commission, International Plant Protection Convention, and International Office of Epizootics' (1999) 26 *Syracuse Journal of International Law and Commerce* 27.

[53] Pauwelyn emphasises that 'no attempt is made to critically assess what has been decided [in dispute settlement]'. Pauwelyn (n 52) 642.

[54] For discussion of the *EC—Biotech* dispute, see S Poli, 'The EC's Implementation of the WTO Ruling in the Biotech Dispute' (2007) 32 EL Rev 705; S Lester and D Bodansky (ed), 'International Decisions: *European Communities-Measures Affecting the Approval and Marketing of Biotech Products*' (2007) 101 AJIL 453. On the *Hormones* dispute, see D Wüger, 'The Never-Ending Story: The Implementation Phase in the Dispute between the EC and the United States on Hormone-Treated Beef' (2002) 33 *Law and Policy in International Business* 777.

[55] See, e.g. JMM Akech, 'Developing Countries at Crossroads: Aid, Public Participation, and the Regulation of Trade in Genetically Modified Foods' (2006) 29 *Fordham International Law Journal* 265; AE Appleton, 'The Labelling of GM Products Pursuant to International Trade Rules' (2000) 8 *New York University Environmental Law Journal* 566; C Carlarne, 'From the USA with Love: Sharing Home-Grown Hormones, GMOs, and Clones with a Reluctant Europe' (2007) 37 *Environmental Law* 301.

[56] See PXF Cai, 'Between Intensive Care and the Crematorium: Using the Standard of Review to Restore Balance to the WTO' (2007) 15 *Tulane Journal of International and Comparative Law* 465 (discussing SPS jurisprudence at length in a study of the standard of review in the WTO dispute settlement process).

[57] J Atik, 'Science and International Regulatory Convergence' (1996) 17 *Northwestern Journal of International Law and Business* 736 (on the role of science in regulation).

obligations and domestic policy. For example, Kalderimis considers that attention paid to WTO compatibility will '*likely* define the [Genetically Modified Organism (GMO)] health policies of a number of countries'[58] and Peel argues that WTO rulings '*may* have far-reaching effects for the area of sanitary and phytosanitary (SPS) risk management'.[59] Others are far less diffident in claiming to have identified a decisive factor in policy formation. SPS rules are pronounced to have 'a significant impact'[60] and 'great implications'.[61] They are viewed as able to 'strike down domestic health regulation'[62] and 'constrain … the domestic policy objectives member countries may pursue, and what policy tools member countries may use'.[63] The power of the SPS regime to impinge upon domestic control causes some dismay. It is perceived to undermine the existing practice of food regulation by 'unmistakably elevat[ing] the policing of trade restrictive measures above the ability of national governments to address risk'.[64] This will 'strip national regulators of their discretion',[65] 'choke the ability of a sovereign nation to decide how best to promote the values of its people'[66] and 'gobble all domestic laws that have any impact on in-

[58] D Kalderimis, 'Problems of WTO Harmonisation and the Virtues of Shields over Swords' (2004) 13 *Minnesota Journal of Global Trade* 305, 326 (emphasis added).

[59] J Peel, 'A GMO by Any Other Name… Might be an SPS Risk!: Implications of Expanding the Scope of the WTO Sanitary and Phytosanitary Measures Agreement' (2006) 17 EJIL 1009, 1011 (emphasis added).

[60] BA Silverglade, 'The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade?' (2000) 55 *Food and Drug Law Journal* 517.

[61] MD Carter, 'Selling Science under the SPS Agreement: Accommodating Consumer Preference in the Growth Hormones Controversy' (1997) 6 *Minnesota Journal of Global Trade* 625, 655.

[62] J Bohanes, 'Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle' (2002) 40 *Columbia Journal of Transnational Law* 323, 356. See also O Aginam, 'Food Safety, South-North Asymmetries and the Clash of Regulatory Regimes' (2007) 40 *Vanderbilt Journal of Transnational Law* 1099, 1111 (claiming that WTO Members 'are often compelled to abandon the obligations they undertook in other pre-existing international regimes'); A Szajkowska, *Regulating Food Law: Risk Analysis and the Precautionary Principle as General Principles of EU Food Law* (Wageningen, Wageningen Academic Publishers, 2012) 59 (arguing that 'the system of trade rules aims to limit discretion as much as possible').

[63] LM Wallach, 'Accountable Governance in the Era of Globalization: The WTO, NAFTA, and International Harmonization of Standards' (2002) 50 *University of Kansas Law Review* 823, 827; DG Victor (n 11) 937 (claiming that the policy-maker's 'freedom is constrained'); See also G Skogstad, 'Internationalization, Democracy, and Food Safety Measures: The (Il)Legitimacy of Consumer Preferences' (2001a) 7 *Global Governance* 293, 295 (noting that '[t]he EU, in particular, finds compromised its policy autonomy and its capacity to render governments accountable').

[64] AO Sykes, 'Domestic Regulation, Sovereignty, and Scientific Evidence Requirements: A Pessimistic View' (2002) 3 *Chicago Journal of International Law* 353, 368.

[65] RA Pereira, 'Why Would International Administrative Activity Be Any Less Legitimate?—A Study of the Codex Alimentarius Commission' (2008) 9 *German Law Journal* 1693.

[66] S Keane, 'Can the Consumers' Right to Know Survive the WTO: The Case of Food Labelling' (2006) 16 *Transnational Law and Contemporary Problems* 291, 331.

ternational trade'.[67] Indeed, 'it is hard to imagine a greater intrusion on conventional notions of sovereignty.'[68]

What is striking is not only the certitude expressed by many of these analysts about the regime's impact, but the tone in which they convey their observations. Far from showing lawyerly detachment, their language is frequently tinged with menace, even violence, suggesting that the WTO has set in motion a change of dramatic proportions. The SPS Agreement acts as a 'wrecking ball',[69] initiating a 'clash of regulatory regimes',[70] and 'hangs like the proverbial sword of Damocles over national risk regulators'.[71] The enforcement of WTO rules is a 'procrustean' process[72] that 'cuts close to the heart of state sovereignty and domestic authority'[73] and leaves national measures like a 'fly caught in a spider's web'.[74] As Bloche has noted, the portrayal of the WTO agreements as 'implacable threats … constitutes pessimism bordering on panic'.[75] Given its recurrence, it is difficult to dismiss this language as mere rhetorical extravagance, an attempt to add a little colour to the insipid world of sanitary measures. Rather, the linguistic choices betray a deeper unease about the damaging grip of the SPS Agreement on national governance.[76]

Part I of this book explores why an international agreement, perceived to be of marginal importance by many regulators, has stirred such emotions among legal writers.

1.4 The EU Food Policy Context

The typical narrative of the development of EU food law—the domestic regulatory setting predominantly treated in this book—describes a clear shift in focus over time, from ensuring the operation of the Single Market to guaranteeing consumer

[67] D Schramm, 'The Race to Geneva: Resisting the Gravitational Pull of the WTO in the GM Labelling Controversy' (2007) 9 *Vermont Journal of Environmental Law* 93, 125.

[68] AT Guzman, 'Food Fears: Health and Safety at the WTO' (2004) 45 VJIL 1, 26.

[69] Shramm (n 67) 110.

[70] Aginam (n 62).

[71] A Arcuri, 'Food Safety at the WTO after Continued Suspension' in A Antoniadis, R Schütze and E Spaventa (eds), *The European Union and Global Emergencies–A Law and Policy Analysis* (Oxford, Hart Publishing, 2011). This echoes the language of Kalderimis who defines the defence of values in the SPS regime in terms of 'swords and shields'. Kalderimis (n 58).

[72] D Winickoff et al., 'Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law' (2005) 30 YJIL 81, 93.

[73] Guzman (n 68) 24.

[74] HS Shapiro, 'The Rules That Swallowed the Exceptions: The WTO SPS Agreement and its Relationship to GATT Articles XX and XXI' (2007) 24 *Arizona Journal of International and Comparative Law* 199, 212.

[75] MG Bloche, 'WTO Deference to National Health Policy: Towards an Interpretive Principle' (2002) 5 JIEL 825, 827.

[76] See Cai (n 56) 538 (describing the 'generalised sense of outrage from thwarted sovereignty').

health and safety.[77] Over its first three decades of law-making, the EU's primary goal was to create a functioning internal market unencumbered by divergent national cultural and regulatory traditions. The initial strategy adopted was the development of 'vertical' directives: essentially, recipes for individual products, commencing with cocoa and chocolate in 1973. Early ambitions for this exercise were thwarted[78] by the technical complexity of establishing compositional rules, by the underlying diversity of national interests, and by the requirement of unanimous support of Member States for each vertical directive.[79] There was a change in strategic direction in 1985 with the launching of the Commission's 'New Approach' to legislating on foodstuffs, which recognised that defining the compositional requirements of individual foods was not essential to permitting free movement of trade.[80] This approach built on the rulings of the European Court of Justice (ECJ), most famously the findings in *Cassis de Dijon*, in which the Court confirmed that products 'lawfully produced and marketed' in the exporting state must be admitted into the importing state unless they were legitimate reasons (such as public health) for not doing so.[81] Nevertheless, because Member States could not be relied upon to respect this principle of mutual recognition in areas where domestic standards existed, the harmonisation process remained important[82] and was facilitated by the transition from unanimous to qualified majority voting in Council.[83] New legislative initiatives were driven by the economic imperatives of the market, rather than any coherent concept of food safety.[84]

This situation changed dramatically with the Bovine Spongiform Encephalopathy (BSE) crisis in 1996 when the consumption of infected beef was linked to the human neurodegenerative new variant Creutzfeldt–Jakob disease. The outbreak

[77] See, e.g. A Alemanno, *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO* (London, Cameron May, 2007) Chap. 1; BMJ van der Meulen, 'The System of Food Law in the European Union' (2009b) 14 Deakin Law Review 305, 313–320; RK O'Rourke, *European Food Law* (London, Sweet and Maxwell, 3rd edn, 2005); D Holland and H Pope, *EU Food Law and Policy* (The Hague, Kluwer Law International, 2004). Although this characterisation fairly reflects the overall trend, it underplays the attention paid to consumer health issues in the early years. See, e.g. D Welch, 'From "Euro Beer" to "Newcastle Brown", A Review of European Community Action to Dismantle Divergent "Food" Laws' (1983) 22 JCMS 47 (describing a 1976 Directive on eruric acid with entirely health-related aims).

[78] Of the around 50 vertical directives on different food sectors envisaged between 1969 and 1973, only 14 had been adopted by 1985. European Commission, 'Completion of the Internal Market: Community Legislation of Foodstuffs' ('Completion of Internal Market'), COM(85) 603 final, 3.

[79] See Alemanno (n 77) 53 and Welch (n 77) 57.

[80] European Commission, 'Completion of Internal Market' (n78) 5.

[81] Case 120/78, Rewe-Zentrale AG [1979], para 14. For comments on the implications of this case, see Alemanno (n 77) 39–42. Notwithstanding the importance of *Cassis de Dijon*, the principles articulated must be seen as the culmination of previous ECJ judgements and 'not a revolutionary case'. Welch (n 77) 62.

[82] Alemanno (n 77) 57.

[83] The Single European Act [1987] OJ L169/1, Art 100A.

[84] E Vos, 'EU Food Safety Regulation in the Aftermath of the BSE Crisis' (2000) 23 *Journal of Consumer Policy* 227, 231.

revealed in the starkest manner the institutional weaknesses in the management of European food safety. The European Parliament Committee created to establish the causes for the crisis produced a devastating account of mismanagement and deliberate manipulation.[85] The Commission responded quickly with a Green Paper establishing three central principles drawn from the BSE experience: separation of the responsibilities for science and legislation, detachment of the legislative and inspection functions, and greater transparency throughout the decision-making process.[86] The Commission took immediate steps to implement these principles, but further food-safety scandals, such as the Belgian dioxin contamination in 1999 (in which toxic oils had been found to have been deliberately fed to chickens), maintained pressure for wholesale reform.[87] The European Commission's 2000 White Paper on food safety provided a new vision for European food law, establishing the need for an independent scientific body and a plan of action including over 80 legislative measures.[88] Equally importantly, it provided the necessary impetus for this rapid overhaul.[89]

The most significant legislative output of this initiative was the General Food Law Regulation 178/2002 (GFL),[90] a comprehensive legal framework for food policy extending across all stages of production (known alternatively as the 'farm to fork' or 'plough to plate' approach). The GFL establishes consumer safety as a central objective of food law, but also protects against deceptive trade practices and ensures that accurate information is provided.[91] It places primary responsibility for legal compliance upon food (and feed) businesses, supported by a system of controls organised by Member States.[92] Risk analysis forms the basis of food law, the risk assessment element of which is undertaken by a newly established European Food Safety Authority (EFSA).[93] The Regulation formally introduces the

[85] Among the failings identified were: inadequate scientific resources, inappropriate political pressure from the UK government, uncoordinated responses between various Commission directorates, and a Commission 'policy of disinformation'. European Parliament, 'Report on alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and national courts' (A4-0020/97, 7 February 1997) in particular s A.I.C.

[86] European Commission, 'Commission Green Paper: The General Principles of Food Law in the European Union', COM (97) 176.

[87] O'Rourke (n 77) 6–7.

[88] European Commission, 'White Paper on Food Safety', COM (1999) 719 final.

[89] Chalmers notes that BSE-related failure 'was to achieve what years of harmonisation of laws had failed to manage. A new European politics of risk emerged'. D Chalmers, '"Food for Thought": Reconciling European Risks and Traditional Ways of Life' (2003) 66 MLR 532, 534. See also Holland and Pope (n 77) 21 (describing the Commission's vigorous pursuit of its White Paper timetable).

[90] Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1 (GFL).

[91] GFL, Art 5.

[92] GFL, Arts 17, 19 and 20.

[93] GFL, Art 6 (on risk analysis) and Chap. III (on EFSA).