RECON Online Working Paper
2010/29

Policy Choice versus Science in Regulating Animal Cloning under the WTO Law

Maria Weimer

Maria Weimer
Policy choice versus science in regulating animal cloning under the WTO law

RECON Online Working Paper 2010/29
December 2010

URL: www.reconproject.eu/projectweb/portalproject/RECONWorkingPapers.html

RECON Online Working Paper Series | ISSN 1504-6907

Maria Weimer is PhD Candidate at the Department of Law, European University Institute, Florence. E-mail: maria.weimer@eui.eu.

Issued by ARENA
Centre for European Studies
University of Oslo
P.O.Box 1143 Blindern | 0318 Oslo | Norway
Tel: +47 22 85 87 00 | Fax +47 22 85 87 10
www.arena.uio.no

Abstract

After genetically modified organisms and nanotechnology, EU food regulators are currently facing the challenge of choosing an appropriate policy approach towards animal cloning for food supply. While different regulatory options are being discussed, the ultimate choice of the EU is likely to have ramifications for EU's compliance with the international legal trade order of the WTO. In this paper I take the EU policy debate as a starting point to outline the main legal issues that future EU regulation on animal cloning could raise with regard to the most pertinent WTO Agreements, the GATT, the SPS Agreement, and the TBT Agreement. I argue that any future legal assessment of EU policy in this area should pay particular attention to the thorough delineation between the scopes of application of these agreements, since the choice of the applicable WTO regime will directly impact on the extent to which the EU enjoys regulatory autonomy to pursue its policy choice. In the light of the recent Panel report in *EC-Biotech* the applicability of the SPS Agreement also to future EU measures on animal cloning appears likely thereby resulting in strong constraints on EU policy choice. This appears problematic seeing that strong criticism is voiced against the extensive interpretation of the concept of an SPS measure, as undertaken by the Panel in *EC-Biotech;* and that doubts persist as to whether potential risks related to animal cloning can, in fact, be characterized as sanitary and phytosanitary risks.

Keywords

GATT — International Trade — Non-discrimination — Non-tariff Barriers — Regulation — Regulatory Politics — WTO

Introduction

The employment of new technologies is today an essential element of modern food production. Corporate science continually develops new technologically designed products making the promise of better, healthier, sustainable, and above all cheaper food while at the same time raising fears of unknown health and safety risks that could in the long term be the consequence of such food innovations. Whether progress or dangerous 'playing with nature', new technologies certainly have the potential to change the future of food consumption worldwide. The European Union (hereinafter EU) currently faces a public debate on whether food products derived from the cloning of farm animals should be allowed to circulate on the common market. As with genetically modified food or nanotechnology also in the case of animal cloning the EU regulators are confronted with a controversial technology, the risks of which cannot be fully assessed at present, and which raises further ethical and socio-economic concerns.

Inevitably, the EU regulatory debate also raises concerns of WTO law. In other countries, above all in the United States, animal cloning for mass food production is seen to be on the verge of commercialization within the next couple of years. Any trade restrictive EU regulations would, therefore, endanger future international imports of products derived from animal cloning outside the EU into the European market thus creating a potential for new international trade disputes in the World Trade Organisation (hereinafter WTO). At the same time, WTO law presents an influential parameter in the current reflection on an appropriate European policy towards animal cloning. The Union along with its Member States is a signatory and party to the WTO, and the EU public authorities are legally bound by the obligations contained in the WTO agreements, for example, when drafting new legislation. What is more, the drafting of new EU legislation in the area of food safety, public health and consumer protection has become very WTO sensitive especially since the experience the EU had in the last two prominent WTO disputes, in which the Union tried and failed to successfully defend its public health policies towards the employment of new technologies in food before a WTO dispute settlement body – the *EC-Meat Hormones* and the *EC-Biotech* cases.[1] The reasoning of the dispute settlement bodies in these cases and their outcome has already shown to have considerable influence on internal EU decision-making in other regulatory areas.[2] It is likely that this WTO jurisprudence will also impact the EU authorities in their choice of a regulatory approach towards animal cloning for food supply.

In this paper I endeavour to contribute to the current reflection process by outlining the main legal issues that future EU regulation of animal cloning for food supply

---

* This paper is forthcoming in the *Finnish Yearbook of International Law 2009*.

[1] See Appellate Body report, *EC – Measures Concerning Meat and Meat Products*, WT/DS26/AB/R and WT/DS48/AB/R adopted 16 January 1998 (hereinafter EC-Meat Hormones); Panel Report, *EC – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291, WT/DS292, WT/DS293, adopted 26 September 2006 (hereinafter EC-Biotech).

[2] For example in the drafting of an amendment to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, OJ 1976 No. L 262/169, see Grainne de Búrca and Joanne Scott, 'The Impact of the WTO on EU Decision-making,' in *ibid* (eds), *The EU and the WTO, Legal and Constitutional Issues* (Hart Publishing: Oxford; Portland Or., 2001) at 1; another example is the drafting of the Commission Communication on the Precautionary Principle, COM (2000) 1 final, see Elizabeth Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart Publishing: Oxford; Portland Or., 2007) at 224 where she describes the impact of the WTO panel's reasoning in the *EC-Meat Hormones* case upon the drafting of the Communication.

could potentially raise with regard to the WTO trade agreements.[3] As will be shown, the critical legal issues arising with regard to future EU regulation revolve around the relationship between the three main WTO agreements regulating the trade of goods: the General Agreement on Tariffs and Trade (hereinafter GATT),[4] the Sanitary and Phytosanitary Measures Agreement (hereinafter SPS Agreement) and the Technical Barriers to Trade Agreement (hereinafter TBT Agreement). Though the WTO Agreement establishing these treaties presents a 'single undertaking,' and all its provisions should be read in a way that gives meaning to all of them, harmoniously,[5] it seems that the balance in the application of the above agreements to domestic regulation has recently shifted towards a considerable extension of the scope of the SPS Agreement to the detriment of the other two agreements. Such a shift, criticised by Joanne Scott as SPS 'imperialism,'[6] can be illustrated by reference to the recent Panel report in the *EC-Biotech* case. The extension of the SPS Agreement entails that a considerable amount of domestic regulations in the area of food safety, public health and environmental protection are likely to fall under this agreement, with the consequence of being obliged to observe its science-based obligations. Arguably, these obligations represent a more rigorous 'test' to domestic regulation than the obligations established by the GATT or the TBT Agreement. All this raises the thorny question of how far the WTO legal order can go in challenging domestic regulation, and thus, in precluding public policy choice made by the Members' democratic constituencies. Exploring the issue of the impact of WTO trade rules on internal regulation will, therefore, be the leitmotif of this paper's discussion of the main aspects relevant for the legal status of future EU measures on animal cloning under WTO law.

In this paper I will proceed in three steps. Firstly, I will provide for some contextual information about the technology of animal cloning as well as its commercialisation at global level, in order to show the pertinence of EU legal regulation in this area for international trade. Subsequently, a presentation of the status of the current policy debate at EU level will offer some insight into what shape future EU regulation could take, in particular, whether and to what extent it can be expected to have an impact on international trade. I will show that while certain regulatory options are being discussed, or even already advanced, by EU's public authorities, at present the precise outcome of the debate is still open. My aim, therefore, is not to accomplish a comprehensive legal analysis of the WTO compatibility of certain imaginable regulatory measures. Rather, in the third section, I will take the EU debate on animal cloning as a starting point to identify some parallels to previous trade disputes, in which the WTO compatibility of a Member's regulation in the area of food safety and public health was at stake. Thus, issues arising with regard to animal cloning under

[3] Therefore, I will not be dealing with legal issues of EU law, which, of course, equally arise with regard to future EU regulation of animal cloning, such as, for example, the question of competence and legal basis for the EU to take action in this area. See Maria Weimer, 'The Regulatory Challenge of Animal Cloning for Food – The Risks of Risk Regulation in the European Union', 1 *European Journal of Risk Regulation* (2010), 31-39.

[4] The text of the original GATT 1947 is now incorporated as General Agreement on Tariffs and Trade, 15 April 1994, in force 1 January 1995, 55 UNTS 194, 1867 UNTS 187 (hereinafter GATT) into the Agreement establishing the World Trade Organization, 15 April 1994, in force 1 January 1995, 1867 UNTS 154 (hereinafter WTO Agreement).

[5] See Gabrielle Marceau & Joel P. Trachtman, 'The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tariffs and Trade,' 36 (5) *Journal of World Trade*, (2002) 811-881, at 866, with further references to WTO case-law.

[6] Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures. A Commentary* (Oxford University Press: Oxford, New York, 2007) at 17.

the SPS Agreement, the GATT, and the TBT Agreement will be identified with the aim of comparing the different requirements stipulated by each agreement.

Animal cloning on the verge of commercialization in the global food market

As often in legal regulation, the devil lies in the details. Understanding the current regulatory developments at EU level and their implications for international trade at first requires some contextual information about the technology of animal cloning as well as its commercialisation at global level. 'Animal cloning' in the sense this term is used in the present regulatory discussion is defined as the reproduction of genetically identical 'copies' of an animal through Somatic Cell Nuclear Transfer (SCNT). At present, SCNT is the most commonly used technique for animal cloning, and it allows scientists to create genetic replicas (clones) from adult animals that share the same nuclear gene set as another organism.[7]

The primary commercial use of this technology today and in the near future is in the breeding of farm animals for food production. The benefits of animals cloning as breeding technique lie in the possibility to produce elite animals to be used in breeding. Thus, the animals to be cloned would be those having traits of interest for farming, such as resistance to diseases, or characteristics of interest for food production, such as quantity of milk, quality of meat or others.[8] The clones themselves have a low probability of entering the food chain. Rather, it is their progeny that shall be used for food production, such as for the production of milk or meat products.[9] Progeny of a clone refers to offspring born from it by sexual reproduction, where at least one of the parents was a clone.[10]

The first animal clone to gain worldwide attention was the sheep Dolly, whose birth was announced in 1997.[11] Since then the SCNT cloning technique has been considerably improved. As previously in the case of biotechnology, the US industry seems to be closest to the commercial use of animal cloning in the mass production of food,[12] therefore, also representing the strongest commercial interest in removing any potential obstacles to the free international trade of animal cloning products. An important step towards free trade at least in the US market was the release of a positive risk assessment of food from animal cloning by the US Food and Drug Administration (FDA) in January 2008. The FDA is an independent federal agency responsible for food safety, and it has found that food derived from healthy animal clones and their offspring does not give rise to more risks than food derived from

[7] See in more detail The European Group on Ethics in Science and New Technologies, *Ethical aspects of animal cloning for food supply*, opinion No 23 from 16 January 2008, at 6 (hereinafter EGE opinion).

[8] See EGE opinion *supra* note 7, at 12-13.

[9] See European Food Safety Authority, 'Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their offspring and Products Obtained from those Animals,' scientific opinion from 15 July 2008, *The EFSA Journal* (2008) 767, 1-49 at 10 (hereinafter EFSA opinion).

[10] See EFSA opinion *ibid,* at 7.

[11] See Elizabeth Weise, 'Dolly was World's Hello to Cloning's Possibilities,' *USA Today*, 4 July 2006, <www.usatoday.com/tech/science/genetics/2006-07-04-dolly-anniversary_x.htm> (visited 2 July 2010) References to online sources are accurate as of 2 July 2010.

[12] USA is the country in which most of the companies have been established with the aim of using animal cloning for the food industry. See EGE opinion *supra* note 7, at 19.

conventionally bred animals.[13] Despite this regulatory green-light from the FDA, food from cloned animals is until today still not made available to consumers in the US. This is due to the voluntary moratorium on the sale of such products, which has been agreed on between the US agriculture and food industry and the US Agriculture Department. The voluntary moratorium is upheld since 2001 and seems to be likely to continue even after the FDA's approval.[14] According to estimates, once the moratorium ends, it will take three to five years before food from the offspring of clones becomes available to the consumer.[15]

To conclude, the EU finds itself in a situation, in which products derived from the offspring of cloned animals (e.g. milk and meat) will begin to be imported into the European market in the foreseeable future.[16] Even now it is faced with imports of other products derived from animals cloned outside the EU, such as embryos or frozen semen from cloned cattle, bulls, and pigs, which are traded for breeding purposes.[17] Seeing that the biggest trade partner in this area will probably be the USA, any restrictive regulatory measures on the part of the EU will make animal cloning a likely candidate for yet another high-profile transatlantic dispute before the WTO dispute settlement bodies.

EU debate on what policy to adopt towards animal cloning

Latest since the release of FDA's draft risk assessment on food from cloned animals in December 2006 the EU public authorities, ahead of all the European Commission, have seen the necessity to develop their own policy approach towards animal cloning for food supply. In February 2007 Commission's president Barroso turned to two different European expert bodies asking them to produce assessments of the new technology; the European Group on Ethics of science and new technologies (EGE) was asked to assess the ethical implications of cloning animals for food supply; at the same time the European Food Safety Authority (EFSA) was entrusted with the task of evaluating the impact of the technology on food safety, animal health and welfare and the environment. In 2008 the Commission's General Directorate for Health and Consumers (DG Sanco) also launched a Eurobarometer survey on EU consumer's attitudes to cloning for food production, the results of which were published in October 2008. One month earlier, in September 2008, the European Parliament contributed to the debate by issuing a resolution on animal cloning for food supply, in which it demanded a comprehensive ban of the technology. Furthermore, in the beginning of 2008 a legislative co-decision procedure has been initiated by the Commission with the aim of amending Regulation 258/97[18] (hereinafter the Novel Foods Regulation) by, *inter alia*, including food from animal cloning into the scope of this regulation. The outcome of all these processes deserves closer attention since it indicates the different issues and concerns at stake. Moreover, it offers some ideas

[13] See US Food and Drug Administration, *Animal Cloning: A Risk Assessment*, opinion from 1 August 2008, <www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalCloning/ucm055489.htm>.

[14] See Reuters, *No end in site for animal cloning moratorium: USDA*, 7 April 2008, <www.reuters.com/article/scienceNews/idUSTON77972120080407>.

[15] See EGE opinion *supra* note 7, at 14.

[16] For an indicative timeline for the commercialization of food from cloned animals see EGE opinion *supra* note 7, at 14 with further references.

[17] See EGE opinion *supra* note 7, at 14.

[18] Regulation (EC) 257/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ 1997 No. L 43/1.

about how future EU regulation of animal cloning for food supply could look like, in particular, in view of its potential impact on international trade.

EFSA's scientific opinion(s)

On 15 July 2008 EFSA issued its scientific opinion on animal cloning for food supply.[19] EFSA has limited its evaluation to cattle and pig clones and their progeny due to the lack of data for the cloning of other species. Overall, EFSA identified animal health and welfare as the main concern arising from animal cloning through SCNT due to the still often occurring malfunctioning of the technique. In contrast, no risks could be identified with regard to food safety and the environment.

As regards risks to human health EFSA stated that based on current knowledge there is no indication that differences exist in terms of food safety between food products (e.g. meat and milk) from healthy cattle and pig clones and their progeny, compared with those from healthy conventionally-bred animals. However, EFSA has also highlighted that there is no sufficient data at present to evaluate whether SCNT has an impact on the immune functions of cloned animals, and therefore on their susceptibility to infections. This raises the question whether and to what extent the consumption of meat and milk from cloned animals or their progeny may also lead to an increased human exposure to transmissible agents. However this question remains open and is referred back to further research on the immunological competence of clones. [20]

Further, EFSA has found that there are significant animal health and welfare issues for surrogate mothers (dams) and clones that can be more frequent and severe than for conventionally bred animals. Surrogate dams suffer from increased pregnancy failure and increased recourse to Caesarean section. Further, the mortality and morbidity rate of clones in the early stage of their development is considerably higher than in sexually reproduced animals. However, clones that survive appear to be normal and healthy. As regards progeny EFSA found no indication of any abnormal effects.

Finally, as regards implications of animal cloning for the environment EFSA concluded that there is no indication that clones or their progeny would pose any new or additional environmental risks compared to conventionally bred animals. However, EFSA also acknowledged that only limited data is available with regard to the environmental impact.

To conclude, it is noteworthy that throughout its opinion EFSA has emphasized the uncertainties surrounding the scientific risk assessment of animal cloning at the present stage of technology development. The reasons stated for these uncertainties are the limited number of studies available, the small sizes investigated and the absence of a uniform approach to allow all the issues relevant to the opinion to be addressed.[21] Thus, EFSA could not answer with certainty all the questions addressed to it by the Commission. Which is why in March 2009 the Commission went back to EFSA, requesting it to further develop its scientific advice especially with regard to animal health and welfare of clones. EFSA's statement with further advice was

[19] See EFSA opinion *supra* note 9.

[20] See EFSA opinion *supra* note 9, at 33.

[21] See EFSA opinion *supra* note 9, at 2.

published on 23 June 2009.[22] Whilst including a number of new publications on SCNT, EFSA overall confirmed the findings and recommendations made in its first risk assessment; at the same time it still was not able to remove the uncertainties.

The European Group on Ethics (EGE) opinion on the ethical aspects of animal cloning

The EGE adopted its opinion on 16 January 2008. After having carried out expert hearings, a public consultation as well as organising a round table with representatives from academia, industry, NGOs, civil society, and international organisations, the EGE reached the conclusion that there are doubts about the ethical justification to clone animals for food supply. The Group stated that 'considering the current level of suffering and health problems of surrogate dams and animal clones, the EGE has doubts as to whether cloning animals for food supply is ethically justified. Whether this applies also to progeny is open to further scientific research.' As a consequence, at present the EGE did not see convincing arguments to justify the production of food from clones and their offspring.[23]

Public perception – the Eurobarometer on animal cloning

Following the recommendation of EGE the Commission's DG Sanco has launched a Eurobarometer survey to find out more about the EU citizens' attitudes towards animal cloning for food production. The results of the survey were published in October 2008[24] showing that the majority of citizens hold negative views of animal cloning. 84 % believe that the long-term effects of animal cloning on nature were unknown; 77 % believe that animal cloning might lead to human cloning; 61 % think that animal cloning was morally wrong. A majority of interviewees (58 %) said that cloning for food production purposes should never be justified. 63 % of citizens stated that it was unlikely they would buy meat or milk from cloned animals, even if a trusted source stated that such products were safe to eat. Finally, special labelling for food products from the offspring of clones was favoured by 83 % of the interviewees.

Overall, it seems that the issues perceived most problematic by the public are the uncertainty of the long-term effects of the technology on nature and the moral justification for using animals for cloning for the purpose of food production. Two moral objections seem particularly pressing: the 'slippery slope' argument against the cloning of animals against the background of immorality of the cloning of humans; and, the fear that animals would run the risk of being treated like commodities rather than creatures with feelings.

The European Parliament's resolution on animal cloning

The EP's resolution[25] added a weighty democratic element to the EU orientation debate on the use of animal cloning. Its call to ban every form of commercialisation of

[22] See EFSA statement, 'Further advice on the implications of Animal Cloning (SCNT)' from 23 July 2009, *The EFSA Journal* (2009) RN 319, 4-15

[23] See EGE opinion *supra* note 7.

[24] See Eurobarometer, *European's attitudes towards animal cloning*, October 2008, <www.ec.europa.eu/public_opinion/flash/fl_238_en.pdf>.

[25] See *European Parliament resolution of 3 September 2008 on the cloning of animals for food supply*, <www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2008-0400&language=EN&ring=B6-2008-0373>.

the technology including imports of related products in the EU was supported by a vast majority of the MEPs. There were 622 votes in favour, 32 against and 25 abstentions. The resolution calls in a very clear and concise way on the Commission 'to submit proposals prohibiting for food supply purposes (i) the cloning of animals, (ii) the farming of cloned animals and their offspring, (iii) the placing on the market of meat or dairy products derived from cloned animals or their offspring and (iv) the importing of cloned animals, their offspring, semen and embryos from cloned animals or their offspring, and meat or dairy products derived from cloned animals or their offspring, taking into account the recommendations of EFSA and the EGE.'

The Commission's orientation debate on animal cloning

In January 2009 the College of Commissioners held an orientation debate in order to see, if in the light of the above-described consultations the EU's current regulatory framework was sufficient or whether additional measures designed specifically for animal cloning were required.[26]

The Commissioners discussed different possible policy options, focussing mainly on three courses of action: (1) not taking any action at present while further debating at EU level and internationally the use of cloning for food supply, (2) using the existing EU legal instruments to regulate products derived from animal cloning, and (3) proposing an outright ban of animal cloning for food supply.[27] The outcome of this orientation debate in the College was that no definitive decisions on a policy approach were taken yet. In order to avoid potential trade issues with third countries, the Commission seems not to be ready to propose new legislation banning or allowing animal cloning and is holding the existing status quo for now. Thus, the Commission seems to want to gain more time for reflection and to carry on the debate between the Commission, the Parliament and the Council. Also, the fact that following the debate in the College, namely in March 2009, DG Sanco requested an additional scientific opinion from EFSA (see above) indicates that the Commission considers the current factual evidence as not yet sufficient to provide the basis for legislative action.

Legislative developments – a new amendment of the novel foods regulation

It is worth noting that, in parallel to the ongoing debate described above, and a half a year before the issue of the EFSA first scientific opinion on animal cloning, the Commission already initiated a legislative process, the outcome of which could directly affect the way that food from cloned animals will be regulated in the EU in the near future. In January 2008, the Commission presented a legislative proposal[28] to revise the Novel Foods Regulation,[29] thereby using an existing legislative instrument to regulate food derived from cloned animals. This Commission proposal is currently

[26] See USDA Foreign Agricultural Service, *EC Orientation Debate on Animal Cloning*, GAIN Report Number E41010 from 30 January 2009, <www.fas.usda.gov/gainfiles/200902/146327190.pdf>.

[27] See *ibid*.

[28] Commission Proposal for a Regulation of the European Parliament and of the Council on novel foods, COM (2007) 872 final, 14 January 2008, <www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0872:FIN:EN:PDF>.

[29] Regulation (EC) 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel foods ingredients, OJ 1997 No. L 43/1 (hereinafter Regulation 258/97).

at the stage of the second reading by the European Parliament[30] within the ordinary legislative procedure under Article 294 of the TFEU.

Before explaining the content of the Commission proposal as relevant for food from cloned animals, the current legal situation shall be briefly described. The Novel Foods Regulation requires a prior authorisation for foods, which fall under the definition of 'novel foods:' they may only be placed on the European market after having undergone a centralised safety assessment by the EFSA. Based on the EU competence to ensure the functioning of the internal market (Article 114 TFEU) this EU Regulation has been enacted to harmonize national regulations aiming at the protection of human health. Therefore, the Regulation itself serves the purpose of protecting public health from risks related to novel foods by establishing a common EU safety assessment for such products.[31] With regard to imported food from cloned animals two different situations should be distinguished. Food products derived from the progeny of cloned animals, and not directly from clones, do not fall under the definition of 'novel foods' under the current Novel Foods Regulation. As a consequence they do not require prior-authorisation, and can legally be placed on the European market being subject only to the general food safety requirements of the Regulation 178/2002.[32] However, food derived directly from an animal clone does fall under the scope of the Novel Foods Regulation as currently in force with the consequence that it is submitted to the prior authorisation requirement. According to present Article 1, para. 2), indent (e) of the Novel Foods Regulation, all food isolated from animals which has not been obtained by traditional breeding and does not have a history of safe food use is considered to be 'novel food' and so requires an additional safety assessment.

The new Commission proposal does not change the status of food obtained directly from cloned animals under this provision, but merely clarifies it by stating that all foods from animals to which has been applied 'a non-traditional breeding technique not used before may 1997,'[33] such as animal cloning, should fall under the definitions of novel foods. Therefore, when presenting its amendment proposal the Commission aimed at clarifying the legislative status quo rather than changing it. In particular, the Commission proposal does not also include products from progeny in the future definition of 'novel foods'. As noted above, the status of such food on the European market seems economically much more significant, especially for international trade, since foods from progeny are likely to present the majority of foods traded or imported into the EU. However, because there is no difference any more between the progeny of clones (created through sexual reproduction with non-clones) and animals obtained through conventional breeding, the former would not be considered as animals to which has been applied 'a non-traditional breeding technique.'[34] Consequently, under the Commission's proposal, products from progeny could still freely circulate on the European market (under the requirements of Regulation 178/2002).

---

[30] See Legislative Observatory of the European Parliament, <www.europarl.europa.eu/oeil/file.jsp?id=5583302>.

[31] See recital (2) of the preamble of Regulation 258/97.

[32] Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 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, OJ 2002 No. L 31/1 (hereinafter Regulation 178/2002).

[33] See Commission proposal, *supra* note 28, at 16.

[34] See Commission proposal, *supra* note 31, at 16.

However, the Commission's proposal has been substantially modified by the other institutions during the course of the legislative procedure. The European Parliament, in its legislative resolution from the first reading held in March 2009, suggested that foods from cloned animals (both from clones and their progeny) should be totally excluded from the scope of application of the Novel Foods Regulation. Instead the EP prompted the Commission to submit a legislative proposal effectively banning animal cloning for the food supply chain.[35]

The Council adopted its first reading position on the Commission proposal in March 2010.[36] Therein, it took a mediating position between the Commission and the Parliament by proposing the inclusion of not only food produced directly from cloned animals but also that produced from their progeny under the scope of the Novel Foods regulation, thereby extending the prior-authorisation requirement to the latter type of products. While acknowledging that the Novel Foods Regulation cannot adequately manage all aspects of cloning and mandating a Commission report on all aspects of animal cloning for food production followed, if appropriate, by a legislative proposal, the Council agreed to use this instrument to regulate food from clones and progeny in order to avoid a legal vacuum until more specific legislation is adopted.[37]

It follows that we are currently facing three different options for treating food products from animal clones and their progeny on the Union market. The Commission presents the least trade restrictive proposal by submitting only direct food products from clones to the prior authorisation requirement. The Council goes further by including also the products from progeny despite the lack of difference of such products with food produced from conventionally bred animals. Finally, the EP defends the most radical approach requesting an outright ban of all kinds of animal cloning products. The outcome of this process cannot be predicted at present. It should be mentioned that from the viewpoint of international trade law, the Council and the EP proposals would have most far-reaching consequences, since they would strongly affect the free circulation of products, which are most likely to be imported in the EU in the future, namely food products from clone progeny.

Animal cloning in the light of WTO law

As we have seen above, the precise contours of future EU legislative measures regulating animal cloning for food supply are not clear at the moment. This applies to their content, stringency, legal basis and legislative purpose as well as to the intensity of their impact on international trade. Nevertheless, the possible measures discussed in the previous section offer some indications for the future evolution of a EU policy on animal cloning. In the following analysis, therefore, I will take the current state of the EU debate as a starting point to identify some parallels of the present case to previous trade disputes, in which the WTO compatibility of a Member's regulation in the area of food safety and public health was contested. When assessing future EU

[35] See European Parliament resolution of 25 March 2009 on the proposal for a regulation of the European Parliament and of the Council on novel foods, <www.europarl.europa.eu/oeil/file.jsp?id=5583302>.

[36] Position of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001, Interinstitutionl file 2008/0002 (COD) from 5 March 2010.

[37] See Draft Statement of the Council's Reasons, Interinstitutional file 2008/0002 (COD) from 2 March 2010, at 7.

measures on animal cloning against the background of WTO law, I will, in particular, refer to the planned amendment of the Novel Foods Regulation as the most concrete regulatory measure in the short term. Whenever possible I will also include into the analysis other possible regulatory measures, which would, as opposed to the Novel Foods Regulation, also aim at protecting public interests other than human health, and which were discussed as relevant concerns in the EU regulatory debate so far (eg animal health and welfare, environment and ethical concerns).

Since the entry into force of the Uruguay trade agreements domestic regulations pursuing public policy objectives, such as public health or environment, have been under increased scrutiny by the WTO Dispute Settlement Bodies, because of the growing importance of non-tariff barriers to trade, which these regulations often present. Despite of the origin-neutrality of such regulatory schemes, [38] they may serve to disguise protective de-facto discrimination hidden or structurally embedded in them, thus undermining the fundamental principle of National Treatment[39] laid down in the GATT. Another crucial test for domestic regulation, especially in the area of public health and food safety is since recently the compliance with the WTO's SPS Agreement. The extent to which the rules of this agreement constrain the Member's regulatory autonomy has been the 'bone of contention' in recent high profile transatlantic trade disputes, such as the *EC-Hormones Meat* case and the *EC-Biotech* case.[40]

The WTO jurisprudence on domestic origin-neutral regulation has provoked a lively academic discussion on the impact of WTO trade rules on internal public decision-making and regulation.[41] At the core of this discussion lies the thorny question of how far the WTO legal trade order can go in challenging domestic regulation, and thus, in precluding public policy choice made by the Members' democratic constituencies. This question refers not only to WTO constraints established through Dispute Settlement case law on already existing regulation. What is more, the WTO rules and their interpretation adopted in this case law may already preclude policy choice in the domestic pre-legislative decision-making phase, such as is currently the case with regard to decision-making on animal cloning in the EU. Legal scholars dealing with the clash between WTO law and domestic regulation have aptly noted,

[38] Such regulations do not on the face discriminate between national and imported products, because they apply equally to domestically produced products as well as to imports of the same products from other countries. However, they can present de-facto discrimination, for example, by favouring regulatory schemes to which domestic producers are better adjusted due to pre-existent structural conditions. On costs of regulatory schemes on exporters see Jacqueline 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,' 17 *European Journal of International Law* (2006) 1009-1031, at 1013.

[39] Art. III GATT. See Robert E. Hudec, 'GATT Constraints on National Regulation: Requiem for an 'Aims and Effects' Test,' 32 *The International Lawyer* (1998), 619-645 at 623.

[40] *EC-Meat Hormones and EC-Biotech supra* note 1.

[41] See Robert Howse and Elisabeth Tuerk, 'The WTO Impact on Internal Regulations – A Case Study of the Canada-EC Asbestos Dispute', in Grainne de Búrca and Joanne Scott (eds) *The EU and the WTO. Legal and Constitutional Issues* (Hart Publishing: Oxford, Portland Or., 2001) at 283; Grainne de Búrca and Joanne Scott, 'The Impact of the WTO on EU Decision-making', in *ibid*, at 1; Robert Howse and Donald Regan, 'The Product/Process Distinction – An Illusory Basis for Disciplining 'Unilateralism' in Trade Policy', 11 (2) *European Journal of International Law* (2000) 249-289; see also Hudec, 'Requiem' *supra* note 39.

> '… the WTO rules may already be having a chilling effect on the strengthening or development of such domestic regulatory schemes in other WTO members, thereby constraining or impeding democratic choices. If the WTO is to regain citizens' confidence, it has to prove its ability to balance the freedom of governments to pursue legitimate domestic objectives with the need to secure the benefits of trade liberalisation.'[42]

Against the background of this discussion, I will in the following examine what, in my view, are the most pertinent questions arising with regard to EU's approach towards animal cloning, and in particular, the amendment of the Novel Foods Regulation as currently discussed. These questions revolve around the relationship between the three main WTO agreements regulating the trade of goods: the GATT, the SPS agreement and the TBT Agreement.[43] By reference to the recent WTO case law, in particular, to the *EC-Biotech* case I will show that the balance in the application of these agreements to internal regulation has recently shifted towards a considerable extension of the scope of application of the SPS Agreement to the detriment of the other two agreements raising concerns over SPS 'imperialism,' as Joanne Scott has aptly put it.[44] Whilst under the GATT the main test for internal regulation is the question of whether it leads to a de-facto discrimination against imports,[45] and the Members can be exempted from the National Treatment obligation where their regulation aims at protecting certain fundamental public goods,[46] under the SPS Agreement domestic laws and regulations are submitted to a considerably more rigorous test of their 'rationality' in the sense of them being scientifically 'sound'.[47] As a consequence, the application of the SPS Agreement necessarily leads to less deference to internal decision-making, and thereby a stronger impact of WTO rules upon it.[48]

I will discuss the problems arising from the broad interpretation of the concept of an SPS measure adopted by the WTO panel in its *EC-Biotech* report, as well as the consequences of this for the compatibility with WTO law of potential future EU regulation of animal cloning. Subsequently, I will turn to the quandaries of applying the GATT and the TBT Agreement to origin-neutral domestic regulations, also here focusing on the question of how much regulatory autonomy is left to the Members seeing the requirements of these two agreements as applied in previous dispute settlement case law. In particular, with respect to the GATT the controversial debate on the legal status of processes and production methods (hereinafter PPMs) under Art. III.4 of the agreement will be of crucial importance. This is so because any potential future regulation that treats food products derived from animal cloning and

---

[42] Howse and Tuerk, 'WTO Impact' *ibid*, at 284.

[43] About this relationship see Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures, supra* note 6, at 27; and Marceau & Trachtman, 'The Technical Barriers to Trade Agreement,' *supra* note 5, at 863.

[44] Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures*, supra note 6, at 17.

[45] See Art. III of the GATT.

[46] See Art. XX of the GATT.

[47] Regulatory measures shall be based on a scientific 'risk assessment', see Art. 5.1 of the Agreement on the Application of Sanitary and Phytosanitary Measures, 15 April 1994, in force 1 January 1995, 1867 UNTS 493 (hereinafter SPS Agreement). Note that in all SPS-related cases to date, WTO tribunals considered the requirements of Article 5.1 in each case finding that they are not fulfilled, see Nathalie Bernasconi-Osterwalder, Daniel Magraw, Maria J. Oliva, Marcos Orellana & Elisabeth Tuerk, *Environment and Trade. A Guide to WTO Jurisprudence*, (Earthscan: London, 2006) at 261.

[48] See Mark A. Pollack & Gregory C Shaffer, When Cooperation fails. The International Law and Politics of Genetically Modified Organisms (Oxford University Press: Oxford, New York, 2009) at 188.

their progeny differently than those derived from conventional animals would be based on the fact that the former products were produced using the technique of SCNT, and therefore on a production method.

Animal cloning and the SPS Agreement – in the shadow of EC-Biotech

In their current contemplation on the appropriate (WTO compliant) policy on animal cloning the EU authorities will hardly be able to ignore the outcome of the last transatlantic dispute in matters of food safety, public health and environmental protection – *the EC-Biotech* dispute. The GMO dispute casts a long shadow over the EU's current reflection since there are significant parallels between the problems involved in EU regulation of both technologies. Both offer new ways of producing food that would not occur naturally, provoking the negative association of 'playing with nature.' Both seem to promise improvement of worldwide food production, at the same time bearing the potential of creating risks to public health and the environment, but which are yet scientifically uncertain. And, both have a broader ethical and socio-economic dimension, which goes beyond the issues of free trade. Seeing the strong public opposition to and political contestation surrounding animal cloning at present, the scenario of a *de-facto* moratorium of the same kind as occurred in the EU authorisations of biotech products[49] can also be imagined for future authorisations of foods from cloned animals under the amended Novel Foods Regulation. The parallels are obvious: a stringent prior-authorisation procedure with individual case-by-case assessments, in which the scientific experts would not identify the existence of risks to food safety and public health,[50] while the Member States – fuelled by strong public opposition from their countries – would be reluctant to approve the entry on the market of the contested products.[51] It can, therefore, be assumed that in their choice of a policy towards animal cloning today the EU public authorities will exert themselves in order to avoid arriving at a similarly standoff political situation as is currently the case with GMO products.[52] This is likely to increase the influence of WTO law, and in particular, of the Panel report in *EC-Biotech*, on the current EU pre-legislative reflection.

In the *EC-Biotech* case the EU legislation on GMOs was scrutinised mainly under the SPS Agreement. But before turning to the Panel's reasoning, let us first have a closer look on the concept of an SPS measure as defined by the SPS Agreement. This will serve the purpose of providing an idea of whether future EU measures on food from animal cloning could potentially qualify as SPS measures.

---

[49] Namely between 1998 and 2004, see Pollack and Shaffer, *When Cooperation fails*, *supra* note 48, at 68.

[50] In the case of animal cloning this is likely seeing the results of the EFSA opinion with regard to food safety. See EFSA opinion *supra* note 9.

[51] In fact, the Novel Foods Regulation in the form in force at the time of the alleged GMO moratorium, was one of the measures examined by the panel in *EC-Biotech*, because at that time it also included the authorization of genetically modified food. On the history and circumstance of the *de-facto* moratorium see Gregory Shaffer and Mark Pollack, 'Agricultural Biotechnology Policy in the EU: Between National Fears and Global Disciplines', in Helene Wallace, William Wallace and Mark Pollack (eds), *Policy-Making in the European Union* (Oxford University Press: Oxford, New York, 2005) 5th Edition.

[52] See for an account of the EU's inter-institutional as well as international conflicts following the *EC-Biotech* report, Sara Poli, 'The Impact of the "Biotech Dispute" on WTO Law and its Challenges for the European Community', 26 *Yearbook of European Law* (2007), 317-353; see also Maria Weimer, 'Applying Precaution in EU Authorisation of Genetically Modified Products – Challenges and Suggestions for Reform', 16 (5) *European Law Journal* (2010) (forthcoming September 2010).

The definition of an SPS Measure under the SPS Agreement

According to Article 1.1 of the SPS Agreement it applies to all 'sanitary and phytosanitary measures' which may, directly or indirectly, affect international trade. The definition of SPS measures can be found in Annex A.1 of the agreement. It states that an SPS measure is any measure applied

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

From this definition it is apparent that the concept of an SPS measure is functionally determined in that, with one exception,[53] it must be applied to protect one of the mentioned public interests: human life or health, animal life or health, and plant life or health. Moreover, the purpose of the measure must be such as to guard these interests against specified risk factors. Therefore, not all measures taken in pursuit of the listed interests will automatically qualify as SPS measures.[54]

This specific focus of the SPS agreement can be explained when considering the agreement in its relationship to the other two WTO agreements, the GATT and the TBT Agreement, and their negotiating history. Jacqueline Peel has dealt with this issue extensively stating that the SPS Agreement has been conventionally regarded as the one with the narrowest scope of operation among the three agreements. It has been developed and negotiated by the WTO Members as an agreement that

> 'would cover only those trade-restrictive regulatory measures introduced to deal with issues of traditional 'sanitary and phytosanitary' concern, such as quarantine risks associated with the entry and spread of pests and diseases via traded agricultural products, or risks posed by toxins, additives or contaminants in imported human foods or animal feed.'[55]

Possible EU measures towards animal cloning do not, at least not at first glance, appear to be 'traditional' SPS measures in this sense. However, as far as the protected interests listed in Annex A.1 are concerned, some of the interests for the protection of which future EU measures, in particular the Novel Foods Regulation, are likely to be designed, do fall under the scope of the SPS Agreement, notably, human health or animal health. In its new legislative proposal for the Novel Foods Regulation, which includes food from cloned animals, the Commission states that the Regulation would serve the purpose of ensuring 'a high level of human health and consumer protection.' In addition, the European Parliament in its amendments to the Commission's proposal further to human health would like to include animal health and welfare, environment and consumer interests as the protected goods of the new

[53] Annex A.1 (d) of the SPS Agreement.

[54] See Scott, *The WTO Agreement of Sanitary and Phytosanitary Measures, supra* note 6, at 12.

[55] Peel, 'A GMO,' *supra* note 38, at 1014.

Novel Foods Regulation. While the inclusion of environment and consumer interests (as far as they go beyond human and animal health) would theoretically be possible only under the provision of Annex A.1 (d)[56] of the SPS Agreement, human and animal health undoubtedly fall under the scope of protected interests included in the definition of an SPS measure.

In the light of the EFSA opinion risks to animal health posed by the use of SCNT as a cloning technique appear to be most pertinent. Nonetheless, in case future EU measures, such as the Novel Foods Regulation or a potential future ban on food products from cloned animals, would be designed to protect animal health, they would most likely fall outside the scope of the SPS Agreement. This is so because the definition of Annex A.1 cited above requires that SPS measures be applied in order to protect animal health within the territory of the regulating WTO Member. In case of imports of food derived from animal cloning (or even of the clones themselves) into the Union, however, the cloning process will already have taken place in the exporting country. Such a EU measure would, therefore, be applied in order to prevent the suffering of animals outside of the EU territory. Such extraterritorial effects with the object of protection being outside the territory of the importing Member are not covered by the SPS Agreement.[57]

Also with regard to the objective of protecting human health difficulties, albeit of a different kind, do arise. An extraterritorial effect of the measure would not occur in this case, because the aim would be to protect the health of EU citizens from potential adverse effects arising from the imported food products. However, if we look at the text of Annex A.1, a further condition for applying this definition to measures regulating food from cloned animals would be that, in the case of human health, they are applied to protect against

- risks arising from additives, contaminants, toxins or disease-carrying organisms in foods, beverages or feedstuffs; or
- risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests.

There seem to be two kinds of difficulties with applying this definition to food from cloned animals and their progeny. Firstly, such food products would need to be considered as containing additives, contaminants, toxins or disease-carrying organisms; or animal clones from which these products derive would have to be considered as carrying diseases; or, finally, animal clones or their products would have to qualify as pests. As shown above, EFSA has found in its risk assessment that there are no significant differences as regards the composition and nutritional value of meat and milk between healthy clones or clone progeny and their healthy conventional counterparts. Further, toxicological and allergenic effects of such products were considered to be unlikely. This makes it difficult to argue that food from cloned animals as such contains any additives, contaminants etc. Since adult clones were considered to be healthy, disease related risks are also difficult to establish. Here, at the most, the possibly weak immune function of clones and, thereby, their susceptibility to infections may be considered. However, this issue is still scientifically uncertain, as the EFSA opinion indicates. Finally, the term pest is not defined by the SPS Agreement. There is only an indication in a qualifying footnote,

[56] The extent and interpretation of this provision is, however, a disputed matter. See critical comments by Peel, 'A GMO' *supra* note 38 and Denise Prévost, 'Opening Pandora's Box: The Panel's Findings in the EU-Biotech Products Dispute' 34 (1) *Legal Issues of Economic Integration*, (2007) 67-101.

[57] See Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures, supra* note 6, at 11.

which states that 'pests' include 'weeds.'[58] Also, the definition used by the International Plant Protection Convention ('pest' is 'any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products'),[59] which could represent a relevant international standard,[60] does not seem to apply to cloned animals or their products.

The second difficulty relates to the term 'arising from' and, thus, to the causal relationship between risks to human health and the causes specified in Annex A.1 definition. As already stated, due to the lack of data and experience with food consumption from cloned animals, the consequences of it to human health are not entirely clear. Although EFSA has concluded that food safety risks are unlikely, it has also indicated the scientific uncertainties of this finding at present. The question, therefore, arises of whether the concept of an SPS measure also encompasses such regulatory measures that are applied to protect from yet unclear, long-term risks related to the employment of a new technology,[61] the causality of which cannot be established at present. Doubts on such an interpretation seem appropriate especially seeing the very specific wording of Annex A.1, which indicates that the negotiators of the SPS Agreement had well-defined risks in mind when they agreed to its rigorous disciplines.[62]

Despite of these considerations, the findings with regard to the scope of SPS measures made by the WTO panel in *EC-Biotech* could significantly increase the chances of future EU measures on animal cloning being qualified as SPS measures. The panel has expanded the scope of the SPS Agreement to apply to the kind of long-term and uncertain risks associated with new technologies, and its reasoning will be explored in the following.

The definition of an SPS Measure in the *EC-Biotech* case

The circumstances and legal issues of the *EC-Biotech* case have been widely discussed in legal commentary.[63] In September 2006 the Panel issued its long-awaited report in *EC-Biotech Products*.[64] The dispute between the United States, Canada and Argentina as complainants and the EU as the responding party revolved around the compatibility of certain measures,[65] adopted in the context of the EU approval system

[58] See Annex A.1 footnote 4 of the SPS Agreement.

[59] Article II of the International Plant Protection Convention, 6 December 1951, in force 3 April 1952, 150 UNTS 67 (hereinafter Plant Protection Convention).

[60] The SPS Agreement refers to the necessity to base SPS measures on such international standards in Art. 3.1; and the Plant Protection Convention is referenced in Annex A.3 of the SPS Agreement.

[61] Though the EGE in its opinion on animal cloning states that cloning is not a new technology, because the first experiments with it date back to the 1950s (see EGE *supra* note 7, at 7). I nevertheless use this term, because in commercial food production the use of SCNT does present a new technology; For a description of the characteristics associated with new technological risks see Ulrich Beck, *Risk Society: Towards a New Modernity* (SAGE: London, Newbury Park, Calif., 1992).

[62] Critical on this Peel, 'A GMO,' *supra* note 38, at 1014.

[63] See Peel, 'A GMO' *ibid*; Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures*, *supra* note 6, at 13-16; Pollack and Shaffer, *When Cooperation fails*, supra note 48, at 187; Ernst-Ulrich Petersmann, 'The WTO Dispute Over Genetically Modified Organisms: Interface Problems of International Trade Law, Environmental Law and Biotechnology Law,' in Francesco Francioni and Tullio Scovazzi (eds), *Biotechnology and International Law* (Hart Publishing: Oxford, Portland Or., 2006); Prévost, 'Pandora's Box,' *supra* note 56; Poli, 'Biotech Dispute,' *supra* note 52.

[64] The Panel was established on 29 August 2003 following complaints by the US, Argentina and Canada. The Panel examined the three separate complaints in a single document, constituting three reports.

[65] Three types of measures were under scrutiny: (1) a general moratorium at EU level on authorizations

for the placing on the market of GMOs with WTO law. The main issues disputed by the parties were the existence of alleged 'undue' delays in the approval of GM products by the EU administration as well as the scientific justification of national safeguard measures of several EU Member States. The Panel, however, also made important findings with regard to the scope of application of the SPS Agreement, which have potentially far-reaching consequences for future dispute settlement in the area of GMOs and beyond.[66] As Christiane Conrad notes, it was the first time that the qualification of measures as SPS measures and applicability of the SPS agreement have actually been contested in a WTO dispute.[67]

The Panel made its interpretation on the wide scope of an SPS measure when examining whether or not the SPS Agreement applied to EU's GMO legislation[68] in force at the time of the alleged breaches of WTO rules. Among the legislative measures under scrutiny was the Novel Foods Regulation, because in its older version it also included GM food, which could accordingly only be placed on the market after undergoing a centralised EU prior-authorisation procedure.[69] The EU measures in question pursued a multiple set of objections (such as human health, environment and consumer protection), which went beyond the scope of protected interests mentioned in Annex A.1 of the SPS Agreement. It, therefore, was controversial whether they could be viewed as SPS measures.

The Panel first found that a single legislative measure could be divided in different parts according to different purposes pursued, and thus falling at the same time under different WTO Agreements.[70] In a second step, however, it rejected EU's argument that not all of the objectives pursued by its legislation would fall under the scope of the SPS Agreement, referring, in particular, to environmental protection being outside that scope. Rather, the Panel turned to the definition of an SPS measure in Annex A.1 of the SPS Agreement, and after meticulously examining almost every word of it arrived at the conclusion that all purposes contained in EU's GMO legislation fell within the scope of the SPS Agreement.[71]

---

of biotech products; (2) various product-specific measures at EU level affecting the approval of specific biotech products; and (3) various safeguard measures adopted by some EU Member States, see para. 7.97-7.102 of the *EC-Biotech* report *supra* note 1.

[66] See Peel, 'A GMO,' *supra* note 38; Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures, supra* note 6, at 13-16; Pollack and Shaffer, *When Cooperation fails*, supra note 49, at 188-191; Poli, 'Biotech Dispute,' *supra* note 52; Prévost, 'Pandora's Box,' *supra* note 56.

[67] See Christiane R. Conrad, *PPMs, the EC-Biotech Dispute and Applicability of the SPS Agreement: Are the Panel's Findings Built on Shaky Ground?,* Hebrew University of Jerusalem Research Paper No. 8-06, <www.ssrn.com/abstractid=920742>. Other disputes concerning the SPS Agreement are *EC-Meat Hormones*, *supra* note 1; Panel report, *Australia-Measures Affecting Importation of Salmon*, WT/DS18/R, adopted 12 June 1998 (hereinafter Panel report *Australia-Salmon*); Panel report, *Japan-Measures Affecting Agricultural Products*, WT/DS76/R, adopted 27 October 1998; Panel report ,*Japan-Measures Affecting the Importation of Apples,* WT/DS245/R, adopted 15 July 2003 (hereinafter *Japan-Apples*).

[68] Namely, Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, OJ 1990 No. L 117/15, Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, OJ 2001 No. L 106/1, and Regulation 258/97 *supra* note 29.

[69] Since the entry into force of the reformed regulatory framework for GMOs, GM food and feed is regulated under Regulation (EC) 1829/2003 of 22 September 2003 on genetically modified food and feed, OJ 2003 No. L 268/1.

[70] See *EC-Biotech*, *supra* note 1, para. 7.162-7.170.

[71] *Ibid* para. 8.4.

On the one hand the Panel had to examine whether the risks specified in Annex A.1 also include the risks associated with GM products. As in the case of animal cloning, the possible long-term effects of genetic engineering are not fully explored at the moment. It was, therefore, not obvious that GMO risks as invoked by the EU could be subsumed under the very specific sanitary and phytosanitary risks enumerated in the Annex. Nevertheless, the Panel by means of a particular broad interpretation of the coverage of terms such as 'animal,' 'plant,' 'pest,' 'additive,' 'contaminant,' and 'arising from,' arrived at the conclusion that GMO risks fell within the scope of the SPS measure definition.[72] On the other hand, the Panel also had to qualify all the protected interests pursued by EU's legislation as falling under the scope of Annex A.1. This was problematic with regard to environmental protection, since it is not included in the above provision. However, the Panel interpreted environmental protection as being 'other damage' in the sense of Annex A.1 (d), the protection of which from 'pests' can exceptionally be captured by the SPS Agreement. Since the Panel by drawing parallels between weeds and GMOs, ie by comparing the potential effects of GMOs on other plants and the environment to the those caused by weeds, also found that GMOs can be regarded as 'pests' in certain situations, it had no difficulties including environmental protection (and some other interests) into the scope of application of the agreement in this case.[73]

The consequence of such extension of the applicability of the SPS Agreement was that other WTO agreements were not considered to assess the EU legislation on GMOs. This was the case, because the TBT Agreement is not applicable to measures qualified as SPS measures.[74] Although the applicability of the SPS Agreement to a measure does not also exclude the application of the GATT,[75] in practice the latter is not of much relevance for the outcome of a dispute, in which the SPS Agreement was found to be applicable. In the past, once a measure was found to be incompatible with the SPS Agreement, panels, relying on the principle of judicial economy, did not continue the examination under GATT.[76]

From that it follows that EU legislation on GMOs had to stand the rigorous test of scientific rationality established by the SPS agreement. This could be considered as a problematic situation especially with regard to domestic measures regulating new technological risks, where the capability of scientific experts to fully identify and assess such risks is arguably rather limited. Furthermore, as the case of GMO regulation within the EU demonstrates, the scientific evaluation of novel risks, even where it can be carried out, is likely to face conflicting scientific opinions creating a situation of scientific uncertainty. The analysis in the next section of the scientific requirements under the SPS Agreement will show that the possibility for domestic authorities to adopt precautionary measures under that Agreement as a reaction to situations of scientific uncertainty is rather limited. Against this background the wide interpretation of the scope of application of the SPS Agreement appears as a considerable constraint on domestic policy choices towards the regulation of new technological risks. At the same time, it will also be shown further below that the

[72] For a thorough analysis of the Panel' reasoning see Peel, 'A GMO,' *supra* note 38 and Conrad, *Biotech Dispute, supra* note 67.

[73] *EC-Biotech*, *supra* note 1, paras. 7.373-7.378.

[74] See Article 1.5 of the Agreement on Technical Barriers to Trade, 15 April 1994, in force 1 January 1995, 1868 UNTS 120 (hereinafter TBT Agreement).

[75] See *EC-Hormones*, *supra* note 1, para 8.38; Panel report *Australia-Salmon, supra* note 67, para 8.38.

[76] See Lukasz Gruszczynski, *Regulating Health and Environmental Risks under WTO Law* (Oxford University Press: Oxford; New York, 2010) at 69.

requirements of the GATT and the TBT agreement would arguably have shown more deference to the EU measures giving them stronger grounds to be upheld.

The question of whether also a future EU prior-authorisation procedure under the new Novel Foods Regulation or other eventually more stringent regulatory measures on animal cloning would fall under this extended definition of an SPS measure is subject to interpretation in future dispute settlement, in which the notions of the WTO agreements are applied on a case-by-case basis. Yet, in the light of *EC-Biotech*, and seeing that the Panel report was not appealed by the parties, the application of the SPS Agreement to such future measures seems likely.

Requirement of a 'proper' risk assessment and the role of science under the SPS Agreement

Should future EU measures on animal cloning fall under the SPS Agreement, the biggest challenge for them is likely to become their compliance with the science-based obligations[77] of that agreement. The basic right of the WTO Members to take SPS measures necessary for the protection of human, animal or plant life or health, as stated in Article 2.1 of the SPS Agreement, is limited by the requirement that such measures be consistent with the agreement's provisions. Among those provisions is the obligation established by Article 2.2 to base SPS measures on scientific principles and, generally,[78] not to maintain them without sufficient scientific evidence. Article 2.2 should be read together with Article 5.1 of the SPS Agreement, since in WTO jurisprudence the latter has been viewed as a 'specific application' of the basic obligation set out in Article 2.2.[79] Article 5.1 requires SPS measures be based on a risk assessment as appropriate to the circumstances. This requirement, and thereby the question of what constitutes a sufficient risk assessment under the SPS Agreement, has become the central issue, and crucial threshold to take, for domestic regulatory measures. As Joanne Scott notes, '(t)he use of science as a benchmark in this agreement marks a radical departure from the predominantly discrimination based approach of the GATT.'[80] This 'turn to science' in the application of WTO law has provoked much critical discussion among legal scholars who questioned the legitimacy of the WTO to impose an allegedly objective common version of scientific rationality and, in this way, to threaten the regulatory diversity among WTO members. While some condemned the SPS Agreement as such, others rather focused their criticism on the excessively rigid approach to science-based obligations of the agreement adopted in the WTO jurisprudence.[81] I will briefly set out the main elements of the obligations established by Article 5.1 as interpreted in the jurisprudence in order to grasp their significance for the case of EU measures regulating animal cloning.[82]

---

[77] See Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures, supra* note 6, at 81.

[78] With the exception of Article 5.7 of the SPS Agreement.

[79] See *EC-Meat Hormones, supra* note 1, para. 180.

[80] See Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures*, *supra* note 6, at 77.

[81] For an overview of the discussion and arguments see Scott *ibid*.; see also Elizabeth Fisher, 'Beyond the Science/Democracy Dichotomy: The World Trade Organisation Sanitary and Phytosanitary Agreement and Administrative Constitutionalism,' in Christian Joerges & Ernst-Ulrich Petersmann (eds), *Constitutionalism, Multilevel Trade Governance and Social Regulation* (Hart Publishing: Oxford, Portland Or., 2006) at 327 who argues in favour of a different approach to discussing the SPS Agreement.

[82] For more extensive discussion see Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures, supra* note 6; Alberto Alemanno, *Trade in Food. Regulatory and Judicial Approaches in the EC and the WTO* (Cameron May: London, 2008) at 247.

The concept of risk assessment is laid down in Annex A.4 of the SPS Agreement, which defines it as:

> '(t)he evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.'

This definition distinguishes between two categories of risk assessment: assessments of food-borne risks to human or animal health, and assessments of disease or pest risks. At the same time it establishes two different standards for risk assessment depending on which risk is to be considered. Whilst in case of food-borne risks to human or animal health described in the second part of the definition it is the *potential* effects on human or animal life that must be assessed, in case of pest and diseases the *likelihood* of entry, establishment or spread needs to be evaluated according to the SPS measure which may be applied.[83] With regard to the latter, the Appellate Body in the *Australia-Salmon* case has held that a risk assessment that 'conclude(s) that there is a *possibility*' of a risk is insufficient. Instead, a risk assessment under Article 5.1 must evaluate the likelihood, i.e. the probability of the risk.[84] However, the Appellate Body has nuanced this position by stating, both in *Australia-Salmon* and later in *EC-Meat Hormones* that the risk assessment may be expressed in quantitative or qualitative terms.[85]

In *EC-Meat Hormones*, the Appellate Body also held that the term 'based on' a risk assessment in Article 5.1. requires a *rational relationship* between the measure and the risk assessment, and that the results of the risk assessment had to sufficiently warrant the SPS measure.[86] Furthermore, the type of risk taken into account in a risk assessment should be above the threshold of a *theoretical risk*. Nonetheless, according to the Appellate Body, the risks taken into account may include not only those risks ascertainable in a science laboratory, but also 'risks in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.'[87]

It is noteworthy that in the *EC-Biotech* case the Panel adopted a rather narrow interpretation of risk assessment when scrutinizing the compliance with Article 5.1 of national safeguard measures against biotech products. It held that national scientific studies presented as evidence of the performance of a risk assessment were found not to meet the threshold of a 'proper' risk assessment, because they lacked an evaluation

---

[83] See Mitsuo Matsushita, Thomas J. Schoenbaum & Petros C. Mavroidis, *The World Trade Organization*, 2nd edition (Oxford University Press: Oxford, New York, 2006) at 512-513.

[84] Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, adopted 6 November 1998, para. 123 (hereinafter AB report *Australia-Salmon*).

[85] See *EC-Meat Hormones, supra* note 1, paras. 184 and 186 and AB report *Australia-Salmon*, *supra* note 84, para. 124.

[86] *EC-Meat Hormones, supra* note 1, para. 193.

[87] *EC-Meat Hormones, supra* note 1, paras. 186-187; see also AB report *Australia-Salmon*, *supra* note 84, para. 125.

of the likelihood of the risks.[88] It, therefore, seems to have favored a quantitative understanding of risk assessment.[89]

The interpretation of the science-based requirements of the SPS Agreement, and in particular, of Article 5.1 is a complex issue and not always did the WTO jurisprudence adopt a consistent approach to it.[90] With regard to the case of animal cloning it can, however, already be deduced from the above (by far not exhaustive) account of the relevant requirements that it would be rather difficult to defend EU measures on animal cloning, once they are designed as SPS measures aiming at protection of human health,[91] under Article 5.1 of the SPS Agreement. The EFSA opinion did not identify risks in relation to food safety of food from cloned animals, which means that any future measure based on this risk assessment would lack the type of *rational relationship* between scientific evidence and measure required in the jurisprudence. Yet, EFSA has indicated that there are scientific uncertainties surrounding its findings, especially due to the lack of relevant data. This makes it necessary to consider the possible application of Article 5.7 of the SPS Agreement to potential EU measures. Article 5.7 states that in cases of insufficient scientific evidence, a Member may adopt provisional SPS measures until more complete information on risks is obtained. This provision is commonly viewed as an expression of the precautionary principle in WTO law.[92]

The crux in the possible application of Article 5.7 to future EU measures, such as the amended Novel Foods Regulation, is the question of whether or not the scientific information provided by EFSA at this stage can be regarded as *insufficient scientific evidence* making it impossible to perform a risk assessment as required by Article 5.1. The Panel in *EC-Biotech*, following previous Appellate Body jurisprudence, has held that Article 5.7 is to be seen as a 'qualified exemption' to Article 2.2 of the SPS Agreement.[93] Therefore, Members who comply with the requirements of Article 5.7 will escape scrutiny under (certain parts of) Article 2.2.[94] Because, following the jurisprudence, Article 2.2 and Article 5.1 have to be read together (see above), the latter being a specific manifestation of the former, the Panel in *EC-Biotech* concluded that Article 5.7 operates as a qualified exemption also from the obligation under Article 5.1 to base SPS measures on a risk assessment.[95] As a consequence, the condition of insufficient scientific evidence with regard to the risks of animal cloning would depend on whether or not the EFSA opinion can be regarded as 'proper risk assessment' in the sense of Article 5.1. In *EC-Biotech* the Panel has stated that relevant scientific evidence is *insufficient* when there is a situation in which 'the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Art. 5.1 and as

[88] See *EC-Biotech, supra* note 1, para. 7.3046; see further account in Poli, 'Biotech Dispute,' *supra* n. 52.

[89] On the inconsistency of WTO case-law with regard to the requirement of a quantitative risk assessment see Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures*, *supra* note 6, at 93-94.

[90] See Scott, *ibid.*

[91] With regard to animal health, it was already stated above, that such measures would fall outside the scope of the SPS Agreement because of their extraterritoriality.

[92] See Joanne Scott, 'European Regulation of GMOs and the WTO,' 9 *Columbia Journal of European Law* (2003), 213-240, at 229.

[93] *EC-Biotech*, *supra* note 1, para. 7.2997.

[94] Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures*, *supra* note 6, at 113.

[95] See *EC-Biotech*, *supra* note 1, para. 7.2997; also Scott *ibid*; on the difficult relationship between the Articles 2.2, 5.1 and 5.7 of the SPS Agreement and a critical comment on the Panel's reasoning in EC-Biotech, see Poli, 'Biotech Dispute,' *supra* note 52, at 561.

defined in Annex A to the SPS Agreement.'[96] Whether the EFSA opinion on animal cloning can be regarded as an *adequate* assessment of risks, seeing the lack of data and scientific uncertainties, is debatable. Article 5.7 might, therefore, be pertinent. It is noteworthy, though, that the *EC-Biotech Panel* put the threshold to the application of Article 5.7 very high by holding that the existence of a situation of scientific uncertainty as such is not enough to enact an SPS measure under Article 5.7, because it can not be considered as equivalent to the situation of insufficient scientific evidence. This would imply that whenever a risk assessment in the sense of Article 5.1. has been carried out, even if this risk assessment is contested by other scientific authorities indicating scientific uncertainty, the scientific evidence would nevertheless be considered as sufficient ruling out the application of Article 5.7.[97] Rather, the national authorities would have to prove that the available scientific evidence does not allow the performance of an adequate risk assessment.[98] As Sara Poli critically comments on the Panel's report,

> 'proving the existence of a situation of insufficient scientific evidence is very difficult. Although Art. 5.7 confers on WTO members a right to adopt temporary SPS measures in a situation in which this would not normally be permitted, the burden of proof for the national authorities wishing to rely on Art. 5.7 is excessively high…'[99]

Arguably, even if these hurdles could be overcome in the case of animal cloning, a further difficulty would be the fulfillment of the next requirement of Article 5.7, namely that also provisional SPS measures, whilst escaping the obligation of Article 5.1, would still need to be based on 'available pertinent information.' Once again, seeing that EFSA did not identify any risks to the consumption of food from cloned animals by humans, it would be difficult to argue that the information provided by EFSA would be *pertinent* for the enactment of trade restrictive measures for the protection of human health.[100]

To conclude, the above (non-exhaustive) account shows that once future trade restrictive EU measures regulating animal cloning are designed as measures to protect public health, as currently proposed under the ongoing co-decision procedure concerning the amendment of the Novel Foods Regulation, they will encounter considerable difficulties of being defended under the SPS Agreement. However, they only would fall under the scope of this agreement and its rigorous science-based obligations, if they can actually be qualified as SPS measures. In the light of the extensive interpretation of the concept of an SPS measure by the Panel in the *EC-Biotech* case, such outcome seems probable. The widening of the scope of application of the SPS Agreement, however, is subject to strong criticism.[101] In the following, I will discuss other possibly applicable WTO rules, and how they might change the legal

---

[96] *EC-Biotech*, *supra* note 1, para. 7.3233.

[97] See a critical account with further references in Poli, 'Biotech Dispute' supra note 52, at 574.; see also a different interpretation of Article 5.7 of the SPS Agreement in the light of the precautionary principle Scott, 'GMOs and the WTO,' *supra* note 92, at 229.

[98] See the test applied in Appelate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted 10 December 2003, para 184 (hereinafter AB report *Japan-Apples)*.

[99] See Poli, 'Biotech Dispute' supra note 52, at 574.

[100] Unless one would use EFSA's (weak) indications with regard to the possibly decreased immune functions of clones and their possible transmissibility to humans, see EFSA report *supra* note 9.

[101] See Peel, 'A GMO,' *supra* note 38; Prévost, 'Pandora's Box,' *supra* note 56; Conrad, *Biotech Dispute*, *supra* note 67.

assessment of how future EU measures on animal cloning for food supply should be construed in order to comply with international trade law.

Animal cloning and the GATT – the debate on processes and productions methods

Assumed that future EU measures regulating animal cloning would fall outside the scope of the SPS Agreement, or that in addition to SPS purposes they would also pursue further objectives not covered by the SPS Agreement,[102] such as an ethical objective, they would have to comply with the general requirements of the GATT.[103] In particular, if designed as origin-neutral internal regulatory measures,[104] they would have to observe the National Treatment principle expressed in Article III of the GATT. Being one of the fundamental market access principles of the GATT/WTO system National Treatment imposes the obligation of equal treatment and non-discrimination between domestic and imported goods.[105] For internal measures, such as laws, regulations and requirements, the National Treatment is manifested in Article III.4, which runs as follows:

> 'The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment *no less favourable* than that accorded to *like products* of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase transportation, distribution or use…' (emphasis added)

According to Robert Howse and Donald Regan, Article III.4 represents a cornerstone of the multilateral trading system, defining the GATT's approach to trade restrictive domestic regulation, and establishing discrimination as the key concept in distinguishing legitimate and illegitimate domestic measures.[106] Should future EU measures on animal cloning be designed as origin-neutral internal regulations, that is, regulations, which regulate (or ban) the placing on the Union market of food from animal clones in general without distinguishing between domestic (EU) and imported products,[107] they would, in principle, fall under the scope of application of Article III.4. Nonetheless, their assessment in the light of WTO obligations could be complicated, if they would qualify as regulating PPMs, as opposed to products as such. The treatment of PPM-based measures under WTO law is highly disputed. Since the Panel reports in the *US-Tuna* cases,[108] it is the prevailing view that measures distinguishing between physically different products are legal, while measures, which

[102] *EC-Biotech supra* note 1.

[103] Note that according to Article 2.4 of the SPS Agreement measures that are found compatible with the SPS Agreement are assumed to be compatible with the GATT; see also See Scott, 'GMOs and the WTO,' *supra* note 92, at 229; For detailed discussion on the relationship between the GATT, SPS and TBT Agreements see Marceau & Trachtman, ' The Technical Barriers to Trade Agreement,' *supra* note 5, at 863.

[104] And not as border measures, such as an import ban, to which Article XI of the GATT applies; at this stage I shall ignore this option, but see below.

[105] Matsushita *et al., WTO*, *supra* note 83, at 234.

[106] Howse and Regan, 'Product/Process Distinction,' *supra* note 41, at 253

[107] Such measures seem most likely, seeing the co-decision procedure on the Novel Foods Regulation or the inter-institutional discussion of a general ban, which would also include imported products. I shall ignore possible border measures, such as an isolated import ban on food from cloned animals.

[108] Unadopted Panel reports *United States – Restrictions on Imports of Tuna*, 3 September 1991, DS21/R-39S/155 and *United States – Restrictions on Imports of Tuna*, 16 June 1994, DS29R (hereinafter *US-Tuna I and II*).

distinguish between products based on the production process alone violate non-discrimination obligations.[109] Moreover, PPM-based measures are held not to fall under the scope of Article III.4, but rather to be treated as border measures, thereby, as quantitative restrictions under Article XI of the GATT.[110] Seeing that there seem to be no significant differences in the composition of food products derived from cloned animals as compared to products produced from conventionally bred animals, the difference in treatment between the two categories would, in fact, be based on the different process and production methods used; in especially, on the use of SCNT for the production of animal clones. Following from this, the PPM debate might become relevant for the assessment of future EU measures, which is why I will present its main aspects in the following.

The PPM debate under GATT

Christiane Conrad draws our attention to the links between the PPM debate under GATT and the questions raised in WTO disputes dealing with compatibility of domestic regulations in the area of public health and the environment with the SPS Agreement, such as in the *Biotech* dispute. Both discussions raise important questions regarding the scope of WTO agreements vis-à-vis national and social regulation, the relevance of non-economic values, jurisdiction, and competence and legitimacy of the WTO adjudicatory bodies.[111] When using PPMs as a basis for domestic regulation, WTO members usually pursue non-economic policy goals, mostly in the field of environment and public health. This is so, because many PPMs can negatively affect these public interests, for example, production methods can pollute the air or water, or cause other harm through the way a product is produced.[112] At the same time, PPM-based measures can have considerable effects on international trade distorting the competition between domestic and imported products, if, for example, they covertly favour PPMs used by domestic producers. Another issue, which makes the PPM-based measures so controversial, is their extra-territorial effect. Critics claim that by basing their regulation on PPMs importing members are imposing their values or ethical and cultural preferences on the exporting members, thus, impinging upon the sovereignty of the latter.[113] It should be noted that different types of PPM-based measures can be distinguished, namely product-related and non-product-related as well as country based and origin-neutral PPM-based measures. In the following I am referring to origin-neutral non-product-related PPM-based measures, since this is the category that applies to regulation of food from animal cloning. Such measures aim to avoid or minimize harm caused by the way in which a product is produced, not by the product itself, and they do not distinguish between exporting countries rather focusing solely on the manner in which a product is produced.[114]

---

[109] See Conrad, *Biotech Dispute, supra* note 67, 6-7 with further references to the prevailing view in footnote 6.

[110] See *US-Tuna I and II, supra* note 108.

[111] Conrad, *Biotech Dispute, supra* note 67, at 6.

[112] See for more examples Bernasconi-Osterwalder *et al.*, *Environment and Trade, supra* note 47, at 203.

[113] For an account on the controversy surrounding PPMs see *ibid*, at 204; see also Howse and Regan, 'Product/Process Distinction,' *supra* note 41, at 251.

[114] See overview of all the categories in Bernasconi-Osterwalder *et al.*, *Environment and Trade*, *supra* note 47, at 204-205. Product-related PPM-based measures are not controversial and are treated as measures regulating products as such.

The prominent *US-Shrimp/Turtle*[115] case has served to somewhat clarify the status of PPMs under the GATT. In this case the GATT compatibility of a US legislative measure prohibiting the importation of shrimp harvested in a way that might harm sea turtles was assessed. Although this measure presented a non-product-related PPM-based measure, the Appellate Body in *US-Shrimp/Turtle* did not explicitly address the PPM problematique. Nevertheless, this ruling was of crucial importance for PPMs, because it changed the prevailing view at that time that PPM-based measures could never be permitted under the GATT. Whilst the Panel has held that the disputed measure violated Article XI of the GATT, and that it could not be justified under Article XX, the Appellate Body rejected the latter point. It found that measures that condition access to domestic markets on whether the exporting state complies with or adopts a policy or policies unilaterally prescribed by the importing state can, in principle, be justified under the general exceptions of Article XX of the GATT.[116] In so doing, it implicitly allowed the use of non-product-related PPM-based measures under certain conditions. However, also in this case PPMs were considered to fall under the scope of Article XI, instead of Article III.4 of the GATT.

Applied to potential EU measures on animal cloning, the interpretation adopted in *US-Shrimp/Turtle* would mean that they would be treated as violations of Article XI with the possibility of being justified under one of the exceptions listed in Article XX. Against the background of the collected expert advice at EU level, defences under Article XX (a), public morals, (b) protection of human or animal health or life, and maybe even under (g) conservation of exhaustible natural resources, if the argument of a threat to biodiversity through animal cloning could be substantiated, are imaginable. A requirement for upholding these defences would be that the measures are not applied in a manner, which would constitute a means of arbitrary or unjustifiable discrimination, or a disguised restriction on trade. Arguably, also the issue of proportionality would be of major importance, since it is required that the measures are *necessary* to protect the public interests invoked.[117]

It should be noted, however, that the stance on PPM-based measures taken in *US-Shrimp/Turtle* has experienced strong criticism. Several legal scholars have questioned the reasonableness of the product-process distinction as such, claiming that non-product-related PPM-based measures should be dealt with under Article III.4 of the GATT, thus being measured by their compliance with the National Treatment principle.[118] It is worth briefly outlining the arguments these authors invoke, since their approach to PPM-based measures considerably changes the lines legal assessment of future EU measure on animal cloning would follow.

---

[115] Appellate Body report *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 12 October 1998 (hereinafter *US-Shrimp/Turtle*).

[116] Ibid, para. 121. Note that in this case the measure was found not to fulfill the requirements of Article XX(g). However in the later Appellate Body report *United States – Import Prohibition of Certain Shrimp and Shrimp Products, 21.5,* WT/DS58/AB/RW, adopted 22 October 2001 the application of the same measure was found to be justified under Article XX(g), thus constituting the first case, in which a non-product-related PPM-based measure was found as GATT consistent. See Bernasconi-Osterwalder *et al., Environment and Trade, supra* n. 47, at 233-234.

[117] On the necessity test in the GATT see Marceau & Trachtman, 'The Technical Barriers to Trade Agreement,' *supra* note 5, at 825-830.

[118] E.g. Howse and Regan, 'Product/Process Distinction,' *supra* n. 41; Steve Charnovitz, 'The Law of Environmental "PPMs" in the WTO: Debunking the Myth of Illegality,' 27 *Yale Journal of International Law,* (2000), 59.

Robert Howse and Donald Regan offer a compelling, critical analysis of the PPM debate.[119] Their arguments can be divided in two kinds: a textual/jurisprudence argument and a policy argument. On the one hand, after meticulously analysing the wording of Article III.4 as well as the relevant WTO jurisprudence, they arrive at the conclusion that nothing in the text of this Article supports the product/process distinction as adopted by the Panel reports in *US-Tuna/Dolphin*. In particular, the formulation of Article III.4 that it applies to 'internal laws, regulations and requirements *affecting* the internal sale … of products' (emphasis added) is scrutinised. In a nutshell, the authors argue that process-based measures do affect the sale of products by, for example, affecting the price and quantity of the product sold; that examples in jurisprudence of the interpretation of the term 'affecting the … sale' in Article III show that this term should be interpreted broadly; and that a narrow reading adopted in *US-Tuna/Dolphin* is inconsistent with the basic structure of GATT because it lets non-product-related PPM-based measures, which are internally enforced and which do not constitute quantitative restrictions in the sense of Article XI of the GATT, totally escape review under GATT despite their potential to be protectionist. Finally, the authors rebut the assumption that the Appellate Body in *US-Shrimp/Turtle* had confirmed the interpretation of the Panels in *US-Tuna/Dolphin*. They show that rather the Appellate Body did not address the issue of whether process-based measures are to be reviewed under Article XI, not Article III, because it was not contested on appeal; and that they there were other reasons in that particular case, namely the fact that the contested measure was an import ban, for qualifying the US legislation as a quantitative restriction in the sense of Article XI. [120]

On the other hand, Howse and Regan analyse a range of policy arguments invoked against the legality of process-based measures, such as them being 'unilateral,' 'extraterritorial' or 'coercive' in nature. Drawing on the economic theory of externalities, the authors arrive at the conclusion that the rationales and effects of process-based measures do not systematically differ from those for product-based regulations. Whilst it would go beyond the scope of this paper to present their abundant analysis in detail, I shall, however, mention the authors' comment on the 'extraterritoriality' criticism of PPM-based measures, since this is commonly invoked as one of the main reasons for disapproving such measures. In a nutshell, the authors argue that the adoption of non-discriminatory process-based measures with the legitimate aim of, for example, protecting the environment, is an expression of the sovereignty of the enacting WTO member. Therefore, forbidding such measures *per se* would simply be a way of 'preferring the "unilateralism" of the producing state to that of the importing state.'[121]

Article III.4 of the GATT: national treatment

The consequence of the approach defended by the critics of the product/process distinction as such is that process-based measures need, as any product related regulatory measure, to undergo the non-discrimination test of Article III.4. It is argued that instead of focusing on the product/process distinction, it should be assessed, against the background of the National Treatment principle, whether products may be considered 'unlike' due to process-based differences. The analysis of process-based measures, therefore, would shift from the discussion of such measures under Article XI and their justifiability under Article XX of the GATT, to the question

[119] Howse and Regan, 'Product/Process Distinction,' *supra* note 41.

[120] See *ibid*, at 253-257.

[121] See *ibid*, at 251 and 275.

as to whether they amount to violations of the National Treatment principle under Article III.4 in the first place.[122]

If we consider potential EU measures on animal cloning, such an approach to PPMs might eventually grant the EU authorities a broader leeway in taking action on animal cloning for food supply, provided the measures to be adopted do not discriminate between products of EU origin and imported products. To restate the wording of Article III.4, it requires that imported products be treated *no less favourable* than *like products* of national origin. Consequently, when assessing measures on animal cloning it would first have to be established that food products from cloned animals are *like* products in relation to food products from conventionally bred animals.

The importance of the concept of 'like products' in WTO law corresponds to the uncertainty surrounding its meaning. In an oft-cited statement the Appellate Body has expressed the difficulties of defining 'like products' in the following metaphoric terms:

> 'The concept of "likeness" is a relative one that evokes the image of an accordion. The accordion of "likeness" stretches and squeezes in different places as different provisions of the WTO Agreement are applied. The width of the accordion in any one of those places must be determined by the particular provision in which the term "like" is encountered as well as by the context and the circumstances that prevail in any given case to which that provision may apply.'[123]

Despite the abundant WTO jurisprudence on the concept of 'likeness,' the exact meaning and parameters of the concept as its variations remain uncertain. This paper is not the appropriate place for addressing this difficult topic in detail.[124] The main 'likeness' criteria as used in the jurisprudence so far, should, nevertheless, be mentioned. Mainly, four criteria have established themselves in the jurisprudence as a reference to assessing the 'likeness' of products: the product's end-uses in a given market; consumers' tastes and habits, which change from country to country; the product's properties, nature and quality; and, the products' tariff classifications.[125] The Appellate Body report in *EC-Asbestos*[126] presents an important ruling with regard to the concept of 'likeness.' Maintaining the four common criteria mentioned above, the Appellate Body sophisticated the 'likeness' test by holding that all evidence relevant to a 'likeness' determination should be taken into account.[127] Moreover, the

---

[122] This could have considerable consequences for the outcome of the legal assessment. It should be noted that the list of exceptions in Article XX of the GATT is considered to be a closed one, and it does not include many public interests deemed important at domestic level, such as consumer protection. For a discussion of this issue with regard to GMOs see Scott, 'GMOs and the WTO,' *supra* note 92, at 230.

[123] Appellate Body Report, *Japan-Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 4 October 1996, section H.1.a (hereinafter *Japan-Alcohol*).

[124] See Howse and Tuerk, 'WTO Impact,' *supra* note 41; an overview of the case law in Bernasconi-Osterwalder *et al*., *Environment and Trade, supra* note 47, at 18.

[125] See Report of the Working Party, *Border Tax Adjustments*, L/3463, 2 February 1970 for the first three criteria and Panel Report, *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, L/6216 - 34S/83, adopted 10 November 1987 for adding the fourth one.

[126] Appellate Body Report, *EC-Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/AB/R, adopted 12 March 2001 (hereinafter *EC-Asbestos*).

[127] *Ibid*, paras. 101-103.

Appellate Body considered the health effects of a product (namely Asbestos) as being relevant for finding its 'unlikeness' with another product that does not produce similar effects. Although the analysis of the health effects was subsumed within the analysis of the existing four criteria, thereby, not creating an additional one, the Appellate Body did state that the list was not exhaustive. This statement is of particular importance for the question as to whether non-economic considerations, such as health, environmental or other policy concerns, might play a role in distinguishing between products. Yet, this is an unresolved issue, and economic considerations, in particular, the competitive relationship between and among domestic and imported products[128] still remains the dominant focus of the 'likeness' test.

Against the background of the cited criteria, it appears that an arguable way to consider food products from cloned animals as 'unlike' to food products from conventional animals would be by means of invoking the negative approach of EU citizens towards the former products, thus using the consumer's tastes and habits criteria. However, such an assessment would have to encompass all the evidence, i.e. also that related to the other three criteria, and to weigh all the information. The outcome of this is uncertain, especially seeing that both categories of products (for example milk from clones and milk from conventional animals) would most likely be in a direct competitive relationship once they are being placed on the EU market. Seeing the physical similarity between the two types of food products, the EU would have to provide convincing arguments, in particular stressing the non-protectionist purpose of its legislation, in order to defend that the PPM of animal cloning does considerably change the nature of the products, which are the result of the use of this new technology.[129]

Nevertheless, one should not forget the second step necessary for the examination as to whether a regulation violates the National Treatment principle under Article III.4 of the GATT, namely the assessment of the presence of a 'less favourable' treatment of imported products. This corresponds to the core idea of Article III.4 read in the light of the general principles expressed in Article III.1[130] that only those regulatory measures violate the GATT, which discriminate against imported 'like' products, thus, in reality being protectionist in nature. Interestingly, the Panel in the recent *EC-Biotech* report has, *en passant*, made some relevant statements in this regard. It responded to claims made by Argentina that EU biotech measures violated Article III.4, because they treated biotech products less favourably than non-biotech products, although both were 'like products.'[131] The Panel found, among other, that even if the EU treated biotech products less favourably than conventional products,

---

[128] *Ibid,* para. 99.

[129] For arguments in favor of such a defense see Howse and Regan, 'Product/Process Distinction,' *supra* n. 41, at 261 who argue that the term 'like' has to be viewed in the context of the regulatory policy pursued by the WTO member. To domestic regulators, such as in the EU, the use of a PPM, such an animal cloning, might well be a reason to consider a product as unlike despite of the physical similarities with other products (for example because of the moral and ethical concerns associated with it). 'Likeness' should therefore be viewed in the context of 'not differing in any respect relevant to an actual non-protectionist regulatory policy.' See also Donald Regan, 'Regulatory Purpose and "Like Products" in Article III.4 of the GATT (with Additional Remarks on Article III.2) in: Petros Mavroidis and George Bermann (eds), *Trade and Human Health and Safety*, (Cambridge University Press: Cambridge, New York, 2006).

[130] Article III.1, containing general principles, informs and provides context for the rest of Article III; see *Japan-Alcohol*, *supra* note 123, para. 96.

[131] *EC-Biotech*, *supra* note 1, para. 7.2493.

this would not suffice to demonstrate that less favourable treatment was accorded 'to the group of like *imported* products than to the group of like *domestic* products.' In so doing, the Panel expressed that a violation of the National Treatment principle requires that the difference in treatment had to be due to *foreign origin* of the products. In circumstances where this is not the case 'it is not self-evident that the alleged less favourable treatment of imported biotech products is explained by the foreign origin of these products rather than, for instance, a perceived difference between biotech products and non-biotech products in terms of their safety, etc.'[132]

The same line of argument could conceivably be adopted with regard to measures distinguishing between food products from cloned animals and those from conventionally bred animals: if the less favourable treatment of the first category is not related to the foreign origin of such products, then there is no discrimination, hence, no violation of the National Treatment obligation.

To sum up, the application of the GATT to possible future EU measures on animal cloning would present as complex an exercise as the application of the SPS Agreement to such measures. This is due to their nature as non-product related PPM-based measures, as well as the difficulties related to determining the 'likeness' concept under Article III.4 of the GATT. Nevertheless, the above account has showed that a defence of the EU measures under the general obligations of the GATT might offer the EU authorities more leeway than a defence under the SPS Agreement. Firstly, following the *US-Shrimp/Turtle* ruling, the EU would have the possibility to justify its measures under Article XX of the GATT. Secondly, if with the critics of the product/process distinction, one would consider the EU measures to be falling under the scope of Article III.4 of the GATT, further paths of reasoning would be open to the EU authorities in defending that their measures do not violate National Treatment in the first place. In particular, in the light of the findings in the *EC-Biotech* case, if EU regulation distinguishing between food from animal clones and food from conventional animals would not be based on foreign origin of the former category of products, but rather on their perceived difference in terms of their safety or ethical implications, it is likely not to be found to violate Article III.4 of the GATT.

Animal cloning and the TBT Agreement

Finally, also the requirements of the TBT Agreement could be applicable to future EU measures on animal cloning. As regards the relationship between this and the other WTO agreements,[133] it should be noted that the TBT Agreement would not be applicable, if the EU measures would be found to qualify as SPS measures in their entirety.[134] In case of a multi-purpose measure, for example aiming at the protection of not only food safety, but also animal welfare, environment or consumer preferences, the measure could be divided according to the purposes pursued, and be assessed under both the SPS and the TBT Agreement.[135] In contrast, the relationship between the TBT Agreement and the GATT is not entirely clear; in particular, there is no provision in the former that relates it to the latter. The jurisprudence did not apply the TBT Agreement as *lex specialis* to GATT. In particular, on the basis of the *Asbestos*

[132] *Ibid*.

[133] See Marceau & Trachtman, 'The Technical Barriers to Trade Agreement,' *supra* note 5.

[134] See Article 1.5 of the TBT Agreement.

[135] See *EC-Biotech*, *supra* note 1, para. 7.162-7.170. See on multi-purpose measures Gruszczynski, *Health and Environmental Risks, supra* note 76, at 66.

ruling of the Appellate Body it seems that the provisions of GATT and the TBT Agreement are concurrently applicable, the TBT Agreement imposing obligations, which are different from, and additional to, the GATT.[136]

The TBT Agreement applies both to voluntary standards and to mandatory technical regulations relating to all products, including industrial and agricultural products.[137] As a consequence, for future EU measures to be covered by the TBT Agreement, they must constitute 'technical regulations' as defined in Annex A of the agreement. Annex A.1 (1) defines a technical regulation as a 'document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory.' In its *Asbestos* ruling the Appellate Body further clarified the notion of a technical regulation by setting out three criteria, which a document must meet to fall under the definition of Annex A. First, the document must apply to an identifiable product or group of products. Second, the document must lay down one or more characteristics of the product. These product characteristics may be intrinsic or they may be related to the product. Third, compliance with the product characteristics must be mandatory.[138]

Would future EU measures foresee a labelling scheme for food products derived from animal cloning, such measures would undoubtedly qualify as technical regulations, and therefore, fall under the scope of application of the TBT Agreement.[139] In contrast, whether also EU legislation foreseeing a prior-authorisation procedure, such as currently envisaged in the Novel Foods amendment procedure, would constitute technical regulations is less clear.[140] To begin with, the eventual approval procedure for food derived from animal cloning, if established by the new Novel Foods Regulation, would be based on administrative provisions, which refer to process and production methods related to the product[141] (food from clones and/or from clone progeny). As can be seen from the definition of Annex A above, in contrast to the GATT, the TBT Agreement undoubtedly applies to PPM-based measures. Moreover, the approval procedure would be compulsory for the marketing of food products from animal cloning in the EC. Doubts could arise with regard to the requirement of a technical regulation to apply to a group of products, which is identifiable. Since there are no physical differences between food from cloned animals and their progeny on the one hand, and food from conventional animals on the other, one could wonder, whether the group of products (food from animal cloning) the future Novel Foods Regulation would regulate is, *de facto*, identifiable as novel foods; for example, whether milk derived from an animal clone would be identifiable as such. The requirement of the 'identifiable group of products' is related to the possibility of enforcement of a technical regulation.[142] However, this difficulty would be removed,

[136] See Scott, 'GMOs and the WTO,' *supra* note 92, at 229-230 and Howse and Tuerk, 'WTO Impact,' *supra* note 41.

[137] Article 1.3 of the TBT Agreement.

[138] See *EC-Asbestos*, *supra* note 126, para 67-70; See also a summary in Appellate Body report, *EC-Trade Description of Sardines*, WT/DS231/AB/R, adopted 26 September 2002, para 176.

[139] See Conrad, *Biotech Dispute, supra.* note 67, at 26

[140] See a comparable analysis, but in relation to GMOs, Conrad *ibid* at 21; see also Scott, 'GMOs and the WTO,' *supra* note 92.

[141] Here, with respect to technical regulations, the term 'related to the product' is understood wider than in the definition of 'product-related PPM-based' measures, where the PPM is directly detectable in the end product. See Bernasconi-Osterwalder *et al., Environment and Trade, supra* note 47, at 204.

[142] See *EC-Asbestos*, *supra* note 126, para. 70.

if a future approval procedure would be combined with provisions of traceability and labelling, which would make sure that food from cloned animals and/or their progeny is identifiable, thereby, making the Novel Foods Regulation enforceable in this respect.

It should be noted, that following the *Asbestos* ruling of the Appellate Body, also an isolated EU measure banning the placing on the market of food from animal cloning, is likely to be qualified as a technical regulation.[143]

Seeing that the applicability of the TBT Agreement to possible future EU measures on animal cloning is arguable, I shall briefly outline the most relevant obligations such measures would have to observe. This will help to compare the stringency of the 'test' they would have to stand under the TBT Agreement as compared to that under the agreements discussed in the previous parts of this paper; and, therefore, the scope left for regulatory autonomy under each of these agreements.[144]

At the outset it should be noted that the TBT Agreement, as compared to the GATT and the SPS Agreement, is recognised for being more generous in recognising values the importance of which overrides the importance of negative effects on trade.[145] The TBT Agreement places emphasis on the obligation of the members to ensure that their technical regulations do not create *unnecessary* obstacles to international trade, while recognising a broader range of policies that can legitimately be pursued through domestic technical regulations.[146] Thus, Article 2.2, 2nd sentence of the TBT Agreement states that in order to avoid unnecessary obstacles to international trade, 'technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create.' This provision does not establish a closed list of permissible policies. Rather, any 'legitimate' policy may be the basis for a TBT regulation. Furthermore, the TBT Agreement does not regulate risk assessments or require regulations be based on science. As Gabrielle Marceau and Joel Trachtman correctly note, '(w)hile necessity or proportionality or other standards applicable under the TBT Agreement or GATT may implicitly require some scientific basis, this implicit requirement can be expected to be significantly less rigorous than the explicit requirements of the SPS Agreement.'[147] As compared to the SPS Agreement, the TBT Agreement would, therefore, pose less rigorous requirements on future EU measures on animal cloning. The basic 'test' for the EU authorities would be to show that their non-discriminatory measures are necessary to fulfil a legitimate policy. As such legitimate objectives in the case of animal cloning are conceivable consumer protection, ethical concerns, public health or the environment.

[143] See Howse and Tuerk, 'WTO Impact,' supra note 41, at 306, who discuss the AB reasoning in rejecting the argument invoked by the respondent EC, and upheld by the Panel, namely that a ban of a product cannot be equated with a measure that specifies the product's characteristics.

[144] See such comparison with regard to the regulation of GMOs in Conrad, *Biotech Dispute*, *supra* note 67, at 25-27.

[145] Conrad *ibid*, at 26.

[146] See Preamble, 5th recital, of TBT Agreement; also Marceau and Trachtman, 'The Technical Barriers to Trade Agreement,' *supra* note 5, at 832.

[147] Marceau and Trachtman *ibid*, at 836.

Concluding remarks

This paper had the aim of outlining the main legal issues future EU regulation of animal cloning for food supply, as currently reflected upon, could possibly raise with regard to international trade law. In the first part of the paper, I have shown that there is an intense political and public debate at EU level about the appropriate policy approach towards this new way of producing food. Seeing that food products from cloned animals are likely to be placed on the market in the near future, and that the main producers will probably be those outside of the EU (above all in the US), the imports of such products into the European market may soon become a reality. Since there is currently no EU legislation specifically regulating food from animal clones, the enactment of such legal instruments is contemplated. The main concerns identified with regard to the use of animal cloning in food production are animal health and welfare (due to suffering of the clones and surrogate mothers) and ethical concerns (related to the suffering of animals, but also to dangers of a 'slippery slope' toward the cloning of humans, or fear of treating animals like commodities). Risks to human health and the environment can currently not be identified, but scientific research is insufficient and surrounded by uncertainties at the present stage. While the European Parliament is demanding a total ban on the use of animal cloning in food supply, which would also extend to the import of related products, the most probable short-term legislative measure seems to be the establishment of a prior-authorisation procedure for food derived from animal clones and/or from their progeny under the Novel Foods Regulation. The developments at EU level indicate that future regulatory measures are likely to have a restrictive effect on the imports of food from animal cloning from third countries, thereby, affecting international trade.

The following presentation of legal issues of WTO law has revealed the importance of delimiting the scopes of application of the three WTO agreements, the GATT, the SPS Agreement, and the TBT Agreement. The results of a future WTO 'test' EU regulation on animal cloning would have to withstand will vary significantly depending on which of these agreements will be considered to be applicable. With regard to the SPS Agreement the main legal query relates to the notion of an SPS measure, which is decisive to declare this agreement applicable. Because of the factual and legal similarities between the discussion on animal cloning and the recent transatlantic dispute in the *EC-Biotech* case, the findings of the Panel in the latter case are deemed to be of crucial importance for the currently ongoing EU policy process. The Panel has considerably extended the definition of an SPS measure laid down in Annex A.1 of the SPS Agreement declaring it to apply to regulatory measures seeking to protect public, animal and plant health not only against traditional sanitary and phytosanitary risks, but also against long-term and uncertain risks as commonly associated with the use of new technologies. In the light of this Panel report, future EU measures on animal cloning, such as an amended Novel Foods Regulation, are likely to fall under the scope of the SPS Agreement, and as a result, to be submitted to its rigorous discipline of science-based rationality. This seems especially problematic seeing that the scientific evaluation of risks related to food from cloned animals is surrounded by scientific uncertainty. At the same time the possibility for the EU to adopt precautionary measures as a reaction to this situation under Article 5.7 of the Agreement is rather limited because of the strict interpretation of the requirement of insufficient scientific evidence under that provision in the WTO jurisprudence. It seems, therefore, that future EU measures on animal cloning would have little chance of being defended under the discipline of the SPS Agreement.

The scope of this paper does not leave much space to appropriately comment on the *EC-Biotech* report. I shall content with noting that the broad interpretation of an SPS measure adopted by the Panel is prone to criticism from several perspectives (history of the negotiation of the SPS Agreement, its purpose, the intrusiveness of its broad interpretation on internal decision-making).[148] The applicability of the SPS Agreement to domestic measures regulating newly emerging technologies, such as GMOs, nanotechnology, or animal cloning, raises particular concerns. To state with Christiane Conrad, '(o)ne main concern with the SPS Agreement is that the emphasis on scientific justification might curtail the ability of WTO members to protect their citizens in case of scientific uncertainty.'[149] Because of scientific uncertainty typically surrounding new technologies as well as the relevance of ethical and socio-economic concerns associated with them, the Panel's extensive interpretation does, in fact, appear as problematic.

Finally, I have shown that the requirements with which future EU measures on animal cloning would have to comply under the GATT and the TBT Agreement would show a less intrusive effect on EU's policy choice. Under the GATT difficult issues would arise seeing the PPM nature of animal cloning. However, with regard to the PPM discussion several lines of argument would be open to EU authorities to defend their measures in the light of WTO law. In particular, there are convincing arguments presented in the relevant legal literature, which speak in favour of treating PPM-based measures under Article III.4 of the GATT with the consequence that as long as internal regulations are origin-neutral and applied in a non-discriminatory way they are not violating the National Treatment principle of Article III of the GATT.

Also the TBT Agreement shows more deference to internal regulation in the area of food safety and public health, since it is seen as more generous in recognising different legitimate domestic policies, and does not require domestic measures be based on risk assessment.

However, the applicability of the GATT or the TBT Agreement to EU measures on animal cloning strongly depends on the definition of the scope of application of the SPS Agreement adopted in future dispute settlement. It should be stressed that once future EU measures would be considered as SPS measures, ie as measures aiming at the protection of human or animal health against the specific risks enumerated in Annex A.1. of the SPS Agreement, they would have to comply with the strict scientific requirements of that Agreement. As a consequence, the applicability of the TBT Agreement would be precluded. Although the applicability of the SPS Agreement would not also exclude the application of the GATT to EU measures on animal cloning, in practice the GATT regime would not be of much relevance for the outcome of the dispute. In the past, once a measure was found to be incompatible with the SPS Agreement, panels, relying on the principle of judicial economy, did not continue the examination under GATT. This stresses the importance of a clear delineation between the scopes of applicability of the three WTO Agreements. Once the SPS Agreement is found to be applicable to a disputed measure, it also constitutes the decisive WTO 'test.'

[148] For extensive discussion of these issues see Conrad, *Biotech Dispute, supra* note 67.

[149] Conrad *ibid.*

To conclude, this paper has shown that several complex legal problems of international trade law could arise in the future with regard to EU's regulation of animal cloning for food supply. It did not aim at discussing these problems in detail, but rather at presenting an outlook of what could be the relevant legal aspects in the future. The main conclusion following from the above examination is that any legal assessment of domestic regulations, which pursue legitimate objectives of public health, consumer, or environmental protection, against the background of WTO law has to pay particular attention to the delineation between the scopes of application of different trade agreements. As has been shown, the extent to which internal regulators enjoy autonomy in pursuing their policy choices depends considerably on the decision on which of the WTO trade agreements applies to the regulatory activity in question. In the case of animal cloning, the application of the SPS Agreement to future EU regulation in this area would show the least deference to EU's regulatory choice. This appears problematic seeing that strong criticism is voiced against the extensive interpretation of the concept of an SPS measure, as undertaken by the Panel in *EC-Biotech;* and that doubts persist as to whether potential risks related to animal cloning can, in fact, be characterised as sanitary and phytosanitary risks.

RECON Online Working Papers

2010/29
Maria Weimer
Policy Choice versus Science in Regulating Animal Cloning under the WTO Law

2010/28
Stefan Collignon
Fiscal Policy Rules and the Sustainability of Public Debt in Europe

2010/27
Cathrine Holst
Martha Nussbaum's Outcome-oriented Theory of Justice
Philosophical comments

2010/26
Waltraud Schelkle, Joan Costa-i-Font and Christa van Wijnbergen
Consumer Choice, Welfare Reform and Participation in Europe
A Framework for Analysis

2010/25
John Erik Fossum and Agustín José Menéndez
The Theory of Constitutional Synthesis
A Constitutional Theory for a Democratic European Union

2010/24
Raúl Letelier
Non-Contractual Liability for Breaches of EU Law
The Tension Between Corrective and Distributive Justice?

2010/23
Sara Clavero and Yvonne Galligan
Gender Equality in the European Union
Lessons for Democracy?

2010/22
Pieter de Wilde, Hans-Jörg Trenz and Asimina Michailidou
Contesting EU Legitimacy
The Prominence, Content and Justification of Euroscepticism During 2009 EP Election Campaigns

2010/21
Rainer Nickel
Data Mining and 'Renegade' Aircrafts
The States as Agents of a Global Militant Security Governance Network – The German Example

2010/20
David G. Mayes and Zaidah Mustaffa
Social Models in the Enlarged EU

2010/19
Tess Altman and Chris Shore
Social Welfare and Democracy in Europe
What Role for the Private and Voluntary Sectors?

2010/18
Aleksandra Maatsch
Between an Intergovernmental and a Polycentric European Union
National Parliamentary Discourses on Democracy in the EU Ratification Process

2010/17
Erik O. Eriksen and John Erik Fossum
Bringing European Democracy back in
Or how to Read the German Constitutional Court's Lisbon Treaty Ruling?

2010/16
Jean L. Cohen
Constitutionalism Beyond the State
Myth or Necessity?

2010/15
Rainer Forst
Two Stories about Toleration

2010/14
Zdenka Mansfeldová and Petra Rakušanová Guasti
The Quality of Democracy in the Czech Republic

2010/13
Emmanuel Sigalas, Monika Mokre, Johannes Pollak, Peter Slominski and Jozef Bátora
Democracy Models and Parties at the EU Level
Empirical Evidence from the Adoption of the 2009 European Election Manifestoes

2010/12
Antje Wiener and Uwe Puetter
Informal Elite Dialogue and Democratic Control in EU Foreign and Security Policy

2010/11
Erik Oddvar Eriksen
European Transformation
A Pragmatist Approach

2010/10
Justus Schönlau
The Committee of the Regions
The RECON Models from a Subnational Perspective

2010/09
Asimina Michailidou and Hans-Jörg Trenz
2009 European Parliamentary Elections on the Web
A Mediatization Perspective

2010/08
Kolja Möller
European Governmentality or Decentralised Network Governance?
The Case of the European Employment Strategy

2010/07
Kjartan Koch Mikalsen
In Defence of Kant's League of States

2010/06
Nora Schleicher
Gender Identity in a Democratic Europe

2010/05
Christian Joerges
The Idea of a Three-Dimensional Conflicts Law as Constitutional Form

2010/04
Meltem Müftüler-Baç and Nora Fisher Onar
Women's Rights in Turkey as Gauge of its European Vocation
The Impact of 'EU-niversal Values'

2010/03
Neil Walker
Constitutionalism and Pluralism in Global Context

2010/02
Dominika Biegoń
European Identity Constructions in Public Debates on Wars and Military Interventions

2010/01
Federica Bicchi and Caterina Carta
The COREU/CORTESY Network and the Circulation of Information within EU Foreign Policy

2009/19
Rachel Herp Tausendfreund
The Commission and its Principals
Delegation Theory on a Common European External Trade Policy in the WTO

2009/18
Marianne Riddervold
Making a Common Foreign Policy
EU Coordination in the ILO

2009/17
Uwe Puetter and Antje Wiener
EU Foreign Policy Elites and Fundamental Norms
Implications for Governance

2009/16
Emmanuel Sigalas, Monika Mokre, Johannes Pollak, Jozef Bátora and Peter Slominski
Reconstituting Political Representation in the EU
The Analytical Framework and the Operationalisation of the RECON Models

2009/15
Meltem Müftüler-Baç and Yaprak Gürsoy
Is There an Europeanisation of Turkish Foreign Policy?
An Addendum to the Literature on EU Candidates

2009/14
Maria Weimer
Applying Precaution in Community Authorisation of Genetically Modified Products
Challenges and Suggestions for Reform

2009/13
Dionysia Tamvaki
Using Eurobarometer Data on Voter Participation in the 2004 European Elections to Test the RECON Models

2009/12
Arndt Wonka and Berthold Rittberger
How Independent are EU Agencies?

2009/11
Tanja Hitzel-Cassagnes and Rainer Schmalz-Bruns
Recognition and Political Theory:
Paradoxes and Conceptual Challenges of the Politics of Recognition

2009/10
Hans-Jörg Trenz and Pieter de Wilde
Denouncing European Integration
Euroscepticism as Reactive Identity Formation

2009/09
Pieter de Wilde
Designing Politicization
How Control Mechanisms in National Parliaments Affect Parliamentary Debates in EU Policy-Formulation

2009/08
Erik Oddvar Eriksen
Explicating Social Action
Arguing or Bargaining?

2009/07
Hans-Jörg Trenz, Nadine Bernhard and Erik Jentges
Civil Society and EU Constitution-Making
Towards a European Social Constituency?

2009/06
Kjartan Koch Mikalsen
Regional Federalisation with a Cosmopolitan Intent

2009/05
Agustín José Menéndez
European Citizenship after *Martínez Sala* and *Bambaust*
Has European Law Become More Human but Less Social?

2009/04
Giandomenico Majone
The 'Referendum Threat', the Rationally Ignorant Voter, and the Political Culture of the EU

2009/03
Johannes Pollak, Jozef Bátora, Monika Mokre, Emmanuel Sigalas and Peter Slominski
On Political Representation
Myths and Challenges

2009/02
Hans-Jörg Trenz
In Search of Popular Subjectness
Identity Formation, Constitution-Making and the Democratic Consolidation of the EU

2009/01
Pieter de Wilde
Reasserting the Nation State
The Trajectory of Euroscepticism in the Netherlands 1992-2005

2008/20
Anne Elizabeth Stie
Decision-Making Void of Democratic Qualities?
An Evaluation of the EU's Foreign and Security Policy

2008/19
Cathleen Kantner, Amelie Kutter and Swantje Renfordt
The Perception of the EU as an Emerging Security Actor in Media Debates on Humanitarian and Military Interventions (1990-2006)

2008/18
Cathrine Holst
Gender Justice in the European Union
The Normative Subtext of Methodological choices

2008/17
Yaprak Gürsoy and Meltem Müftüler-Baç
The European Union's Enlargement Process and the Collective Identity Formation in Turkey
The Interplay of Multiple Identities

2008/16
Yvonne Galligan and Sara Clavero
Assessing Gender Democracy in the European Union
A Methodological Framework

2008/15
Agustín José Menéndez
Reconstituting Democratic Taxation in Europe
The Conceptual Framework

2008/14
Zdzisław Mach and Grzegorz Pożarlik
Collective Identity Formation in the Process of EU Enlargement
Defeating the Inclusive Paradigm of a European Democracy?

2008/13
Pieter de Wilde
Media Coverage and National Parliaments in EU Policy-Formulation
Debates on the EU Budget in the Netherlands 1992-2005

2008/12
Daniel Gaus
Legitimate Political Rule Without a State?
An Analysis of Joseph H. H. Weiler's Justification of the Legitimacy of the European Union Qua Non-Statehood

2008/11
Christopher Lord
Some Indicators of the Democratic Performance of the European Union and How They Might Relate to the RECON Models

2008/10
Nicole Deitelhof
Deliberating ESDP
European Foreign Policy and the International Criminal Court

2008/09
Marianne Riddervold
Interests or Principles?
EU Foreign Policy in the ILO

2008/08
Ben Crum
The EU Constitutional Process
A Failure of Political Representation?

2008/07
Hans-Jörg Trenz
In Search of the European Public Sphere
Between Normative Overstretch and Empirical Disenchantment

2008/06
Christian Joerges and Florian Rödl
On the "Social Deficit" of the European Integration Project and its Perpetuation Through the ECJ Judgements in *Viking* and *Laval*

2008/05
Yvonne Galligan and Sara Clavero
Reserching Gender Democracy in the European Union
Challenges and Prospects

2008/04
Thomas Risse and Jana Katharina Grabowsky
European Identity Formation in the Public Sphere and in Foreign Policy

2008/03
Jens Steffek
Public Accountability and the Public Sphere of International Governance

2008/02
Christoph Haug
Public Spheres within Movements
Challenging the (Re)search for a European Public Sphere

2008/01
James Caporaso and Sidney Tarrow
Polanyi in Brussels
European Institutions and the Embedding of Markets in Society

2007/19
Helene Sjursen
Integration Without Democracy?
Three Conceptions of European Security Policy in Transformation

2007/18
Anne Elizabeth Stie
Assessing Democratic Legitimacy From a Deliberative Perspective
An Analytical Framework for Evaluating the EU's Second Pillar Decision-Making System

2007/17
Swantje Renfordt
Do Europeans Speak With One Another in Time of War?
Results of a Media Analysis on the 2003 Iraq War

2007/16
Erik Oddvar Eriksen and John Erik Fossum
A Done Deal? The EU's Legitimacy Conundrum Revisited

2007/15
Helene Sjursen
Enlargement in Perspective
The EU's Quest for Identity

2007/14
Stefan Collignon
Theoretical Models of Fiscal Policies in the Euroland
The Lisbon Strategy, Macroeconomic Stability and the Dilemma of Governance with Governments

2007/13
Agustín José Menéndez
The European Democratic Challenge

2007/12
Hans-Jörg Trenz
Measuring Europeanisation of Public Communication
The Question of Standards

2007/11
Hans-Jörg Trenz, Maximilian Conrad and Guri Rosén
The Interpretative Moment of European Journalism
The Impact of Newspaper Opinion Making in the Ratification Process

2007/10
Wolfgang Wagner
The Democratic Deficit in the EU's Security and Defense Policy – Why Bother?

2007/09
Helene Sjursen
'Doing Good' in the World?
Reconsidering the Basis of the Research Agenda on the EU's Foreign and Security Policy

2007/08
Dawid Friedrich
Old Wine in New Bottles?
The Actual and Potential Contribution of Civil Society Organisations to Democratic Governance in Europe

2007/07
Thorsten Hüller
Adversary or 'Depoliticized' Institution?
Democratizing the Constitutional Convention

2007/06
Christoph Meyer
The Constitutional Treaty Debates as Revelatory Mechanisms
Insights for Public Sphere Research and Re-Launch Attempts

2007/05
Neil Walker
Taking Constitutionalism Beyond the State

2007/04
John Erik Fossum
Constitutional Patriotism
Canada and the European Union

2007/03
Christian Joerges
Conflict of Laws as Constitutional Form
Reflections on International Trade Law and the *Biotech* Panel Report

2007/02
James Bohman
Democratizing the Transnational Polity
The European Union and the Presuppositions of Democracy

2007/01
Erik O. Eriksen and John Erik Fossum
Europe in Transformation
How to Reconstitute Democracy?

Reconstituting Democracy in Europe (RECON)

RECON seeks to clarify whether democracy is possible under conditions of complexity, pluralism and multilevel governance. Three models for reconstituting democracy in Europe are delineated and assessed: (i) reframing the EU as a functional regime and reconstituting democracy at the national level; (ii) establishing the EU as a multi-national federal state; or (iii) developing a post-national Union with an explicit cosmopolitan imprint.

RECON is an Integrated Project financed by the European Commission's Sixth Framework Programme for Research, Priority 7 – Citizens and Governance in a Knowledge-based Society. Project No.: CIT4-CT-2006-028698.

Coordinator: ARENA – Centre for European Studies, University of Oslo.

Project website: www.reconproject.eu

RECON Online Working Paper Series

The Working Paper Series publishes work from all the researchers involved in the RECON project, but it is also open to submissions from other researchers working within the fields covered by RECON. The topics of the series correspond to the research focus of RECON's work packages. RECON Online Working Papers are widely circulated and included in online social science databases. Contact: admin@reconproject.eu.