The coproduction of the global regulatory regime for food safety standards and the limits of a technocratic ethos

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Abstract
Several socio-legal scholars have studied how the Codex Alimentarius Commission (Codex) was empowered by the World Trade Organization (WTO) and how, under this transition, its standards became quasi-binding. What has gone less studied is how the WTO has transformed the very *modus operandi* of Codex. In particular, it has been argued that the WTO has infused Codex with a technocratic ethos. Building on this scholarship, this article investigates the dynamic relationship between the WTO and Codex and the evolving role of expert knowledge in the global regime for food safety standards. The article’s main thesis is that technocracy (as the rule of the knowers) is an unsustainable regulatory paradigm in the field of global food safety standards, as evidenced by the controversial ractopamine case, discussed in the article. The article concludes by arguing that the global food safety regime is turning towards a paradigm that marries science with democratic values.

Keywords
World Trade Organization; Sanitary and Phitosanitary Agreement; Codex Alimentarius Commission; Food Safety Standards; Risk Regulation; Global technocracy
1. Introduction

The standardization of food safety on a global scale is a particularly challenging endeavour because of the very nature of food, which is central to the well-being, identity and the very essence of human beings, as illustrated by the old saying ‘we are what we eat’. Two main bodies are co-producing the global regime for food safety standards: the Codex Alimentarius Commission (hereafter referred to as Codex) and the World Trade Organization (WTO).

Codex can be safely considered as the global regulatory agency in the field of food safety. It is rather uncontested that the WTO has contributed to the transformation of Codex from a rather obscure standard-setting institution into a powerful global regulatory agency. The adoption of the Sanitary and Phytosanitary (SPS) and the Technical Barriers to Trade (TBT) Agreements transformed Codex standards from merely voluntarily standards to quasi-binding obligations. Socio-legal scholars have amply studied the transition by which Codex standards have become quasi-binding. What has gone less studied, however, is how the WTO has transformed the philosophy underpinning the standardization work of Codex. At a closer scrutiny of the history of Codex empowerment, it becomes clear that Codex was not simply vested with regulatory powers by the WTO, but its modus operandi was profoundly influenced by the WTO. In particular, it has been argued that the WTO has infused Codex with a technocratic ethos.

Building on this scholarship, this article sets out to investigate the dynamic relationship between the WTO and Codex and shed light on the evolving role of expert knowledge in the global regime for food safety standards. The article’s main thesis is that technocracy (as the rule of the knowers) is an unsustainable regulatory paradigm in the field of global food safety standards. The technocratic paradigm rests on an idealized conceptualization of science, according to which science (and scientific experts) can solve international disputes over food safety policy. Such vision of science – or better Science, capital S - has been criticized by a wide scholarship. The controversial ractopamine case, discussed in the article, bears witness of the limits of a purely technocratic approach to global food safety standards. The article concludes with a note of optimism (at least from the perspective of this author), showing how the global food safety regime is turning towards a paradigm that marries science with democratic values.

The article is organized as following. The next section introduces the reader to the area of international food safety standards, by tracing the evolution of the international food standards regime, from the early twentieth century to our days. Section 3 analyses the regulatory philosophy underpinning this evolving regime. It will be shown that the initial Codex regime was not build around the Science paradigm, but was aimed at creating food standards following what is called a multiple approach. It is only after the establishment of the WTO that the practice of risk assessment became central within the organization of Codex. Section 4 zooms-in on the ractopamine case; this case, which echoes the previous hormones case, well illustrates the problematic features of a regime based on a naïve conception of science, where values apparently play no role. To further substantiate this thesis, this section briefly reviews the social science scholarship shedding light on how values unavoidably shape science. It is further argued, in Section 5, that the recent evolution of WTO jurisprudence

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1 In this article the term Codex will be used to refer to the Codex Alimentarius Commission. Codex can also refer to the set of standards adopted by the Commission (the Code itself); in fact, the Latin Codex means Code. In this article it will be specified when the term is used to specifically refer to the set of standards.
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departs from the technocratic ethos, allegedly underpinning the global food safety regime. Being the
global food safety regime coproduced by WTO and Codex institutions, this section looks also at the
vision of science endorsed by key documents of Codex such as the Working Principles for Risk
Analysis and it finds some coherence within the regime. Section 6 draws conclusions.

2. The international food standards regime: from early days to today

A. The pre-Codex regime (in a nutshell)

In the early twentieth century, a varieties of transnational initiatives of food standardization emerged
to facilitate trade in food products. Standardization initiatives intensified in the fifties. At the
international level, the Food and Agriculture Organization (FAO) and the World Health Organization
(WHO), \(^2\) started joint work on a number of issues related to food quality and safety. In 1955 they
established the Joint WHO/FAO Expert Committee on Food Additives (JECFA), still operating as one
of the scientific committees advising Codex. \(^3\) Building on the work that the International Dairy
Federation started in the thirties, FAO did also convene the Committee of government experts on the
Code of Principles concerning Milk and Milk Products. Next to these initiatives, two projects of
regional standardizations were also set up. \(^4\) In 1958 the Council of the Codex Alimentarius Europeaus
was first proposed by the then Austrian Minister for Agriculture Hans Frenzel, and it was created
under the aegis of the International Commission on Agricultural Industries and the Permanent Bureau
of Analytical Chemistry. \(^5\) In 1959, several Latin American countries also created their own Code, the
Código Latino-Americano de Alimentos. \(^6\) In order to overcome the fragmentation of this system and
to better address the challenges of international trade, the FAO and WHO launched the joint
FAO/WHO food standard programme, in 1962 in Geneva. \(^7\) One year later the Codex Alimentarius
Commission was born as a subsidiary body of FAO and WHO, with the mandate of implementing the
programme. \(^8\) Codex would have also subsumed and continued the work of the Codex Europeaus.

B. The Birth of Codex (the pre-WTO regime)

Codex is a multilayered international body, composed by a multitude of committees dealing with both
horizontal and vertical issues: next to an Executive Committee, there are 11 commodity committees

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\(^2\) FAO and WHO were created respectively on 16 October 1945 and 7 April 1948.


\(^4\) For an overview of the early history of Codex see http://www.codexalimentarius.org/about-codex/codex-timeline/en/ (last
visited 21 March 2014).

\(^5\) This code was in turn the evolution of the Code and standards developed under the Austro-Hungarian Empire, which
were consolidated in the Codex Alimentarius Austriaicus; for a more detailed account see M Masson-Matthee, *The Codex

\(^6\) CA Guajardo, Código alimentario argentino: su valoración jurídica (1998), available at
http://www.worldcat.org/title/codigo-alimentario-argentino-su-valoracion-juridica/oclc/39456182/viewport (last visited 8
May 2014).

\(^7\) The proposal to ‘internationalize’ the already existing standards was made by the Council of the Codex Alimentarius
Europeaus (see Masson-Matthee, above note 5, for an overview of this process). From this angle Codex can be seen as
the continuation of the Codex Alimentarius Europeaus. This may explain the preponderant influence exercised by
European actors on Codex in the first years of its existence.

\(^8\) Codex was first approved by the FAO and later by the WHO Assembly. Cfr. Resolution No. 12/61 of the FAO
Conference, ‘Codex Alimentarius’, adopted at the 11th Session of the FAO Conference, Report of the 11th Session of the
Standards (Codex Alimentarius)’, adopted at the 16th Session of the World Health Assembly, Geneva 7-23 May 1963,
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(e.g. Codex Committee on Milk and Milk Products, Codex Committee on Cocoa products and Chocolate) and 10 General subject committees (e.g. Codex Committee on Food Additives and Contaminants). Each committee is administered, organized and financed by a Codex Member (so called host country); most commonly, countries that have a specific interest on a certain Codex issue are the host of that specific committee (e.g. Switzerland is the host country for the Codex Committee on Cocoa products and Chocolate). The scientific meta-analysis that are used in Codex decisionmaking process are produced by one of the several expert committees, which have been jointly established by the WHO and FAO and provide the studies that are further used to adopt standards (e.g. the JECFA and the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA)). The decision-making process of Codex consists of an eight-step procedure, starting with the proposal of a standard by a Committee or a Member, followed by several evaluations and discussions (step 2 to 7) and ending with the submission of the standards for adoption by the Codex Commission. At step 2, a draft text is prepared and an assessment by an expert body (e.g. JECFA) with recommendations of Acceptable Daily Intakes (ADIs) and/or Maximum Residue Levels (MRLs) is prepared. This is arguably one of the most important phases of the decision-making process because experts’ recommendations are typically endorsed in the final standards.

The 1962 Report of the joint FOA/WHO Conference that has led to the establishment of Codex sheds light on the purpose and scope of Codex and on the nature and types of standards. The Guidelines for Codex standards, part of the 1962 Report, clarify that food standards have a dual purpose: protect consumers’ health and ensure ‘fair practices in food trade’. The Guidelines draw a distinction between ‘minimum platform standard’ and ‘trading standards’. The former are to be ‘acceptable on as wide basis as possible (on the understanding that acceptance of the minimum standard in no way limits the existence or establishment of higher national standards)’. Trading standards by contrast are characterized as ‘higher’ standards. These standards are not per se superior, but are a ‘matter of consumer preference’. These standards imply that members accepting them should not restrict the importation of those products on the basis of food safety/quality considerations. The latter standards were mainly conceived for more integrated communities, such as regional areas. With very few exceptions (e.g. the European standard on fresh fungus ‘chantarelle’), the development of regional Codex standards never materialized and global standards became the norm in Codex.

C. The post-WTO regime

The pre-1995 Codex regime has been described as a ‘gentlemen’s club’. Standards were mainly voluntary, and Codex members followed the norm of not obstructing the adoption of standards, even if these were not in their interests. The number of delegates attending Committees meetings was overall small, which facilitated a process of consensus building. Accordingly, standards were always adopted by consensus, even if the procedural manual provided for voting, in cases when such consensus could not be reached. The voluntary nature of the standards and the small size of meetings to reach agreements were radically changed with the establishment of the WTO. The principal legal framework that has enabled this transformation is the WTO Sanitary and Phitosanitary Agreement (SPS Agreement), which provides that Members shall either base their measures on international standards

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9 For a more detailed explanation of how these committees operate see Masson-Matthee, above note 5, at 31-50.
13 Masson-Matthee, above note 5.
or on science and risk assessment. Article 3.1 and 3.2 SPS Agreement provide that ‘[t]o harmonize sanitary and phytosanitary measures ... Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist;’ and that (2) Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be ... presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994'.

Since Codex is listed among the international standardization bodies, it is clear that conformity with Codex standards implies almost invariably conformity with WTO law. A contrario, the decision to set standards higher than the Codex ones, imposes on Members a higher burden to defend its own measures. Moreover, the WTO is endowed with a uniquely strong dispute settlement system. Under the General Agreement of Tariffs and Trade (GATT), disputes were initiated only on the basis of consensus. Equally, rulings by Panels were adopted by consensus. Under the WTO, disputes and the adoption of rulings are quasi-automatic. In case of non-compliance, complaining Members are authorized to retaliate (suspension of concessions).

The WTO enforcement system is accordingly one of the most powerful in the international legal arena. For this reason, the nature of post-1995 Codex standards has been characterized as ‘semi-binding’. The new normativity gained by Codex standards may explain why voting has been resorted to at Codex, in the post-WTO era. By virtue of the Technical Barriers to Trade Agreement (TBT Agreement), Codex is also relevant for technical barriers to trade, such as labelling. While this Agreement does not explicitly refer to Codex, it does refer to international standards as benchmark for legality of regulatory measures that may adversely impact trade and it is highly likely that Codex standards qualify as international standards.

The fact that, as of today, virtually no measures disputed at the WTO and diverging from Codex standards has been found WTO compatible may be indicative of the new role played by the post-SPS Codex standards. The words of a European Commission representative, commenting the new regime, well capture this transition: ‘In the past, if we disagreed with Codex Standards … we could ignore and take our own legislation. Now we can’t.’

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16 Agreement on Sanitary and Phytosanitary Measures, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, General Agreement on Tariffs and Trade, Annex 1A, 15 April 1994 (hereafter ‘SPS Agreement’).
18 Veggeland and SO Borge, above note 14.
19 Yet, the prediction by some that voting would have become the main decision-making mechanism did not materialize. In fact, consensus remains the customary practice and voting was used only in few controversial cases, such as the approval of standards for growth promoting hormones and for ractopamine discussion below section 4.
20 From an interview reported by F Veggeland and SO Borge, above note 14, at 683, conducted by the authors in 2000 with an employee of DG Consumer and Health Protection at the European Commission, conducted and.
3. Global Food Safety Standards: Co-production and the emergence of a technocratic ethos

Several scholars in the past have tried to clarify the relationship between Codex and the WTO. This article adheres to the theory that the international regime for food safety standards is being co-produced by both Codex and WTO institutions. One of the central arguments of the co-productionist approach is that the WTO has influenced the regulatory philosophy underpinning the global regime for food safety standards, by setting ‘Science’ at the centre of the regime. To better understand this argument, it is worth to first identify the approach underpinning Codex in the pre-WTO era.

A. The Origin: the Multiple Approach

‘It is due to its scientific basis that Codex texts are considered by WTO as the international reference for food safety standards.’

The narrative of the official Codex website suggests that the international trade regime has chosen Codex for its adherence to a scientific paradigm. This narrative, however, may be somewhat reductivist and a glimpse into Codex’s history sheds lights on the different factors that have played a role in the food standardization processes developed by Codex. If it is normal today to associate Codex standards with science, the early years of Codex were not characterized by a science-centric approach.

The 1962 Guidelines briefly discussed in the previous section, did not endorse science as the main paradigm underlying the new standardization project. While science is undoubtedly one of the factors that should be resorted to when adopting Codex standards, the Guidelines refer to a multiplicity of criteria, as evidenced by the following paragraph: ‘The Conference drew attention to the many problems involved in setting up such standards and emphasized the need to study them from the health, scientific, technological, economic and administrative points of view. Only by following this multiple approach would it be possible to make the widely desired progress in this fields.’ Such an approach appears reconcilable with legal pluralism and more at odds with a universalistic vision of science that enables the formation of uniform global standards. This is further exemplified in the possibility granted by the 1962 Guidelines of adopting different standards for the same product. The Guidelines in fact clarify that when there is a division of views, ‘two or more standards could be proposed, each with its own area of application’. This is better understood because Codex was initially conceived as a forum where also regional standards could have been adopted. Hence, in no case standards wanted by one region could have been rejected by outside countries. In this context it is interesting to read in the Guidelines that ‘a food standard … does not intend to affect consumer preference, but aims at ensuring that the consumer can know what he is buying’. By granting a status to consumer preferences, the Guidelines implicitly concede that factors other than science may play a

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22 Codex institutions comprise the many committees and subsidiary bodies operating within Codex realm. WTO institutions include the rules as drafted in the final Agreements (most importantly the provisions of the SPS and the TBT Agreement) and the evolution of these rules through the process of interpretation by the WTO quasi-judicial bodies.
23 Winickoff and Bushey, above note 21.
26 Ibidem para 32, p. 12.
27 Ibidem, para 7.
role in the determination of standards. Overall, the initial regime was not framed within the boundaries of the science/risk grammar, that figures prominently in the SPS Agreement.

B. How the WTO has transformed Codex: Towards ‘sound science’ imperialism?

According to science and technology studies scholars David Winickoff and Douglas Bushey, the WTO has transformed the regulatory epistemology underpinning much of Codex standard setting processes. These scholars focus especially on the SPS Agreement, which they characterize as the ‘most extreme example’ of the technocratic paradigm promoted by the GATT/WTO regime. According to the authors, together with the new normative status, Codex was also endowed with the technocratic aspiration of the SPS Agreement. As put by them:

‘The central coproductionist point is this: although the trading regime claimed to be adopting pre-existing science based standards at the international level, the WTO’s legal and executive power was necessary to transform the Codex into a global agency that could generate such standards. The Codex had been an international body with fairly low visibility. As its increase in power became imminent, the Codex began acting with an invigorated mandate and a sense of itself as “science based” organization. It was the rising trading system that drove the development of new norms and practices for the management of knowledge, expertise and evidence in regulatory decision making at the Codex – in short its regulatory epistemology’. 29

Winickoff and Bushey discuss a number of initiatives launched with the aim of creating the scientific framework allegedly necessary for the new scientific identity of Codex. For instance, the 1995 Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standard Issues was convened in order to enhance consistency and transparency in these practices. The fact that the consultations resulted in recommending changes in Codex practices, in order to promote ‘harmonized approaches, consistent with science-based risk assessment’ is a clear indication that the pre-existing Codex practices were lacking such consistency. 30 In short, they contend that a well-established regime of ‘risk analysis’ did not exist under the pre-WTO era; it was envisaged and standardized only in the post-1995 era. Other scholars have noted how the discussion about the role of science within Codex became topical, as it became clear that the normativity of Codex standards would have been strengthened by the adoption of the SPS Agreement. 31 Several reports of joint FAO and WHO conferences, starting from 1991 when the negotiations of the SPS Agreement were already concluded, 32 discuss the role of science in Codex. The Codex Committee on General Principles (CCGP) was requested to provide guidance on the role science should play in the process of standard setting. After lengthy negotiations, the CCGP produced a text, eventually adopted by Codex in 1995, with four ‘Statements of Principle concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors are Taken into Account’ (Statements of Principle). 33 The first statement provides that ‘[t]he food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence’. 34 The next statement allows ‘other legitimate factors’ to be taken into account in Codex decision-making.

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28 Winickoff and Bushey, above note 21.
29 Ibidem, at 360, emphasis added.
32 For an analysis of the negotiation process that led to the adoption of the SPS Agreement see T Buthe, above note 21.
34 Emphasis added
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While it is clear that Codex started to profile itself as a science-based institution, the question of the relation between ‘sound science’ and ‘other legitimate factors’ remained open. The debate became very heated in the controversial process that led to the adoption of standards for growth promoting hormones. In 1987, the JECFA assigned Acceptable Daily Intakes (ADIs) for a number of growth promoters used in farm animals (particularly cattle) and maintained that it was not necessary to establish Maximum Residue Levels (MRLs). Following the JECFA opinion sic et simpliciter would have implied the adoption of Codex standards for the controversial growth promoting hormones. However, a number of countries, led by the European Communities, opposed these standards because of consumers concerns as well as concerns over the practical difficulties of controlling and enforcing the administration of the hormones in meat. The Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) considered the standards in October 1989 and put them forward for a Codex decision. As the standard reached step 8 in 1991, when the draft for the SPS Agreement was ready, Codex members were split as to the adoptions of these standards. In this context, ‘sound science’ and ‘other legitimate factors’ have been used as arguments to defend the opposite positions of the US and the European Communities. Besides the divisions on the questions of whether standards should have been adopted, Codex members seemed to agree that adopting standards would have meant endorsing a sound science approach, whereas the decision of not adopting the standards could have been based on ‘other legitimate factors’. In a 1991 discussion of the matter, the Codex Secretariat informed the Commission that the ‘FAO Legal Counsel had noted that the Statutes, Rules and Procedures of the Commission did not bind the Commission to science as the basis of the decision-making process’. In later documents, the US contrasted this view arguing that ‘Codex … must show that its standards … rested on a sound scientific basis,’ meaning that a departure from JECFA opinion would have corresponded to a scientifically unsound decision. This use of the term ‘sound science’ has proliferated ever since. But is it analytically accurate and intellectually honest to juxtapose sound science to other legitimate factors? The next section will argue that it is not.

4. Why does my heart feels so bad? Ractopamine and Scientism limits

On July 5, 2012, Codex has adopted standards on MRLs for ractopamine hydrochloride (ractopamine), a beta-agonist used in meat (mainly in pigs and cattle) for achieving fast growth and leanness of the meat. The process that has led to the adoption of the standards is unusually controversial and it reminds the hormones episode. The Codex standard was not adopted by consensus, as it is normally the case, but by a vote in which a thin majority voted in favour of the standard (69 in favour vs. 67

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36 The hormones for which standards were adopted are the following Estradiol 17β, Testosterone, progesterone, trenbolone and zeranol.
37 For the record of the debate where different arguments were reported see FAO/WHO (1991). Codex Alimentarius Commission - Report of the 19th Session. (ALINORM 91/40). FAO/WHO Food Standards Programme, Rome; (arguments of the EEC at para. 155)
opposing and 7 abstentions).\textsuperscript{41} About 160 countries, including major meat importers and exporters, such as China and the EU, do not allow the use of ractopamine. The risks related to the administration of ractopamine in animals were assessed a number of times by the JECFA: in 1993, 2004, 2006 and 2010 respectively. In its first 1993 evaluation, the JECFA did not establish Acceptable Daily Intakes (ADIs) for ractopamine, because of lack of data to determine safe levels.\textsuperscript{42} In its subsequent evaluations in 2004, the JECFA assigned both ADIs and MRLs on the basis of new data provided by Elanco, the major producer of ractopamine.\textsuperscript{43} The recommendations were later confirmed, also when revised on the basis of new data.\textsuperscript{44}

The adoption of MRLs for ractopamine has been hailed as a victory of science-based regulation. The adoption of the standard has been characterized by Kathy Simmons, the National Cattlemen’s Beef Association (NCBA) chief veterinarian, as ‘the Codex decision to move forward with science-based standards’.\textsuperscript{45} Likewise the American delegate, in his oral statements at the 35\textsuperscript{th} Codex session concluded that ‘… by not adopting MRLs … we risk other factors to overshadow science … when the science is the core competency of Codex’. Countries opposed to the adoption of the standards have lamented the fact that ‘[a]s an international organisation seeking to harmonise standards across the globe, Codex should respect consensus-based decision-making, one of the fundamental principles of the organisation. It is clear that for standards to be universally applicable, they also need to be universally accepted.’\textsuperscript{46} Interestingly, the two arguments used to defend opposite positions seem to echo the schism sound science/other legitimate factors. To understand the troubling feature of this schism it may be useful to briefly introduce some of the science underpinnings the arguments that have been used to oppose the use of ractopamine for factory farming.

\textbf{A. The Science of Ractopamine Politics}

Ractopamine, a phenethanolamine β-adrenoceptor agonist (beta-agonist), is administered to animals, to increase the rate of weight gain and the leanness of the carcasses.\textsuperscript{47} Such effects, in turn, increase the economic value of the animal.\textsuperscript{48} Ractopamine works by accelerating the heart-beat and it causes the relaxation of blood vessels. The drug has not been approved for human use and producers acknowledge its negative effects. For example, the label of Paylean (the commercial version of ractopamine administered to pigs) explicitly states that the drug is not for human use and that ‘individuals with cardiovascular disease should exercise special caution to avoid exposure’.


\textsuperscript{42} This was decided during JECFA 40\textsuperscript{th} meeting.

\textsuperscript{43} Elanco is a subsidiary of Ely Lilli.

\textsuperscript{44} The JECFA monographs on ractopamine and the respective standards are available at: http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-vetdrugs/en/. The MRLs established by JECFA related to different parts of the meat; they are 10 µg/kg for muscle and fat for cattle and pigs, 40 µg/kg for liver and 90 µg/kg for kidney; the ADI are 0-1µg/kg bw.


\textsuperscript{47} See the label of Paylean (the commercial version of ractopamine used in finishing swine).

\textsuperscript{48} According to data from Elanco, the increased gain are $2 per head; as reported by H Bottemiller, ‘Dispute Over Drug in Feed Limiting US Meat Exports’, (January 25, 2012) Food and Environmental Reporting Network, available at http://thefern.org/2012/01/dispute-over-drug-in-feed-limiting-u-s-meat-exports/ (last visited 8 May 2014).
The concerns over the use of ractopamine are of different kinds. Some relate to human health and others to animal health and welfare. In relation to human health, the concern is rather straightforward: given its properties of accelerating heart-beat, being exposed to residues of such a substance may increase the risks related to cardiovascular diseases. JECFA, by recommending MRLs has clearly considered these risks negligible. However, the risk assessment conducted by the JECFA has been criticized, among others, by the scientific food safety body of the European Union, the European Food and Safety Authority (EFSA). According to a lengthy Opinion of the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), administering ractopamine to animals could possibly be dangerous to humans exposed to traces of it. The main argument of the FEEDAP is that data are not sufficient to derive safe residue levels, particularly in relation to most vulnerable groups such as people with cardiovascular diseases or children. Methodologically, the FEEDAP contested the appraisal by JECFA because ‘... the safety factor applied by JECFA to derive the ADI from the NOEL does not sufficiently take into account population subsets at higher risk of adverse events after β-adrenergic stimulation’.

Without entering into the merits of the dispute, one thing is clear. Two scientific panels reached different conclusions on the safety of a certain substance. The Panels are both institutional bodies, composed of arguably well-established ‘regulatory scientists’. Arguing that following JECFA recommendations is sound science and all the rest is not means disqualifying EFSA science as unsound. The boundary work implicit in this logic should be puzzling for legal scholars and policy makers. Labelling as sound science only the recommendation coming from Codex expert bodies means entrusting the monopoly of science to a few dozens of embedded scientists. The risk is that global trade wars will be transformed into turf wars among few experts on narrowly defined scientific issues. But who would subscribe to such a model? The first lesson from the ractopamine case is that a purely technocratic paradigm is at best reductivist and at worst illiberal.

The other concerns on the use of ractopamine are related to animal welfare and health. Several studies have shown that animals treated with ractopamine become more aggressive and difficult to handle, and as a consequence are ‘more likely to be subjected to rough handling and increased stress during transportation.’ In light of these studies, the FEEDAP expressed concerns in relation to the safety of the pigs. While there may remain some doubts as to the extent of the phenomenon, it is undeniable that ractopamine has some negative effects on animal welfare. Even producers have a

49 Another question, not discussed in this section, is the residue levels of ractopamine in different body organs of the animal (particularly offal). China was particularly concerned with higher concentration of the substance in offal, given the consumption of offal by Chinese and submitted new studies to JECFA. JECFA reviewed the studies and concluded that, besides concentration in lungs, her previous assessment, recommending ADIs and MRLs were not to be reviewed; see JECFA Monograph, No. 9. (2010).


51 JN Marchant-Forde, DC Lay Jr., EA Pajor et al., ‘The effects of Ractopamine on the Behavior and Physiology of Finishing Pigs’ (2003) 81(2) Journal of Animal Science 416; R Poletto, HW Cheng, RL Meisel et al., ‘Aggressiveness and Brain Amine Concentration in Dominant and Subordinate Finishing Pigs fed the β-adrenoreceptor agonist ractopamine’ (2010) 88(9) Journal of Animal Science 3107. As reported by Marchant-Forde et al. ‘Pigs fed ractopamine were more difficult to handle and had elevated heart rates and catecholamine levels after 4 weeks of administration. Pigs that are more difficult to move are more likely to be subjected to rough handling and increased stress during transportation, implying reduced welfare, increased workload for the handlers and, potentially, poorer meat quality.’

52 The EFSA Journal, above note 51, at 1041.

53 According to one report [w]hen Elanco studied the drug in pigs for its effectiveness, it reported that “no adverse effects were observed for any treatments.” But within a few years of Paylean’s approval, the company received hundreds of reports of sickened pigs from farmers and veterinarians, according to records from the FDA’s Center for Veterinary Medicine.'
disclaimer in this regard on the label; Paylean label reads: ‘Caution: Ractopamine may increase the number of injured or fatigued pigs during marketing. Not for use in breeding swine.’

The question of animal welfare has been often listed among the ‘other legitimate factors’ that ought to be taken into account in the context of Codex decision-making. For the purpose of our analysis, it is worth emphasizing that no matter under which category we may want to put the category of animal welfare, the studies showing the effects on the animals can be plausibly classified as scientific. Thus, even when animal welfare is considered under the rubric of ‘other legitimate factors’, to stigmatize as unscientific a decisions taken on such basis is incorrect and possibly demagogic.

Some commentators have pointed at the ractopamine case, which is echoing the previous hormones case, as evidence of Codex’s limits. However, rather than Codex’s limits, the ractopamine case points at the limits of a rigid technocratic model of legitimacy, that proves untenable before a political and scientific divided community.

**B. The Sound of Science: Science vs Scientism**

As illustrated above, decisions diverging from the recommendations of Codex expert bodies may be scientifically sound as much as those portrayed as science-based. Disagreement among scientists may legitimately exist because science does not provide univocal answers to policy problems, in contrast with what an over-simplistic view of science may suggest. Science is fraught with uncertainties and value-choices: models of extrapolation (from animals to humans) can be more or less conservative; decisions to study certain variables (and certain hazards) instead of others may differ; some studies may look at potential effects on average people, while others may consider vulnerable groups (e.g. children, pregnant women, people with diseases, etc.); studies can consider cumulative effects or not and so on. This means that within the realm of scientific studies it is possible to reach different conclusions, all plausible according to generally agreed standards of how to conduct scientific research. Moreover, the assessment of factors outside the scope of the reports of Codex expert committees, such as JECFA, is not in itself unscientific. The assessments of effects on animal welfare and/or on the environment are as scientific as the assessment of the carcinogenic properties of a certain substance and the relative risks to humans. Symmetrically, the judgments of whether it is acceptable to let animal suffer or to pollute the environment or to allow the marketing of a substance with a carcinogenic potential are all equally political. It is thus unfortunate that the term ‘sound science’ is often used to stigmatize all the standards not based on the recommendations of Codex expert bodies. Using the jargon sound science to characterize only specific assessments of certain types of risk and discount all other considerations as unscientific is either banal, or parochial.

Political scientists have coined the term ‘scientism’, to refer to a ‘discourse or framework for discussion that excludes considerations of distributional and other social impact criteria in the determination by a regulatory agency that a product is or is not suitable for markets … In its neoliberal form, scientism tends to restrict democratic participation and weakens the option for governments to regulate …’ This concern is echoed by Winickoff and Bushey who worry that in the context of Codex the adoption of ‘risk as the single dominant grammar of global food regulation’ may create certain governance biases: ‘[r]isk discourse implicitly empowers some people as experts while marginalizing others as inarticulate or irrelevant.’ To better understand how a reductivist view of the

55 Lin, above note 41.
57 Winickoff and Bushey, above note 21, 364
risk analysis paradigm can degenerate into scientism and create a regime of exclusion, it is worth a brief excursion into the academic literature on risk.\textsuperscript{58}

Social scientists have amply shown that, beyond the conclusions of so-called experts, there are many factors that could be legitimately taken into account when deciding about risks. Several studies in the field of cognitive psychology have shown that people value different qualitative characteristics of risks and do not merely focus on the probabilities related to morbidity and mortality.\textsuperscript{59} For instance, people prefer voluntary over involuntary risks, they are sensitive towards perceived inequities of distribution of risks, and so on.\textsuperscript{60} Preferences towards risk are also shaped by culture.\textsuperscript{61} Several studies have shown that people sharing similar values fear similar risks; for instance, egalitarians tend to be more afraid of environmental risks and the risks of gun possession, whereas individualists may be more concerned about security issues and disfavour gun controls. The different attitudes of Americans and Europeans towards biotech food products may then be seen as pertaining to ‘cultural cognition’ rather than stemming from different attitudes towards science. As put by Kahan et al., ‘[i]f risk disputes are really disputes over the good life, then the challenge that risk regulation poses for democracy is less how to reconcile public sensibilities with science than how to accommodate different visions of the good within a popular system of regulation.’\textsuperscript{62}

Against this background it may be clear why the risk analysis paradigm enlisted by the WTO/Codex co-produced regime risks being a form scientism, if it is not entrenched in democratic values. Acknowledging the role that values play within scientific processes does not mean to corrupt science with values; to the contrary, it means aspiring to a more transparent scientific process that can enable dialogue on divisive issues.

5. An Evolving Regime: Marrying Science and Democracy?

If technocracy may have been the driving paradigm in the post-WTO phase of Codex, the incapability of this paradigm to solve international trade disputes is becoming apparent. The main claim of this article is that the ‘regulatory epistemology’\textsuperscript{63} that has driven the erection of the global regime, co-produced by Codex and WTO institutions, is changing. The emerging paradigm is not a radical departure from technocracy, but it could be seen as an attempt to reconcile technocratic and

\footnotesize{\textsuperscript{58} While the scholarship on risk is vast, this article will deal only with a limited subset of studies. Important contributions not discussed in this article, and yet relevant for the issues discussed, are: SO Funtowicz and JR Ravetz, ‘Science for the Post-Normal Age’ (1993) Futures 739; M O’ Connor, S Faucheux, G Froger, S Funtowicz, and G Munda, ‘Emergent Complexity and Procedural Rationality: Post-Normal Science for Sustainability’ in R Costanza and O Segura (eds), Getting Down to Earth: Practical Applications of Ecological Economics (1996); K Shrader-Frechette, ‘Reductionist Approaches to Risk’ in DG Mayo and RD Hollander (eds), Acceptable Evidence—Science and Value in Risk Management (1991); B Wynne, ‘May the Sheep Safely Graze? A Reflexive View of the Expert-Lay Knowledge Divide’ in S Lash, B Szerszynski and B Wynne (eds), Risk, Environment and Modernity: Toward a New Ecology (1996).


\textsuperscript{60} P Slovic, above note 59.


\textsuperscript{62} Kahan et al., above note 61, at 1073.

\textsuperscript{63} The term is used by Winickoff and Bushey to refer to the ‘norms and practices for the management of knowledge, expertise, and evidence in regulatory decision making’ and it draws on the concept of civic epistemology previously elaborated by Sheila Jasanoff; see S Jasanoff ‘Ordering Knowledge, Ordering Society’. In: S Jasanoff (ed) States of Knowledge: The Coproduction of Science and Social Order, (2004).}
democratic approaches to food safety regulation. Such an approach is more in line with a model advocated by a rich and diverse body of social science scholarship, briefly presented above.

A. WTO jurisprudence

As already explained, with the establishment of the WTO, the international trade system has been endowed with a unique dispute settlement mechanism. This system does not only confer normative byte to WTO obligations, but it also greatly contributes to the clarification and evolution of trade rules. Paying attention to how the rules of the SPS and TBT Agreements are being interpreted is thus crucial for a better understanding of the global regime for food safety standards.

The SPS Agreement allows WTO Members to adopt sanitary and phytosanitary measures more stringent than international standards (in our case, Codex standards), only when these measures are justified by risk assessment or when there is no sufficient scientific evidence to base the measures on risk assessment. The concepts of ‘risk assessment’ and ‘(in-)sufficiency of scientific evidence’ are then crucial in understanding the role of Codex standards in the international regulatory space. A broad interpretation of these conceptual categories will imply that WTO Members have more freedom to diverge from Codex standards and vice versa. It follows that the degree of normativity of Codex provisions depends on how the provisions of the SPS Agreement are interpreted. At a more fundamental level, the interpretation of concepts such as a risk assessment reflects the regulatory epistemology endorsed by WTO institutions.

A key case to understand the turn taken by WTO jurisprudence in the interpretation of the SPS Agreement is Canada/US – Continued Suspension. This case is the follow-up of the Hormones case. Let me briefly summarize the main steps that led to the Continued Suspension dispute, for the readers not familiar with this body of case law. After the Appellate Body ruling in EC - Hormones, where Europe was faulted for not having based its measures on risk assessment, the US and Canada were allowed to retaliate against the non-compliant Union. In the meanwhile, Europe asked its food-science body, then the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH), to conduct a new risk assessment of the disputed hormones. On the basis of the new SCVPH opinion, Europe amended its laws, adopting Directive 2003/74/EC, which prohibits the use of oestradiol-17β for growth promotion purposes because of its carcinogenic and genotoxic properties and it prohibits, on a provisional basis, the other disputed hormones because the available data, while indicative of risk, were not sufficient to conduct a proper risk assessment. At this point, Europe argued that it was complying with the AB ruling in EC – Hormones. The US and Canada did not agree and continued to retaliate. As the WTO dispute settlement understanding (DSU) is silent on what do in these cases, Europe initiated a new dispute against the US to challenge the legality of their retaliatory measures. In Canada/US – Continued Suspension, the AB did not resolve the saga about the use of hormones for growth promotion purposes but, in reversing the Panel’s Report, has shed light on the interpretation of crucial norms for the global governance of food safety. Most importantly, the concepts of ‘risk assessment’ and ‘sufficiency of scientific evidence’ have been interpreted by the Appellate Body as ‘relational’ concepts; this implies that issues, such as ‘the appropriate level of protection’ chosen by a

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65 The first SCVPH ‘Assessment of Potential Risks to Human Health from Hormones Residues in Bovine meat and Meat Products’ was produced on April 30, 1999. The SCVPH conducted two new assessments on May 3, 2000 and on April 10, 2002 respectively. The latter assessments confirmed the conclusions of 1999. This body has been replaced by EFSA.

66 In May 2009, the EU and the US signed a Memorandum of Understanding (MoU) “regarding the importation of beef from animals not treated with certain growth promoting hormones and increased duties applied by the United States to certain products of the European Communities”, which they notified the WTO of in September of that same year.

67 Panel Reports, Canada/United States – Continued Suspension of Obligations in the EC – Hormones Disputes.
government, can shape the methodology and questions studied in the risk assessment.68 Such a conceptualization subscribes to a vision of science that is shaped by social values. The Appellate Body in *Continued Suspension* has unequivocally embraced this approach, as evidenced by the following quote:

> The risk assessment cannot be entirely isolated from the appropriate level of protection. There may be circumstances in which the appropriate level of protection chosen by a Member affects the *scope or method* of the risk assessment. This may be the case where a WTO Member decides not to adopt an SPS measure based on an international standard because it seeks to achieve a higher level of protection. In such a situation, the fact that the WTO Member has chosen to set a higher level of protection may require it to perform certain research as part of its risk assessment that is different from the parameters considered and the research carried out in the risk assessment underlying the international standard.69

The quote shows how the Appellate Body has relativized the centrality of international standards. Hence, international standards may be less central than previously thought. In the ractopamine case, where the EFSA report focused on risks left unaddressed by JEFCA (e.g. risks to people with cardiovascular diseases), it may well be the case that Codex standards will not be decisive in the determination of compliance with WTO law.

The turn taken by the Appellate Body in *Continued Suspension* can be read as a more general sign that the regulatory epistemology underpinning the global food safety regime rests on a vision of science that acknowledges its value-laden nature. This turn may have been favoured by the experience gained during the development of SPS jurisprudence. The evolution of the *Hormones* case is exemplary of the limits of scientism and thus, it may be no coincidence that in *Continued Suspension* the Appellate Body has clarified that the WTO regime needs to deal with the value-laden nature of science. Moreover, in another salient case, the *EC – Biotech*, where the European regulatory regime of Genetically Modified Organisms was at stake, the WTO was directly exposed to the reasoning of social scientists. In fact, a group of well-known social scientists submitted an *Amicus Brief* to the Panel in *EC – Biotech* where the arguments showing the value-laden nature of science are lucidly presented.70 While the *EC – Biotech* case never reached the appeal stage, it is likely that the Appellate Body has been exposed to the *Amicus Brief* submitted in the Biotech case. Is this approach also reflected by Codex?

**B. Codex General Principles for Risk Analysis**

In spite of the emphasis placed on science-based decisionmaking, the new approach endorsed by the Appellate Body is also compatible with the general principles for risk analysis negotiated and agreed at Codex. Two key documents define these principles: 1) the Working Principles for Risk Analysis for Food Safety for Application by Governments71 (*Working Principles for Governments*) and 2) the ‘Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius’ (*Working Principles for Codex*).72 Both sets of principles have been negotiated for several years and both have been adopted in the new millennium (in 2007 and 2003 respectively) and may thus be seen

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68 For a more detailed analysis of this issue see A Arcuri, above note 64.
69 Appellate Body Report, *Continued Suspension*, para 534 (emphasis added).
71 These principles are the result of seventeen years of negotiations and were finally adopted in 2007, Cfr Codex Alimentarius Commission, Working Principles for Risk Analysis for Food Safety for Application By Governments (2007), CAC/GL 62-2007.
72 These principles were agreed upon in 2003 and are now included in the Procedural Manual, above note 10, at 107.
as representing the existing consensus on the constitutive elements of risk analysis. They are therefore an important piece of the puzzle in understanding the regulatory epistemology underpinning the current global food safety regime.

Both sets of principles share similar features. The principles endorse an Anglo-Saxon model of risk analysis originally articulated in the US in the 1983 National Research Council (NRC)’s report on Risk Assessment in the Federal Government – Managing the Process, also known as the Red Book.73 According to this Report risk assessment is separated from risk management. This functional separation is clearly endorsed by Codex principles, where it is established that ‘[t]here should be a functional separation of risk assessment and risk management’.74 The debate on the functional separation between risk assessment and risk management has evolved over time and, within the US, several NRC reports succeeding the Red Book asserted the importance of having an iterative process where risk assessment and management are in a dialogical relationship.75 The acknowledgement of the importance of a linkage between the two phases is premised on the idea of value-laden science.

In line with the evolution of this debate, Codex principles also acknowledge the need of linking risk assessment and risk management and set limits to the functional separation of the two. In the first place, risk assessment and risk management are to be separated ‘to the degree practicable’.76 In addition, the risk analysis process is framed as an iterative one: ‘it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.’77 Even more importantly, both sets of principles recognize that ‘Precaution is an inherent element of risk analysis.’78

Asserting the importance of the interaction of risk assessment and risk management, as well as recognizing the role of precaution in risk analysis, means acknowledging the value-laden nature of science. In other words, the ‘technē’ or ‘episteme’ that serves the decisionmaking process is itself shaped by values. While other Codex documents and general principles may still be inspired by a narrow vision of science and display a technocratic aspiration, the conceptualization of risk analysis in the Working Principles contrasts with an eminently technocratic approach. It can thus be concluded that the current guidelines for risk analysis are not informed by a purely technocratic approach, which is commonly associated with Codex practices.

74 Codex (2007), above note 71, para. 11.
76 This sentence, which is only included in Codex (2007) was the result of intense negotiations; for a recollection of the negotiations on these principles see D Demortain, ‘Enabling global principle-based regulation: the case of risk analysis in the Codex Alimentarius’ (2012) Regulation and Governance 207, at 215-217.
77 Codex 2007, above note 71, para.11; ‘Working Principles’ in Procedural Manual, above note 72, para.9 second sentence. The importance of this interaction is further recognized in other Codex documents. For instance, Principle 3 of the ‘Risk Analysis Principles Applied by the Codex Committee on Food Additives’ establishes that ‘CCFA and JEFCFA recognize that continuous interaction between risk assessors and risk managers is critical to the success of their risk analysis activities’, Codex Procedural Manual, above note 10, at 116.
6. Concluding remarks

The locution ‘sound science’ has dominated the global battlefield of food politics. It has been often used to defend measures following from the recommendations of Codex expert bodies and to discount all the rest as unscientific. The ractopamine case, where different scientific bodies have produced diverging opinions, shows that science cannot be the ultimate arbiter on divisive issues fraught with uncertainties. As beautifully put by Bruno Latour: ‘When scientists add their findings to the mix, they do not put an end to politics; they add new ingredients to the collective process.’\footnote{B Latour, ‘From the World of Science to the World of Research?’ (10 April 1998) 280 no. 5361 Science 208.} The challenge for the 21\textsuperscript{st} century is thus to rethink our legal and political institutions so that they can better cope with the value-laden nature of science. While the ractopamine case shows the problematic side of global food politics, this article suggests that the coproduced regime by the WTO and Codex is starting to take up this challenge.
List of cases


The coproduction of the global regulatory regime for food safety standards and the limits of a technocratic ethos

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