HEALTHY INSTITUTIONS: TECHNOCRACY,
DEMOCRACY, AND LEGITIMACY IN EU GMO REGULATION

A THESIS APPROVED FOR THE
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Abstract

As a result of several food and chemical-related public health scares as well as strong activism by environmental organization such as Greenpeace, longstanding majorities of EU citizens support restrictions on the authorization and use of GMOs for human and animal consumption in the European Union. Given the EU's ongoing Democratic Deficit and the deepening crisis of faith in recent years in European institutions, the European Commission under the leadership of Jean-Claude Juncker has been attempting to respond to these public desires with a series of proposed regulatory reforms.

However, Juncker's policy proposals pose an enormous quandary for European Institutions for several reasons. Namely, they contravene rulings by both the European Court of Justice and the World Trade Organization and threaten the integrity of the European Single Market and the vitality of European economic competitiveness; further, when placed in the context of long-term regulatory changes in the EU, they threaten to reduce the role of scientific expertise in policymaking decisions, with implications for European technological and scientific leadership.

Several key questions arise from the current predicament regarding GMO Regulations in Europe, and which this thesis will attempt to address. First, how did the history of European food and GM regulation lead to this current impasse and how does it frame the current debate? Second, what are the arguments in favor of the reforms proposed by the Juncker Commission? Third, what are the primary arguments against these reforms? This research will show that there is strong evidence both for and against the reforms. In light of this evidence, this thesis will provide tentative answers to a final question: what should European institutions do about the GMO question, and are there possible resolutions to this dilemma?

To answer the questions, after situating the situation in the institutional history of food and GMO regulations, this work will take the following course: first, it will detail the regulatory history and comitological rules that create one element of the dilemma, and the proposed reforms that would resolve the dilemma. Second, it will analyze the nature of Europe's democratic deficit and ongoing populist legitimacy crisis as informed by the political philosophies of Jürgen Habermas. Then, it will explain the institutional and structural constraints such as European law and World Trade Organization rulings that pose an enormous quandary for the proponents of Juncker's reforms and show that Schumpeter's elaboration of the Public Choice Dilemma is at work. Ultimately, the broad strokes of the regulatory status quo should be preserved, but several specific points can be reformed in more democratic ways. This investigation draws implications for the intersection of public opinion, regulation, and science policy in the EU and throughout Western democracies, and finds that science and democracy should and do occupy separate spheres.

Keywords: European Union; GMOs; Technocracy; Health and Safety Regulation; Limits of Democracy; Scientific Community; Precautionary Principle; Technology Assessment; Biotechnology.

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Introduction

Science and technology have long been key drivers of global economic, social, and political relationships. From gunpowder and the telescope to evolutionary theory and nuclear technology, scientific changes have often entailed enormous upheavals that bring the promise of greater human prosperity while threatening the established social, political and cultural order. Political leaders, regulatory bodies, and the people they serve must, when confronted with new advances, grapple with questions of societal good, cost-benefit analyses, and market dynamics. In an organization as complex and influential as the European Union, this process of regulating new technologies is a long and circuitous one, involving several institutions and governing bodies, sometimes failing to deliver policies that are in line with popular opinion. In recent decades, however, the European Union has been adopting regulatory processes that are more responsive to public desires and employ more democratically legitimate decisionmaking structures. Though these changes have been transpiring across many European regulatory fields, one particularly contentious and salient test case for such reforms is the topic of Genetically Modified Organisms (GMOs).

As a result of several food and chemical-related public health scares as well as strong activism by environmental organization such as Greenpeace, longstanding majorities of EU citizens support restrictions on the authorization and use of GMOs for human and animal consumption in the European Union. Given the EU's ongoing Democratic Deficit and the deepening crisis of faith in recent years in European institutions, the European Commission under the leadership of Jean-Claude Juncker has been making an effort to respond to these public desires with a series of proposed regulatory reforms.

The Juncker Commission has made two main reform proposals. First, in 2015, the Commission proposed legislation that would have allowed member states to prevent products

containing ingredients of GMO origin to be sold on their territories. Second, after failing to receive traction on the "GMO ban," in 2017 the Commission proposed a reform to regulatory committee procedure, backed by anti-GMO advocacy groups, which would allow committee deadlocks (that have resulted in the approval of new strains of genetically modified organisms) to be resolved in the favor of the EU Member States who oppose the approval. Upon again not receiving sufficient support for this proposal, the Commission, and Commission President Juncker himself, have continued to agitate for ways to restrict the continued approval and sale of GMO products in Member States whose governments and populations are generally opposed to such products. These efforts on behalf of the Commission do seem to represent a genuine desire on the part of the Juncker administration to respond to public pressures and introduce more transparency and democracy into the regulation of GM technologies.

However, Juncker's policy proposals pose an enormous quandary for European Institutions for several reasons. Namely, they directly contravene rulings by both the European Court of Justice and the World Trade Organization and threaten the integrity of the European Single Market and the vitality of European economic competitiveness; further, they threaten to sideline scientific expertise in making decisions with implications for public health.

In the first case, the European Court of Justice has repeatedly upheld the core EU principle of the Single Market – the idea that all goods that can be legally sold in one EU country can be sold across the EU without institutional trade barriers of any kind, be they tariff or non-tariff in origin.[1] This idea of the Single Market is of such importance to the integrity of the European Union that its principles are known as the Four Freedoms – free movement of services, people, capital, and goods – that form the bedrock of European integration and jurisprudence. As such, the idea

[1] "Judgment of the Court of 20 February 1979," EUR-Lex, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61978CJ0120 .

that some Member States might be granted the authority to prevent the sale of GM products that are the legal products of other Member States would be deleterious to the integrity of the Single Market and European law – regardless of the level of popular support that such a policy might achieve (the exception regarding Health and Safety is discussed in chapter IV) .

In the second case, the European Union, as a member of the World Trade Organization, enjoys treaty-regulated access to the markets of other WTO members in return for its own commitment to the elimination of trade barriers to their products. Though the EU has sought in the past to use public health and popular opinion as rationale for stringent GMO regulatory policies, the WTO arbitration body has ruled against the EU for, in the WTO opinion, a de-facto moratorium on the approval of GM products, which effectively constitute a trade barrier against the GM products of other countries.[2] Once more, applying greater restrictions on GMOs, though in keeping with popular opinion and the expressed desires of democratically-elected governments, would contravene international WTO rulings and result in significant difficulties for EU trade growth, particularly in its ongoing trade negotiations with the United States.

Further, related to the issue of the WTO and trade, GM technology and biotechnologies as a whole are a rapidly growing industry that attracts billions of dollars in international investment; as a possible result of the EU's skeptical attitude toward many GM-related biotechnologies, the EU is falling significantly behind China and the United States in biotechnology investment; further, those EU countries that have adopted more GM-friendly stances have received disproportionate shares of the biotech advancement and investment that does occur in Europe. Thus, while European consumers may be seeking to secure a certain conception of their own best

[2] "Dispute Settlement DS292: European Communities — Measures Affecting the Approval and Marketing of Biotech Products," World Trade Organization, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds292_e.htm

interests through regulating or eliminating GMOs, they may be doing so through policies and attitudes that are injurious in other regards.

Finally, though more abstractly, such policies and procedures as proposed by the Juncker Commission and supported by members of the Anti-GMO coalition form part of a growing trend in European regulation that seeks to prioritize popular sentiment about scientific concepts over consensus within the scientific community, and dilutes the role of subject matter experts. In 2017 article that excoriates EU GMO regulatory policy, Giovanni Tagliabue draws attention to the patchwork nature of European GMO regulations, and the paradoxes inherent in the status quo: a restrictive regulatory framework on GMO cultivation but relatively unrestricted imports of genetically modified organisms for animal feed; the commonplace prohibitions on protection against cultivation, juxtaposed with the European Parliament's 2015 rejection of Commission-proposed prohibitions on importation on grounds of damage to the common market; perhaps most importantly the labelling of "genetic modification" as a new and risky technology while the products of the most invasive and scientifically corporatized breeding and hybridization programs and monocropping can be considered relatively "natural." Tagliabue remarks that "This dynamics [sic] may be seen as an ongoing 'Schumpeterian' chain of public choices: the calculus of consent drives politicians more than a science-based approach to law-making."[3]

Tagliabue thus raises a vital and important point regarding the nature of regulatory behavior: to what extent should policymakers respond to the "calculus of consent" over a "science-based approach" to regulation?[4] As further sections shall discuss, a Public Choice dilemma occurs when there is significant divergence of opinion between the desires of the public and the

[3] Tagliabue, Giovanni, "The EU Legislation on 'GMOs' between nonsense and protectionism: An ongoing Schumpeterian chain of public choices," *GM Crops Food*, (2017): 57-73.
[4] Idem.

preferences of subject matter experts and policy makers. Though the dangers of technocracy and elitism must be kept in mind, anti-expert populism comes with its own downsides as well, and thus the narrow regulatory issue of GMOs has implications that have become all the more relevant in the current age of populist sentiment throughout the West.

Together, these strands constitute a major dilemma: between institutionally, legally, and economically constrained policy on the one hand, and popular democratic desires on the other – a situation that, as Tagliabue points out, qualifies as a Schumpeterian Public Choice Dilemma. Though the discursive and regulatory philosophies of Jürgen Habermas offer several suggestions to resolve these conflicts in the direction of democracy, transparency, and legitimacy, the school of Schumpeterian Public Choice theory offers rebuttals, arguing for an embrace of technocratic expert consensus over the preferences of the people who have little expertise in the subjects under discussion or the consequences of proposed policies. Ultimately, the package of reforms proposed by President Juncker would be harmful if passed in their current forms, but, further, the conflict between popular preferences and institutional and economic realities calls into question several assumptions about the relationship between the body politic and "elite" decisionmakers, and has much broader resonance in this new age of populist iconoclasm.

Research Questions and Scope of Work

Several key questions arise from the current predicament regarding GMO Regulations in Europe, and which this thesis will attempt to address. First, how did the history of European food and GM regulation lead to this current regulatory impasse and how does it frame the current debate? Second, what are the arguments in favor of the reforms proposed by the Juncker Commission? Third, what are the primary arguments against these reforms? This research will

show that there are strong arguments both for and against the reforms. In light of this evidence, this thesis will touch on a final question: what should European institutions do about the GMO question, and are there possible resolutions to this dilemma?

The answers to these questions are informed by the philosophical outlooks of Jürgen Habermas on the one hand and Joseph Schumpeter on the other. Habermas argues for increasing democratization and transparency of European regulatory processes to ward off the growing democratic deficit and legitimacy crisis in the Union; Schumpeter, in contrast, argued against over-democratization of policymaking, seeking instead to follow the consensus of experts that would avoid the pitfalls of populism. How this conflict between public opinion and attainable policy goals plays out may, in the end, have significant consequences for the structure of both European liberal democracy and the global economy more broadly, for what public pressure demands is significantly out of step with what is attainable given current international structures.

To answer the questions, after situating the current debate in the institutional history of food and GMO regulations, this work will take the following course: first, it will detail the regulatory history and comitological rules that have led to the dilemma and the proposed reforms that would resolve the dilemma of whether to allow increased barriers to GMOs in the EU. Second, it will analyze the nature of Europe's democratic deficit and ongoing populist legitimacy crisis as informed by Habermas's proposals. Then, it will explain the institutional and structural constraints such as European Law and World Trade Organization rulings that pose an enormous quandary for the proponents of Juncker and Habermas, and show that Schumpeter's elaboration of the Public Choice Dilemma is certainly at work in this situation.

The research does not investigate the nature of the ideological divide regarding GMOs in the European Union, nor does it attempt to weigh in on the veracity or truth-claims of GMO

proponents or opponents. Suffice it to say, there are strong arguments that should be carefully considered on all sides of the debate. Rather, this investigation will take it as sufficient to demonstrate that there is a substantial difference between public opinion on the one hand and the scientific community more generally. This difference, combined with the structural problems of EU law and international agreement, constitute the corpus of this dilemma, regardless of who (if anyone) is "right."

Chapter I: The History and Challenges of European GMO Regulation

Science and Regulation in the EU

The European Commission, originally known as the Commission of the European Communities, was forged in 1968 from the European Coal and Steel Community, Commission of the European Economic Community, and Commission of the European Atomic Energy Community. With the advent of the European Commission, EU governance bodies succeeded in a centralization of European research direction and funding under its authority. The 1992 ratification of the Maastricht Treaty, which came into force in 1994 heralding the official beginning of the European Union, created numerous institutions that drastically changed the course of EU science policy. First, the Maastricht Treaty Enshrined the precautionary principle (discussed below) as the regulatory standard.[5]

The 2000 Lisbon Agenda brought even greater changes. "The 2000 Lisbon Agenda announced the EU's strategy to facilitate Europe's transition into a full-fledged and efficient 'knowledge-based society' by 2010. Science, not surprisingly, is portrayed as central to achieving this vision." [6] The Lisbon Agenda was externally focused and geared toward economic competitiveness. Surrounding this strategy was a proliferation of new scientific institutions including the European Research Area (renamed European Research Area Board in 2001), the reaction to Commissioner for Research Philippe Busquin's lament of the EU's still-fragmented research agendas and networks, as well as the 2007 European Research Council.[7]

As part of a greater push toward scientific competitiveness, in 2011, Commission President Jose Emmanuel Barroso appointed Professor Anne Glover as Chief Science Advisor (in

[5] Barbara Berthoud, "The Precautionary Principle in EU Risk Regulation: A Matter of Priorities," (Anchor Academic Publishing, 2014).
[6] Anwar Tlili and Emily Dawson, "Mediating Science and Society in the EU and UK: From Information-Transmission to Deliberative Democracy?" *Minerva* 48, no 4 (2010): 436.
[7] Robert Koenig, "Research Chief Wants to Make Science Matter," *Science Magazine* 286, no. 10 (December 1999).

accordance with his 2009 declaration of intention to do so). The position was created to "provide [the president] high-level and independent scientific advice throughout all stages of policy development and delivery. The Chief Scientific Advisor will provide advice directly to the President and will give regular updates on major scientific and technological developments.[8] Throughout her tenure, Professor Glover was an outspoken proponent of the cultivation and advancement of genetically modified foods and related technologies. However, this overt advocacy was not without political consequences.

The Policies of Jean Claude Juncker, in stark contrast to those of Barroso, tend to take a very different tone regarding the scientific community and its role in EU policymaking. Soon after taking office, in November 2014 Juncker abolished the position of science advisor, firing Professor Glover. In the May 2015 "Better Regulation" communication, the Juncker administration responded to member states who decried the Commission's regulatory overreach by prioritizing member state input and devolving some comitological procedures.[9] The official announcement declared that "Political priorities drive Commission action on the challenges that the EU faces today. Better regulation is a tool to provide a basis for timely and sound policy decisions - but it can never replace political decisions,"[10] stating in no uncertain terms that politics would be the ultimate rationale for regulatory decisions.

Though the initiation of the Better Regulation initiative has far larger implications for the future of EU regulatory decisionmaking, the abolition of the post of EC Science Advisor stirred the greater controversy. In dismissing Professor Glover, signs indicate that the Juncker

[8] "Appointment of Chief Scientific Advisor," EU Commission Press Release (December 5, 2011), http://europa.eu/rapid/press-release_IP-11-1497_en.htm
[9] "Better regulation for better results - An EU agenda," European Commission, ec.europa.eu/smart-regulation/better_regulation/documents/com_2015_215_en.pdf
[10] Ibid.

administration was heeding the calls of a coalition of environmental groups, the most notable being Greenpeace, who called for the dismissal of Anne Glover and abolition of the position on grounds of the role's "intransparency" as well as outrage at the fact that Glover had given "one-sided, partial opinions in the debate on the use of genetically modified organisms."[11] The dismissal earned a vociferous rebuke from members of the science community. As a Telegraph article highlights following the dismissal, "'It's a sad day for science, policy, politics and the public in Europe,' said Professor Colin Blakemore and the University of London," [sic], a view that the article concatenates with similar opinions from a variety of viewpoints, including the representative of the World Health Organization to the EU.[12] However, the dismissal was not based on expert difference on the matter; rather, "As the former prime minister of Luxembourg, a country that along with France, Austria, Greece and Hungary, that has banned, and is opposed, to the use of GM crops on political grounds, Mr. Juncker's personal views are well known. On taking the post as commission president… Mr Juncker has announced plans to review EU rules on authorising biotechnology in order to allow countries to ban their use."[13]

A Fragmented Regulatory Regime

GMO policy in the EU is fractured. Only six of the currently 28 member states cultivate GMOs on their territory.[14] The majority of this cultivation is concentrated in Spain and Portugal (Spain has the largest number of companies active in biotechnology in the OECD – 2,981 in

[11] "The position of Chief Scientific Advisor to the President of the European Commission," Greenpeace, http://www.greenpeace.org/eu-unit/Global/eu-unit/reports-briefings/2014/20140722%20NGO%20letter%20on%20EU%20chief%20scientific%20adviser.pdf

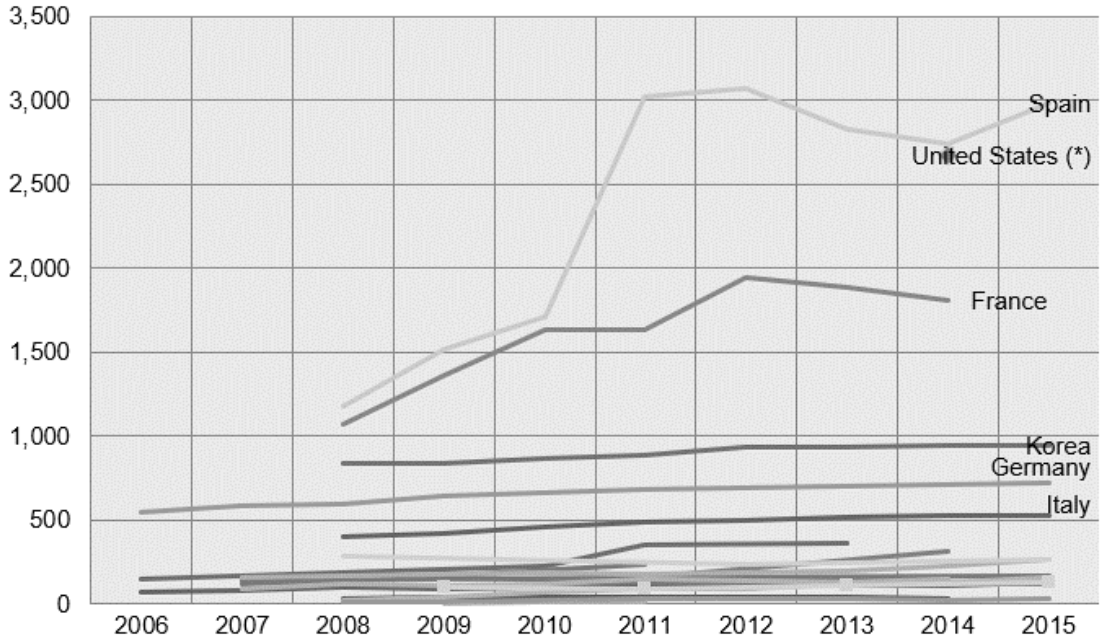
[12] Bruno Waterfield, "Jean-Claude Juncker 'sacks' EU scientific adviser over her pro-GM views," *The Telegraph*, 13 November 2014.

[13] Idem.

[14] François Randour et al, "The Cultivation of Genetically Modified Organisms in the European Union: A Necessary Trade-Off?" *Journal of Common Market Studies* 52, no. 6 (2014): 1316.

2015).[15] GMO-averse Austria, in contrast, has only 4% as many such firms despite an overall GDP that is more than 30% of that of Spain.

Figure 1: Biotech firms by Country (OECD Biotechnology Indicators. 2015)



Austria's staunch anti-GMO stance has been the catalyst for numerous legal disputes within the EU. In the mid-1990s Austrian voters chose by referendum to ban the cultivation of GMOs outright on Austrian territory; the EU commission, seeing this as a potential obstacle to the free market, requested on three separate occasions for the EU Council to invalidate the referendum, which the Council refused by qualified majority to do on each occasion. Nevertheless, the Commission did succeed in forcing Austria to lift its ban for purposes of food and feed, to the detriment of the Commission's public image in Austria and elsewhere.[16] This history of what some see as strongarm tactics against member state anti-GMO policies – and the resulting damage in the perception of the ability of the EU to represent the desires of EU citizens – forms an important part of the backdrop to the Juncker Administration's current and proposed GMO regulatory policies.

[15] "Key biotechnology indicators," OECD Directorate for Science Technology and Innovation, oe.cd/kbi Last update November 2017.
[16] Randour 1316.

The Juncker regime strives to improve public perceptions of the EU, the majority of whose citizens and governments do not look favorably upon the expansion of GMO cultivation and consumption.

Coalitions and Stakeholders

Central to the debate are two opposing groups whose areas of concern overlap on the issue of GMO regulation. One of the most influential frameworks on the nature of coalitions and how they interact with policymaking is the Advocacy Coalition Framework (ACF), which describes advocacy coalitions as "people from a variety of positions[…]who show a non-trivial degree of coordinated activity over time" on a policy issue or set of policy issues.[17] By incorporating and disseminating new information "on their own terms," coalitions "adapt to the beliefs of another coalition, particularly when its views become 'too important to ignore'".[18] Further, they do and must compete with other coalitions to translate their positions into policy, for "coalitions have to exercise power effectively to maintain or improve their positions within subsystems."[19]

In an analysis of the establishment of GMO policy in Turkey, Yagci (2018) uses the ACF to argue that Biotechnology companies and anti-GMO advocates were the main forces in articulating Turkish GMO policy, compromising on a protectionist strategy in a "Baptist-bootlegger" fashion. In like fashion, Brooks (2018) employs the ACF to analyze coalitions that formed for and against Direct to Consumer Advertising (DTCA) of prescription drugs, finding that active influence, persuasion, and governmental "control" were key to the victory of the anti-DTCA coalition.[20] Though the biotechnology industry is a significant player in influencing public opinion

[17] Paul Sabatier, "The Advocacy Coalition Framework: Revisions and Relevance for Europe," Journal of European Public Policy, 5, no. 1 (1988):98-130. 139.
[18] Cairney 488
[19] Ibid 489.
[20] Eleanor Brooks, "Using the Advocacy Coalition Framework to understand EU pharmaceutical policy," European Journal of Public Health 28, no. 3 (2018): 11-14.

in the EU on the GMO question, and the regulations discussed naturally have effects on the biotechnology industry, the subject of this research is not the formation of public perception but rather the successes and hopes of GMO opponents in achieving policy changes that contravene the opinions of, and diminish the regulatory influence of, the EU scientific community. For purposes of this research, therefore, the two primary groups of analysis are the Anti-Biotech Coalition and the Scientific Community. The Anti-Biotech coalition has been successful in translating policy preferences into European Union policy over the objections of the Scientific Community and to the detriment of the Biotechnology Industry.

The Biotechnology Industry

Thought not a main focus of this research, the European biotechnology is certain affected by the topics under discussion. The European biotechnology industry remains a substantial driver of European technological and economic growth, with biotechnology having been named a "Key Enabling Technology" as part of Europe's Horizon 2020 program which aims to catalyze European technological leadership.[21] Further, EU funding backs the Bio-Based Industries Joint Undertaking, "a €3.7 billion partnership between the EU and the Bio-based Industries Consortium," similarly focused on creating jobs and scientific and technological infrastructure for future European leadership.[22] The European biotechnology industry is substantial, though small compared to that in the US. In 2017, Europe boasted 234 public biotech companies versus 331 in the US; European IPOs resulted in €866 million raised, while American IPOs amounted to €2.03 billion; however,

[21] "Key Enabling Technologies," European Commission, http://ec.europa.eu/programmes/horizon2020/en/area/key-enabling-technologies.
[22] "About BBI JU," Bio-Based Industries, https://bbi-europe.eu/about/about-bbi.

of the 234 public European biotech firms, only 1 was classified as an "agribiotechnology" firm.[23] According to 2015 OECD data (the most recent available), 2,005 dedicated biotechnology firms operated in the EU, contributing a total of 3.8 billion USD in purchasing power parity.[24] More detailed data on the size of the European biotechnology industry or sector is either vague or difficult to find; however, in 2016 an industry group reported that industrial biotechnology (just one part of the overall biotechnology industry, which also includes agricultural biotechnology and biomedical biotechnology) sustains 486,000 full-time equivalent jobs and contributes €31.6 billion in added value to the EU economy, with projection of 57.5-99.5 billion by 2030.[25]

The Anti-Biotech Coalition

The first significant coalition in the GMO debate is that which is opposed to GMOs and certain types of biotechnology more broadly. The previous section's criticisms of GMOs do not represent disparate isolated voices but rather a bloc of many likeminded consumers and citizens. Biotechnology is a broad field encompassing technologies as diverse as biofuel production, medical treatment, and genetic engineering. As Kurzer and Cooper point out, there is a stark difference between perceptions of "red" (medical-related) and "green" (agriculture-related) biotechnology, with general acceptance of the former and much more widespread rejection of the latter. A coalition opposed to green biotechnologies, comprising "environment NGOs, consumer groups, and small traditional or organic farmers," has been an effective force on the issue, and "intense popular opposition to GMO…provided a critical resource for the anti-biotech coalition." For reasons that merit further investigation, the perceptions of the public – and consequently the

[23] Data on private companies was not available. "European Biotechnology Science and Industry Guide," European Biotechnology, https://european-biotechnology.com/euro-guide-2019.html
[24] OECD Key Biotechnology Indicators
[25] EuropaBio. "Jobs and Growth Generated by Industrial Biotechnology in Europe"

perceptions of their democratically elected governments – exhibit intractable differences on the topic of genetic modification, with naturalistic and ecologically-motivated beliefs dominating the opposition.[26]

Critically, the anti-Biotech coalition has managed to both foster and draw on majority acceptance of its GMO policy preferences among European consumers. In a 2001 Eurobarometer poll, 71% of Europeans surveyed looked negatively on GMO food; "In 2001, an average of 71 per cent of the EU-15 public 'did not want GM foods,' while in 2005 62 per cent of the EU-25 public was 'worried' about GM foods and beverage."[27] By 2010, this number had changed to 54% though showing a strong correlation with having heard of or being knowledgeable about GMOs; no Eurobarometer polls on GMOs have been released since that time, though national polls reveal strongly negative attitudes.[28] Further, a majority (51%) of Europeans expressed that the EU has taken insufficient action on environmental protection.[29]

Kurzer and Cooper continue to outline that the Anti-Biotech Coalition has, as a result of this majority agreement, managed to achieve "three significant victories in the last decade": first, "a de facto moratorium from 1998 to 2004 on the authorization of biotech crops," second,

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[26] "Since Europe didn't need GMOs and in general were suspicious of big agri-business, it became easy for Green parties, notably Greenpeace, to conflate the two issues," Nobel Laureate Sir Richard Roberts. Sarantis Michalopoulous, "Nobel Laureate: EU politicians ignore 'politically unwelcome' GMO science," *Euractiv* September 27, 2016, https://www.euractiv.com/section/science-policymaking/interview/nobelist-eu-politicians-ignore-politically-unwelcome-science/

[27] Paulette Kurzer and Alice Cooper, "Consumer Activism, EU Institutions and Global Markets: The Struggle over Biotech Foods," *Journal of Public Policy* 27, no. 2 (May-Aug 2007): 108.

[28] Sylvie Bonny, "Why are most Europeans opposed to GMOs? Factors explaining rejection in France and Europe," *Electronic Journal of Biotechnology* 6, no. 1, (April 15, 2003).
Ouest France, "Sondage. Les OGM inquietent de plus en plus les Francais," *Ouest France*, September 27, 2013, https://www.ouest-france.fr/europe/france/sondage-les-ogm-inquietent-de-plus-en-plus-les-francais-420229.
"Eurobarometer, Biotechnology – Report," European Parliament Eurobarometer Survey, ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_341_en.pdf

[29] "Democracy on the Move," *European Parliament* Eurobarometer Survey, http://www.europarl.europa.eu/pdf/eurobarometre/2018/oneyearbefore2019/eb89_one_year_before_2019_eurobarometer_en_opt.pdf

"labelling and traceability requirements" of products that contain GM material, and third "[closing] the European market de facto to GM foods."[30] Though the most intense opposition to GMO is concentrated in and has access to political power in only a few Member States, these elements have enjoyed critical levels of influence at the EU level compared to other large interest groups in the European Union: the latitude conferred to member states in the areas of health and safety and possible implications for disruption to the Common Market have resulted in the Commission agreeing to "stricter standards and procedures than they otherwise would have preferred."[31] Further, Kurzer and Cooper cite the outreach efforts of trans-national actors, namely Greenpeace, at coordinating continent-wide messaging while also articulating anti-GMO messages to the unique cultural and economic circumstances of each Member State, for example appealing to rural and local traditions of cultivation and farming lifestyle.[32] Finally, as discussed above, the anti-biotech coalition's views on Professor Anne Glover were widely seen as pivotal in her dismissal as Chief Science Advisor.

The Scientific Community

The scientific community in the European Union operates differently than the Anti-Biotech Coalition. Primarily, Scientists are often much more reluctant than other groups to engage in public advocacy and coalition-building in the political sense.[33] Nevertheless, as a de facto coalition, they do engage in adaptation, taking stands and adapting messaging when opposing coalitions become "too important to ignore." On the GMO issue, as the Anti-GMO coalition and its messages have

[30] Paulette Kurzer and Alice Cooper, "Consumer Activism, EU Institutions and Global Markets: The Struggle over Biotech Foods." *Journal of Public Policy* 27, no. 2 (May-Aug 2007): 104-5.
[31] Idem 110.
[32] Idem
[33] See e.g. Robert Lackey, "Science, Scientists, and Policy Advocacy," *Conservation Biology* 21, no. 1 (2007): 12-17.

grown to majority acceptance within the European Union, the Scientific Community has become increasingly vocal in its position on GMOs.

For example, the European Academies Science Advisory Council, a body representing, and funded by, the national science academies of 27 European countries, has recently expressed strong opinions on the need for changes in what it views as regressive GMO regulation. In 2014, in the midst of a debate on the reform that would allow EU Member States to opt out of GMO cultivation on their territories, the EASAC issued a summary stating that "Compared with other regions of the world, the EU has fallen behind in its adoption of crop plant genetic modification and one of the reasons for this has been the time-consuming and expensive regulatory framework, compounded by politicisation of decision-making by Member States. Many in the scientific community are concerned that this situation will worsen."[34] Indeed, when in late 2018 the European Court of Justice ruled that new gene modification technologies must be classified according to decade-old GMO regulations, the Chief Science Advisors of the European Commission issued a rare rebuttal, noting that "there is danger that unless the EU improves the regulatory environment for products of gene-editing, it will be left behind in this field, which could also diminish EU influence on ongoing debates at the international level with respect to specific applications and regulatory processes."[35]

Precautionary Principle

[34] EASAC, "European Academies inform MEPs on GMO legislation," EASAC, October 24, 2014. https://easac.eu/news/details/european-academies-inform-meps-on-gmo-legislation/

[35] Chief Science Advisors of the European Commission, "A Scientific Perspective on the Regulatory Status of Products…," European Commission, November 13, 2018. https://ec.europa.eu/info/publications/status-products-derived-gene-editing-and-implications-gmo-directive_en

Of note as well is the EC's usage of the Precautionary Principle, which although conceived as a mechanism to prioritize public protection and safety in the minds of regulators, remains "an abstract legal principle that is implemented through policy making, and, as such, it can produce different policy responses."[36] This standard is defined in numerous ways, though in principle places the onus on new technologies to prove themselves safe rather than placing the onus on regulators to prove them unsafe. However, the Commission left the principle officially undefined, an oversight which would in many respects set the stage for the current debate over regulation of GMOs.[37] For example, in 2000 EC published a communication to bring the precautionary principle line with WTO standards since it was previously "ill-defined,ad hoc and, to a certain extent, nonscientific application of the precautionary principle."[38]

The precautionary principle is generally agreed to have arisen in the 1970s in West German environmental policy and began to be incorporated into various international agreements and environmental laws in the 1980s. In 1990s the principle gained general worldwide acceptance, being included in agreements by the UN and the EU.[39] In 1998, 35 scientists and policymakers from the US and Europe attended the Wingspread Conference on the Precautionary Principle, in which the principle was defined as "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically"[40] In the US, in stark contrast, "uncertainty is used

[36] Jale Tosun, "How the EU Handles Uncertain Risks: Understanding The Role Of The Precautionary Principle," *Journal of European Public Policy* 20, no. 10 (2013): 1517–1528.
[37] Ragnar Löfstedt, "The precautionary principle in the EU: Why a formal review is long overdue," *Risk Management* 16, no. 3 (2004): 137–163.
[38] Ibidem.
[39] Elizabeth Fisher et al, (authors and editors) *Implementing the precautionary principle: perspectives and prospects,* (Northampton, MA: Edward Elgar Publishing, 2006), 3.
[40] Joel Tickner and David Kriebel, "The role of science and precaution in the environmental and public health policy," in *Implementing the Precautionary Principle*, ed. Elizabeth Fisher et al, (Northampton, MA: Edward Elgar Publishing, 2006), 44.

strategically by the regulated community as reason to justify inaction …lacking such data, substances are deemed safe simply by default (U.S. Environmental Protection Agency, 1998)…Many laws in the U.S. assume potentially harmful activities safe by default and require near proof of damage before government agencies can act."[41]

However, the Precautionary Principle has long been seen as at risk for politicization to slow innovation and science when they were deemed politically unwanted; "the precautionary principle has often been portrayed as contrary to the tenets of sound science and inconsistent with the norms of 'science-based' decision making."[42] Even before the Juncker administration, the commission showed clear signs of sociopoliticization of the Precautionary Principle and regulatory decisionmaking more generally, for "Although the Commission, in principle, favours cost-benefit analysis, it argues that it should not only consider the costs to the 'Community' as a whole but also to a number of non-economic considerations such as public acceptability, leaving the Commission plenty of vague language for interpretation."[43] Finally, the EC may use the Precautionary Principle "to legitimise decisions that are irrational," which shall be further evidenced below.[44]

In a preliminary European Court of Justice ruling on EU GMO regulation 1829/2003, the Precautionary Principle was defined to imply that in certain circumstances as long as "*scientific uncertainty* persists, *provisional* risk management measures necessary to ensure the *high level of health protection* chosen in the Community may be adopted, pending further scientific information for a *more comprehensive* risk assessment."[45] Nevertheless, observers note that the official

[41] Idem 55.
[42] Idem.
[43] Idem.
[44] Joanne Scott and Ellen Vos, "The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO," in *Good governance in Europe's integrated market,* ed. Christian Joerges and Renaud Dehousse (Oxford: Oxford Scholarship Online, 2002).
[45] "Judgment of the Court (Third Chamber)," European Court of Justice, September 13, 2017, http://curia.europa.eu/juris/document/document_print.jsf;jsessionid=9ea7d2dc30d692a45d3ac71e48c3834cb31c

definitions are one thing, and applications are quite another; Lofstedt (2014) notes that "regulators and policy makers are consistently misusing the precautionary principle and the European courts have not been systematic in their interpretations of it."[46] Though scientific uncertainty can never be fully eliminated, in effect this definition implies that until the safety of a new technology is sufficiently established, regulators may prevent its propagation in the name of the protection of public health. As Skogstad (2011) puts it, "Analysts characterize the EU political culture of GMO regulation as a precautionary one whose epistemological underpinnings are skepticism about the capacity of science to know and assess the risks of this novel technology and, understandably therefore, less willingness to grant scientific experts exclusive authority in risk regulation."[47] In one sense, this regulatory perspective is left with important ambiguities: who is to decide what constitutes "scientific uncertainty"? What is a sufficiently comprehensive risk assessment? What degree of restriction constitutes the "measures necessary to ensure…health protection"? These are indeed important questions that to some extent remain open to interpretation and contestation. In practice, however, the Precautionary Principle can be reduced to a simple motto: the burden of proof rests upon those who claim safety. But just as in US regulatory rules the burden of proof rests roughly on harm and yet thousands of substances are not permissible in foods, in turn so does the burden of proof resting on safety not prevent the approval of new foods.

Participatory Technology Assessments

14de1ec4.e34KaxiLc3qMb40Rch0SaxyMbxj0?doclang=EN&text=&pageIndex=0&part=1&mode=DOC&docid=194406&occ=first&dir=&cid=230658

[46] Ragnar Löfstedt, "The precautionary principle in the EU: Why a formal review is long overdue," Risk Management 16, no. 3 (2014): 137-163: 157

[47] Grace Skogstad, "Contested Accountabiity Claims and GMO Regulation in the European Union," *Journal of Common Market Studies* 49, no. 4 (2011): 901.

A further key term in the regulatory toolkit, Participatory Technology Assessment, is a concept that has existed since 1980. Beginning in the mid-1980s, several science-related crises – Chernobyl (1986), Bhopal (1984), Mad Cow (1980s) and Dioxins (1999) – triggered and sustained increasing public skepticism in the effectiveness and legitimacy of regulatory procedures.[48] In European regulatory circles this has led to a demand for greater public participation in such regulatory processes, discussed in greater detail below. "Since the mid-1990s, following a series of food-related scares and debates, with Bovine Spongiform Encephalopathy (BSE) and genetically modified (GM) foods as the most prominent issues, food safety institutions in Europe have been facing growing demands for a more effective, efficient and, at the same time, balanced and fair regulatory process that is also characterised by more transparent and participatory decision-making procedures."[49] The concept of Participatory Technology Assessment (henceforth "PTA"[50]) is the process of involving various constituent viewpoints outside of the scientific community into the process of determining the potential impacts of new technologies. For example, in 1996 the Danish government attempted to evaluate new plans for ensuring a clean supply of drinking water; five industry and stakeholder groups each presented its plan before a panel of 60 subject matter experts, 60 politicians, and 60 randomly selected citizens, all ultimately casting votes regarding the 5 plans.[51]

Such a model represents a stark contrast to a more technocratic system in which the plans would be decided between merely politicians and experts, or perhaps drafted only amongst

[48] Matthew Cotton, "Ethics and Technology Assessment: A Participatory Approach," *Studies in Applied Philosophy, Epistemology and Rational Ethics*, *Volume 13*, (Berlin Heidelberg: Springer–Verlag July 2014).
Mitchell P. Smith, *Environmental and Health Regulation in the United States and the European Union* (New York: Palgrave Macmillan, 2012), 42.
[49] Marion Dreyer and Ortwin Renn, *Food Safety and Governance: Integrating Science, Precaution, and Public Involvment* (Berlin Heidelberg: Springer-Verlag, 2009), 3.
[50] Though sometimes in other documents rendered as "pTA" or "participatory TA".
[51] "EUROPTA," Cordis, European Commission, https://cordis.europa.eu/docs/publications/7078/70781441-6_en.pdf, 53.

regulatory or industry experts and submitted to politicians, who could choose whether to present it to their constituents, for approval. In contrast to US regulatory agencies, this represents an high level of layman participation. The US Food and Drug Administration, for example, makes extensive use of Advisory Committees, composed of "qualified experts" as well as nominated, vetted "consumer representatives" who must be able to "analyze scientific data, understand research design, discuss benefits and risks, and evaluate the safety and efficacy of products under review," a significant contrast to the randomly selected and broad-based participants in some European PTAs.[52] In some European cases, no experts are involved in the PTA panel, such as the 1997 Baden conference on ozone in which the "panel consisted of young people aged 18-26 only. The panelists were instructed by written material and during two preparatory weekends with several weeks interval. During the weekends, no experts were heard" [sic].[53] It may merit consideration in which situations each approach may be preferable to the other, and a worthy topic for future research.

PTA was first codified as an assessment and regulatory mechanism in the 1980s and has grown to see widespread use throughout Europe.[54] A large body of research and meta-research, sponsored or commissioned by EU funding and coordination mechanisms and listed on the EU Commission's website (specifically, its CORDIS database), makes use of PTA or studies its use.[55] Most notably, the 2000 European PTA review, known by its abbreviation EUROPTA, was carried out

[52] "Advisory Committees," US FDA website, http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/default.htm. Retrieved December 10, 2015.
[53] "EUROPTA" 50.
[54] Michael Orntzeder and Karen Kastenhofer, "Old problems, new directions and upcoming requirements in participatory technology assessment," Editorial in Poiesis Prax (2012): 1–5.
[55] "CORDIS is the European Commission's primary public repository and portal to disseminate information on all EU-funded research projects and their results in the broadest sense."

> "to advance the understanding of the role of PTA by critically assessing the experiences to date of different European national participatory initiatives, to identify criteria for the practical implementation of participatory methods, and to contribute to the development of participatory methods and practices in technology assessment"

and further, a principal objective of the assessment was to "make recommendations about the use of PTA at a national as well as a (European) transnational level."[56] A 2008 European Parliament study was undertaken "to ensure successful pan-European PTA cooperation."[57] The Logic of PTA has thus permeated many aspects of EU decisionmaking.

A Brief History of GMO Policy

The late 1990s were a landmark period in GMO policy in the European Union. Though other institutions (such as the EU Council) can decide on political priorities, and the European Parliament must ultimately approve new legislation, the European Commission and its subsidiary agencies (such as the European Food Safety Authority) and committees are tasked with interpretation and enforcement of regulations; Furthermore, the Commission must originate all proposed legislation[58]. The EU Council is formed by the Heads of State of European Member States, and thus gives political will and direction to the European Union, but lacks administrative oversight authority. This separation of powers, as outlined in the EU's foundational treaties, has been the source of ongoing tension and frustration on the GMO issue.[59] The Commission's "Directive 90/220/EEC…covered the development of GM crops and the placing on the market of

[56] "EUROPTA."
[57] "Technopolis Report," European Parliament, April 2014, http://www.europarl.europa.eu/RegData/etudes/etudes/join/2012/488798/IPOL-JOIN_ET(2012)488798_EN.pdf
[58] "European Council," European Union Website, https://europa.eu/european-union/about-eu/institutions-bodies/european-council_en, retrieved November 11, 2018.
[59] "The European Commission," European Parliament Website, http://www.europarl.europa.eu/factsheets/en/sheet/25/the-european-commission, Retrieved November 11, 2018.

live GMOs such as fruit, seeds, and other products" However, the legislation did not regulate "processed products containing GMOs."[60] In 1996, the "GMO crisis" began in the UK with the launch of a "tomato puree containing GM tomatoes" which stoked consumer ire and was branded as a "frankenfood."[61] Following on the heels of the tomato puree dispute, the European Commission passed Regulation (EC) No. 258/9, which required "compulsory labeling for all products containing GM ingredients placed on the market on or after May 16, 1997." A key word in this regulation is "novel," as "ingredients that had been authorized for use before May 15, 1997" were grandfathered into approval, which included several "roundup-ready" varietals of Soy and Corn.[62] Additionally, the regulation "does not apply to additives or flavorings." These loopholes were patched in the following year with 1139/98/EE, which retroactively and proactively regulated any products in which genetically modified DNA or Proteins could be detected; in other words, if it was possible to tell from analyzing the end products that they arose from a genetically modified source, they were unauthorized.[63]

The 1997 Dispute

A contest in 1997 between the regulatory authority of the Commission and those of member states culminated in a standoff that still colors the discussion of GMO regulations to this day. "In 1997, the Commission's decision power led to a first confrontation with the Council over Bt 176 maize. Neither the comitology committee nor the Council succeeded in reaching a qualified majority and the Commission ultimately approved a GM maize for sale despite the fact that only

[60] Ross 9.
[61] Ibid.
[62] Idem 9-10.
[63] Idem 10.

one Member State supported its approval."[64] This move led the governments of Austria, Italy and Luxembourg to ban the cultivation of the maize outright, which the Commission considered an illegal contravention of the Single Market principle, and consequently required the bans be lifted. The culmination of this dispute was that "In June 1999 Member States in the Environment Council announced that they would not authorize any new GM products until existing procedures were reformed."[65] 12 of the then 15 Member States agreed not to authorize new GMOs, resulting in a de facto moratorium.[66]

Recent Development

The EU's current policy on GMOs can be traced to 2010 with the proposal to grant the Member States authority over the cultivation of GMOs in their territory, a policy "described as 'renationalization' of prerogatives previously exercised at the European level."[67] Randour (2014) analyzes the 2010 devolution of regulatory authority from a multi-level governance framework, arguing that the interplay of Subnational Resistance (environmental groups, namely the GMO-free Regions Network), the European Parliament (Green MEPs who accepted the devolution as a compromise), The EU Council (only 6 member states have GM crops on their territories) , and looming pressure from the WTO (in May 2003 several countries including the United States initiated a trade dispute regarding the de facto moratorium on new biotechnology) forced a reckoning. Caught between the rock of external trade pressure and the hard place of intransigent member states, the Commission chose to surrender some authority and devolve power to members– indeed, resolving the problem by avoiding it and placing the regulatory onus on national

[64] Randour 1310.
Skogstad 901.
[65] Skogstad 902.
[66] paraphrase of Randour 1311. Skogstad 901.
[67] Randour 1408.

governments.[68] Randour observes that several factors indicate that the EU conducted this multi-level balancing act: "first, the proposal tried to avoid breaching WTO rules by not altering the science-based assessments and the authorization process…second, the arguments to be used under the 'new' opt-out clause are to be entirely separated from environmental and health concerns" which demonstrates deference to political pressures, and "third, this compromise specifically aims to…ensure the functioning of the internal market" (1318). Randour poses the question of why the EU would voluntarily devolve this authority to Member States despite the above evidenced history of seeking generally to maximize authority over a wide range of issues, clearly including policies on science and technical regulation, and much of Randour's analysis remains valid for understanding criticisms of the current 2017-2018 comitological reform proposal.

Devolution was not the only option available to the Commission, however, as many countries do use WTO obligations as weapons in a fight for internal reform, and a threat of a victory for retaliatory sanctions from the United States may have proven an effective bludgeon against internal prohibitions on GMO cultivation. As Skogstad observes, "EU policies…have been under attack for some time both within the EU and outside, from EU trading partners and fellow WTO members like the US."[69] Skogstad continues: "Both internal and external criticisms fault the failure of the EU GMO regulatory regime to conform to 'rendering account' standards…The ascendant precautionary EU political culture of risk regulation, emphasizing the uncertainty of GMO risks and sceptical of scientists' capacity to assess GMO risks, is reluctant to delegate regulatory authority to scientific experts and measures the accountability of EU decision-makers against democratic principles of popular control."

[68] Skogstad 902.
[69] Skogstad 896.

The question of why the political culture is reluctant to side with scientific experts over democratic principles is one that is explored further, but one possible answer lies in the desire to address the "democratic deficit" - explored in greater depth in Chapter III, but generally referring to the perceived lack of democratic input into the decisionmaking processes of EU institutions, particularly as those decisions are moved "higher" into EU institutions and away from the people or their national governments. While legislative processes may represent a model of what Skogstad calls a "shared political authority" that rests on democratic processes, the "implementation of these same regulations by comitology procedures" – using internal Commission mechanisms to avoid relying on Member State input – is an element of a "delegated" form of authority not democratically exercised by individual states but rather by the body they delegate to exercise them (i.e. the Commission).[70] However, "The EU" is not a unitary actor, and as a nominally democratic institution the member states and representatives that compose decisionmaking bodies are bound to some extent, at least in norms, by the desires of Member State governments – the majority of whom desired the ability to prohibit GMO cultivation, but some of which represented countries with sizeable biotech industries that would be devastated by an EU-wide ban. Given such circumstances, there may have been little room for maneuvering.

Nevertheless, the policy of devolution or "renationalization" represents a divergence from standard operating procedure in many policy areas: "Although comitology rules permit a qualified majority of Member States to prevail over a dissenting minority of states, in practice representatives of Member States in committees and the Council work toward consensus-building" – GMO policy thus represents a particularly intractable area of EU policy that defies established

[70] idem 899.

norms of consensus-seeking behavior of member states.[71] Rather, the GMO issue seems to play out according to different rules.

Four Pillars

Four Commission directives that have been produced in the past 20 years form the pillars of the European stance on GMOs. "This package of reforms can be read as an effort to strengthen both democratic (participation) accountability standards of popular control as well as delegated fiduciary-based principles of performance accountability."[72]

1. Directive 2001/18, the Deliberate Release Directive. Its objective is to ensure the environmental safety of 'live' GMOs, like GM maize kernels or rapeseed. Like Directive 90/220 which it replaced in April 2001, Directive 2001/18 requires a risk assessment of every GMO before it is released into the environment.
2. Regulation 1829/2003, the Food and Feed Regulation (Commission, 2003a), which replaced the 1997 Novel Food Directive. Its regulatory procedures are designed to ensure the human and animal health and safety of any GM food and feed, and processed food made from GMOs (like cornstarch) that are marketed in the EU.
3. Third is Regulation 1830/2003 on the labelling and traceability of GMOs and food and feed produced from GMOs (Commission, 2003b). Labelling is intended to ensure consumer choice, and traceability provisions are intended to track and recall GM products in the event of a safety issue.
4. The fourth pillar in the EU GMO regulatory framework is not specific to GM products. It is Regulation 178/2002 which laid out European food law and the role of EFSA (Commission, 2002). Since it began operations in 2003as a permanent body dispensing advice to the Commission on food safety issues (and GMOs' risks), EFSA has replaced Commission-appointed scientific committees.[73]

Driving Forces

[71] Ibid.
[72] Skogstad 903.
[73] Ibid.

Regulation requires striking a balance between different competing drawbacks and benefits, often resulting in dilemmas for regulators. In the classic formulation, this balancing act occurs between the priorities of economic competitiveness on the one hand and environmental and health protection on the other.[74] A classic case in recent years, for example, would be the choice of whether to require companies to install carbon dioxide scrubbers on exhaust ports even if those scrubbers are expensive and would cut into the companies' bottom line. Löfstedt (2004) notes that EU regulation tends to behave like a pendulum, swinging between the technocratic and democratic extremes.[75] What Löfstedt identified as the driving force behind the movement between these two extremes is the changing balance of priorities among "competitiveness, sustainable development, and governance," which Löfstedt identifies with the Commission's aim of creating "better regulation" to satisfy all three. This is a different take than the classic regulatory dilemma (protection versus competitiveness) as noted above by Kapstein. It also differs from the "regulatory trilemma" (protection, competitiveness, and EU integration) proposed by Smith – in this latter formulation, the classic concerns of balancing competitiveness and protection are met with the third priority of harmonizing European economic and regulatory integration, creating an even more difficult equation to solve than the relatively simple problem of balancing protection and competitiveness.[76] Löfstedt and Smith thus both gravitate toward a trilemma, the difference here being the substitution of "protection" for "sustainable development" and "EU integration" for "governance." For the analysis in this paper, Smith's regulatory trilemma – Protection,

[74] Ethan Kapstein, "Resolving the Regulator's Dilemma: International Coordination of Banking Regulations," *International Organization* 42, no. 2 (Spring 1989): 324.
[75] Ragnar Löfstedt, "The Swing of the Regulatory Pendulum in Europe: From Precautionary Principle to (Regulatory) Impact Analysis," Journal of Risk and Uncertainty, 28 no. 3 (May 2004): 237-260.
[76] Mitchel P. Smith, *Environmental and Health Regulation in the United States and the European Union: Protecting Public and Planet*, (New York: Palgrave MacMillan, 2012).

Competitiveness, EU Integration – seems to most closely describe the facts at work in EU GMO regulations.

Further, though, this study proposes that alongside the dimensions of the above di- and trilemmas, when public opinion diverges significantly from scientific opinion, there is an entirely different dimension of concerns, priorities, and interests that must be balanced: public legitimacy on the one hand and scientific and policy expertise on the other – a Schumpterian Public Choice dilemma. Under the leadership of Jean-Claude Juncker, the European Commission has been pursuing a package of reforms that make decisive choices in both dimensions of regulatory decisionmaking – not only strongly pursing public legitimacy over the recommendations of the scientific community, but also pursuing a conception of environmental protection at the expense of both economic competitiveness and the integrity of the European Union. Though Juncker may be pursuing these reforms out of combination of a genuine concern for the safety of GMOs and genuine attempt to respect popular opinion and address the democratic deficit, the potential nobility and necessity of these causes does not exempt the reforms from consequences in international trade and investment and international and European law.

Chapter II: Proposed Reforms and Their Discontents

The Proposed Reforms

The Juncker Commission's attempts to respond to both personal and popular opinions on the nature of Genetically Modified Foods have taken two main forms: first, a proposed law that would have allowed EU Member States to opt of out of allowing Genetically Modified Food products to be sold on their territories, and second, a proposed comitological reform that would allow member states who hold a simple majority, but not a qualified majority (55% of voting Member States representing 65% of the EU population), to decide whether to approve or reject the authorization of a new GMO.[77] Both of these proposed reforms, as shall be seen, would have serious negative consequences for European institutions and citizens. Further, when combined with recent European moves that weaken the influence of scientists and health experts in determining GMO policy, these moves constitute a minimization of scientific input within the workings of EU regulatory policy that could have long-term effects.

The European Food Safety Authority, for example, states in its self-description that it bases decisions on "science-based advice and clear communication grounded in the most up-to-date scientific information and knowledge," and in its food law general principles stresses that "food law, and in particular measures relating to food safety must be underpinned by **strong science**," and further "**Risk assessment** must be undertaken in an independent, objective and transparent manner based on the best available science" [emphasis in original]**.**[78] However, the role of the EFSA in any inconsistencies is attenuated by the fact that "EFSA does not authorise GMOs, which

[77] "Comitology," European Commission Website, https://ec.europa.eu/info/implementing-and-delegated-acts/comitology_en.
[78] "Principles," EFSA Website, http://www.efsa.europa.eu/en/aboutefsa and http://ec.europa.eu/food/safety/general_food_law/principles/index_en.htm

is done by the European Commission and Member States in their role as risk managers. EFSA's role is strictly limited to giving scientific advice."[79]

Comitological Reforms

The primary manifestation of the EU's attitudes and policy on GMOs is the authorization procedure by which GMOs are allowed or denied entry into cultivation or sale in the European Union. As the EU's policies have evolved, so too have the rules about how authorization is gained and which allowances and prohibitions are subject to EU regulatory assent. "According to Directive 90/220/EEC, the authorization of GMOs is decided through comitology – more particularly through a so-called 'regulatory procedure' in the (pre-Lisbon) comitology terminology (see Blom-Hansen, 2011). The Directive indeed delegates the power to decide on individual applications of GMO producers for the authorization of a particular GM crop to the Commission, which must work with Member State representatives gathered in a comitology committee."[80] To resolve the issue of, as the Juncker Administation sees it, too many GMOs being authorized over the democratic objections of European consumers, the Commission has proposed a reform to the comitological procedures by which such GMOs are accepted or rejected.

The EU process for the authorization of a genetically modified organism requires a series of approvals from various levels of EU decision-making bodies. In the EU legal framework, which enshrines the Precautionary Principle as the cornerstone of regulation, the burden of proof lies on safety, not on harm – "every authorization for placing a product on the market must be duly justified, and the main ground on which such a justification can rely is scientific assessment,"

[79] Ibid.
[80] Randour 1310.

responsibility for which is delegated to the EFSA. "From a legal point of view, decisions to authorise GMOs take the form of implementing acts adopted by the Commission." At multiple stages in the procedure, member states must vote on the acts and reach a qualified majority. "Whilst the commission therefore plays a decisive role in the authorization process, Member States are also very much involved." Since the implementation of Regulation EC 1829/2003, "member states have never obtained a qualified majority," and thus all such deliberations have resulted in "no opinion" – therefore, a lack of authorization.

> *"The 1829/2003 Food and Feed Regulation, which amends the 2001 Directive, provides the Member States with an alternative to restrict GM crops: co-existence measures. As Dobbs (2011, p. 181) argues, these co-existence measures are 'a crucial provision for the states and the central compromise to encourage the lifting of nation outright bans and the de facto moratorium'. In other words, the 2001 Directive strengthens the conditions to restrict GMOs' under the safeguard clause and it gives more flexibility to the Member States by granting them the possibility to define 'appropriate measures' to achieve a separation between GM and non-GM crops."*[81]

That is to say, although comitological rules have not led to member states outright rejecting the approval of GMOs, member states could determine internally what safeguard procedures were necessary to prevent the contamination of non-GM crops by GM pollen, runoff, and seeds. By imposing wide berths around existing non-GM cultivation, for example, countries could effectively impose significant restrictions on cultivation within their territories.

According to the infographic "GMOs: EU decision-making process explained," a biotech entity wishing to attain authorization for a GM product applies to a member state who then requests a risk assessment from the EFSA.[82] The EFSA then delivers its opinion to the EU commission, which is commented on by the member states experts committee, which can adopt or not adopt

[81] Randour 1312

[82] "GMO Decision-Making Process Explained," EU Commission, https://ec.europa.eu/food/plant/gmo/authorisation/decision_making_process_en.

outright. When there is no opinion, the matter is again referred to the EU commission which sends the matter to an appeals committee. The appeals committee can adopt or reject outright, but a decision of "no opinion" leads to direct adoption by the commission.

However – and this is the crux of the comitological issue – the workaround established to placate anti-GMO member states has proven a double-edged sword. The Regulation EU No 182/2011 was conceived to grant member states more opportunities to voice concerns on GMO authorization and to create "mechanisms for control by Member States of the Commission's exercise of implementing powers."[83] The procedure allows, in situations in which "no opinion" is registered in the comitological proceedings, for the Commission to adopt the draft implementation. However, for products for which authorization is required before entry to market (such as GMOs), "the Charter of Fundamental Rights and the case-law of the Court of Justice, requires the Commission to adopt a decision."[84] Products cannot, therefore, simply "default" into authorization or non-authorization when the commission reaches a decision of "no opinion"; rather, the Commission is forced by current comitological proceedings to expressly approve the authorization. As Skogstad puts it, "if that compromise cannot be found, decision-making rules require the Commission to exercise its delegated powers as a fiduciary and approve the proposal it initiated."[85] This requirement for the Commission to overtly approve GMO applications when the committee becomes deadlocked is the core of the comitological reform proposal put forth by the Juncker Commission. As stated in President Juncker's Political

[83] "Regulation (EU) No 182/2011 of the European Parliament and of the Council…," EUR-Lex, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2011.055.01.0013.01.ENG&toc=OJ:L:2011:055:TOC13–18.
[84] Jean-Claude Juncker, "Opening speech on GMOs - Plenary meeting," Speech, European Parliament, Strasbourg, October 28, 2015. https://ec.europa.eu/commission/commissioners/2014-2019/andriukaitis/announcements/opening-speech-gmos-plenary-meeting-28102015-european-parliament-strasbourg_en
[85] Skogstad 904.

Guidelines, "I will make sure that the procedural rules governing the various authorisations for GMOs are reviewed. I would not want the Commission to be able to take a decision when a majority of Member States has not encouraged it to do so. In general, let us avoid ideological debates which only sow division"[86].

To complicate matters, the enormous regulatory latitude by which member states could *de facto* control the cultivation of GM crops on their territories was given a de jure foundation in 2015, with the Adoption of Directive (EU) 2015/412. This directive allows member states to opt out of the cultivation of GMOs on their territory given "that such measures are justified on the basis of compelling reasons other than the risk to human or animal health and the environment," which fall under the purview of the EFSA risk assessment. This system has two notable gaps: first, this directive works in only one direction: member states can restrict cultivation that the EU authorizes, but cannot allow cultivation that the EU does not authorize. Second, this directive only applies to cultivation, and not to GMOs introduced into food and feed directly. "The issues raised by Member States who have opposed authorisations are most often not based on scientific considerations, but reflect national concerns which do not only relate to issues associated with the safety of GMOs for health or the environment." [87]

In 2015, the Commission proposed another regulatory reform that is also considered alongside the comitological reform as part of a joint thrust by the Juncker Commission to reduce or eliminate the authorization of GMOs in the EU. In line with the goals of the Better Regulation initiative, the Commission submitted proposed legislation to the EU Parliament "to restrict or prohibit the use of genetically modified food and feed on their territory," "even though these crops

[86] Juncker, October 28, 2015.
[87] European Union, "DIRECTIVE (EU) 2015/412 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 March 2015," Official Journal of the European Union, 68 no. 1 (March 13 2015). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L0412&from=EN

were approved at the EU level following a rigorous scientific assessment."[88] In the September 2015 State of the Union, President Juncker stated that "European problems require European solutions, national problems require national solutions. In respect of this principle, and because citizens' concerns about Genetically Modified Organisms may vary greatly among Member States, the Commission has proposed to return the power to restrict or prohibit the use Genetically Modified food and feed to national authorities."[89] This statement evidences a line of thinking in the Juncker administration that is placing high emphasis on the need to improve the democratic legitimacy of European regulatory processes in order to address a democratic deficit. However, the result demonstrates some of the unintended consequences of such a prioritization. In the weeks leading up to the Parliament's October vote on the proposal, nineteen European countries submitted requests for the proposed opt-outs, allowing them to roll back common market obligations to treat all EU products equally, and to instead prevent the import or commercialization of GMOs.[90] In many of these cases, a political rather than a scientific motivation was overt: "without a trace of embarrassment, a spokeswoman for Nicola Sturgeon, the leader of the Scottish National Party, admitted that the first minister's science adviser had not been consulted because the decision [to opt out and prevent GMO cultivation] 'wasn't based on

[88] 1st quote from European Commission, "Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL…restrict or prohibit the use of genetically modified food and feed on their territory," EUR-Lex, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52015PC0177.
2nd "Why the EU's GMO Vote Matters to Farmers," AgWeb, http://www.agweb.com/article/why-the-eus-gmo-vote-matters-to-farmers-naa-tanner-ehmke/
[89] Jean-Claude Juncker , "2015 State of the European Union," Speech, European Union, September 9, 2015, https://ec.europa.eu/commission/sites/beta-political/files/state_of_the_union_2015_en.pdf
[90] Austria, Bulgaria, Croatia, Cyprus, Denmark, France, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, and Slovenia requested full opt-outs; Germany requested a partial opt-out, "Nineteen EU Countries Seek GMO Opt-Out," *Deutsche Welle*, October 4, 2015, https://www.dw.com/en/nineteen-eu-countries-seek-gmo-opt-out/a-18760718

scientific evidence.' Instead, the priority was to protect the 'clean green image' of the country's produce, according to the secretary for rural affairs, food and environment."[91]

The Juncker Commission argued that this proposed reform was the logical extension of the decision allowing the prevention of cultivation. "The Commission suggested that this proposal should be modelled on another EU law, on GMOs intended for cultivation, which entered into force in early April 2015. This allows member states to ban the cultivation of EU-approved GMOs on their territory." [92] The EU Parliament, however, did not consent to the proposed measures. Rather, "A large majority in European Parliament has voted to reject a European Commission proposal that would enable member states to opt out of EU authorisations for genetically modified food," with one MEP having "never seen so much consensus."[93] In a different situation, this struggle over GMO policy would be run-of-the-mill political disagreement between the EU Commission and EU Parliament. However, given that it represents a fundamental debate between the scientific community and the EU commission, with the Commission going so far as to abolish a science advisor position based on personal political differences of opinion on the matter, this proposed and failed reform legislation forms part of a larger pattern of anti-GMO proposals that threaten the efficacy of EU institutions and call into question the "sound science" upon which EU regulatory decisionmaking is nominally based.

2017 – The Venting of Frustrations

[91] Lynas, Mark, "With G.M.O. Policies, Europe Turns Against Science," *The New York Times*, October 24, 2015, http://www.nytimes.com/2015/10/25/opinion/sunday/with-gmo-policies-europe-turns-against-science.html
[92]"Parliament Rejects National GMO Bans Proposal," European Parliament, http://www.europarl.europa.eu/news/en/press-room/20151022IPR98805/parliament-rejects-national-gmo-bans-proposal
[93] Louch, William, "MEPs reject 'half-baked' EU Commission GMO opt-out plans," *The Parliament Magazine*, October 28, 2015, https://www.theparliamentmagazine.eu/articles/news/meps-reject-half-baked-eu-commission-gmo-opt-out-plans

Several events in rapid-fire succession in early 2017 serve to demonstrate the growing frustrations of the Juncker Commission and like-minded Commissioners about the institutional and comitological inability to more tightly regulate GMOs, and serve as a further background for the push to resolve the resulting institutional tensions. The frustrations resulted in the Juncker Commission promulgating a new comitological reform proposal in late 2017 in explicit response to the comitological difficulties illustrated below.

27 January 2017 Committee Meeting

In the 27 January 2017 meeting of the EU Commission Standing Committee on Plants, Animals, Food and Feed (PAFF), Committee on Genetically Modified Food and Feed and Environmental Risk, the Committee voted "no opinion" on the authorization of two strains of GMO Maize: Bt11 (SYN-BTØ11-1), Bt11 × 59122 × MIR604 × 1507 × GA21, and 1507 (DAS-Ø15Ø7-1). The exact vote totals of these committee meetings are not released publicly (a point specifically targeted for reform by the Juncker administration's proposed reform package). Member states can voluntarily lodge individual opinions, however, and on both cases the representative from Sweden lodged a written statement, arguing that "glufosinate ammonium [the pesticide against which the GM traits in both crops provide protections] is a pesticide so dangerous that Sweden must vote NO in order to continue to work towards a non-toxic environment in the EU."[94] The Czech Republic took a less uniform standpoint on the proposals, having abstained on

[94] "Summary Report of the Standing Committee on Plants, Animals, Food and Feed Held in Brussels On 17 January 2017," European Commission Health and Food Safety Directorate-General, https://ec.europa.eu/food/sites/food/files/plant/.../sc_plant-health_20170126_sum.pdf.
The Swedish objection cuts to an important issue in the GMO debate, namely that while many EU Citizens view genetic modification as inherently untested and unsafe, others may view the genetic modification technology as safe *per se* but feel intense reservation regarding the externalities, such as increased ability to use pesticides, herbicides, or monocropping technologies. Others yet take a "don't throw the baby out with the bathwater"

the votes of Bt11 and 1507 but agreeing to the approval of another GM product up for approval at the same meeting: "*Regarding the voting of the Czech Republic … the positions differed due to lack of consensus among the Competent Authorities at this stage. Therefore the Czech Republic voted in favour in the case of MON810 (under Regulation 1829/2003) and abstained as regards GM maizes 1507 and Bt11 (under Directive 2001/18/EC).*"[95]

Comitology Reform Proposal

On 14 February 2017, barely 2 weeks after the above votes, the EU Commission proposed a Comitology Procedural Reform. In this proposal, the Commission specifically criticized the inability to prevent GMO authorizations with a simple majority: "In specific policy areas, such as GMO authorisations, or if a simple majority of Member States is against the draft act, the Commission cannot go ahead with adoption when the Committee reaches a 'no opinion' situation."[96] This contrasts with the line from the same statement that "The overall system works very well and should be maintained" – if the system is generally working well, is the hitch of GMO regulation sufficient to merit changing the otherwise well-functioning system? Rather, possibly, this proposal cuts directly to the issue of GMOs as the perennial bugbear of the Juncker Commission; Jean-Claude Juncker has quite clearly intended to enact similar reforms for at least two years: "As President Juncker said in his State of the Union address in 2016, *"It is not right that when EU countries cannot decide among themselves whether or not to ban the use of glyphosate in herbicides, the Commission is forced by Parliament and Council to take a decision.*

approach, acknowledge the potential negative externalities but arguing for the GMOs for their potential to be perfected and improved, transcending the negative externalities.

[95] Idem

[96] "Comitology Procedure Reforms: Questions & Answers," European Commission, http://europa.eu/rapid/press-release_MEMO-17-273_en.htm.

So we will change those rules." Once more, this statement evidences a high degree of emphasis placed on subsidiarity, devolution, and increasing the perceptions of democratic legitimacy of regulatory decisionmaking, in an attempt to address the democratic deficit.

The exact nature of the proposed reforms merits further elaboration. This is not a case, like in the US, where a product is considered safe "by default." Currently, in a 'no opinion' scenario, there is still one very significant hurdle that proposed GMOs must face: the EFSA safety report. As it stands, in the case where member states cannot come to an agreement under the current comitology rules, the decision is not to default to approval – the decision is instead devolved to the findings of the EFSA. This may be a system of primarily political institutions, but one which defaults to technocratic one when a qualified majority cannot be reached and the mechanisms of political decision are stuck.

The administration wishes to reform comitological procedures along the following lines[97]:

- **changing the voting rules** in the Appeal Committee, so that only votes in favour or against an act are taken into account [i.e. not counting absentions].
- **involving national Ministers** by allowing the Commission to make a second referral to the Appeal Committee at Ministerial level if national experts do not take a position … this will ensure that sensitive decisions are discussed at the appropriate political level;
- **increasing voting transparency** at the Appeal Committee level by making public the votes of Member State representatives;
- **ensuring political input** by enabling the Commission to refer the matter to the Council of Ministers for an Opinion if the Appeal Committee is unable to take a position.

The proposal drew vociferous responses from many different groups, not only partisans of the GMO debate. The Biotechnology Innovation Organization, an industry trade group, naturally claimed that the "EU's Anti-Science Comitology Reform Threatens Innovation" and that even the current procedure "allows politics to undermine the risk assessment function of the European Food

[97] "Comitology: Commission proposes more transparency and accountability in procedures for implementing EU law," European Commission Press Release, http://europa.eu/rapid/press-release_IP-17-264_en.htm, Retrieved November 6, 2018.

Safety Authority"[98]. Euractiv, an organization in favor of increased European integration, took a very different tack and criticized the move on the grounds that it weakened centralized EU decisionmaking authority, noting that the reform "attempts to return to the pre-Lisbon Treaty system, without getting there…it is doomed to failure before any talks have begun"[99] As of this writing, no movement has been made on this proposed reform measure.

27 March 2017 Appeals Committee Meeting

On 27 March, the Appeal Committee of the Genetically Modified Food and Feed Regulatory Committee met in Brussels to discuss the "no opinion" decision reached by the Committee in January.[100] The reasons given for negative votes or abstentions were broadly similar for the two crops but with some notable differences:

Reasons for negative vote or abstention for the authorization of Bt11	**Reasons for negative vote or abstention for the authorization of 1507**
• No agreed national position • Negative public opinion • Political reasons • Risk of harm to the national agri-food industry • Lack of comprehensive data on long-term potential impact of GMOs • Precautionary principle • Uncertainties in risk assessment • Safety concerns for the environment	• No agreed national position • Negative public opinion • Political reasons • Risk of harm to the national agri-food industry • Lack of comprehensive data on long-term potential impact of GMOs • Precautionary principle • Risk assessment deemed not sufficient • National GM-free strategy • EFSA minority opinion • Lack of long-term feeding studies

[98] Batra, Karen, "EU's Anti-Science Comitology Reform Threatens Innovation," *Biotechnology Innovation Organization,* February 14, 2017, https://www.bio.org/press-release/eu%E2%80%99s-anti-science-comitology-reform-threatens-innovation.

[99] Guegen, Daniel, "Comitology reform: Doing, undoing, and redoing is still hard work," *Euractiv*, February 16, 2017, https://www.euractiv.com/section/public-affairs/opinion/comitology-reform-doing-undoing-and-redoing-is-still-hard-work/.

[100] "Summary Report of the Standing Committee on Plants, Animals, Food and Feed Held in Brussels On 27 March 2017," European Commission Health and Food Safety Directorate-General, https://circabc.europa.eu/w/browse/8440f2ea-e2ad-4ce2-b520-d2f3b03f8c22.

- Potential risks for the environment and health due to tolerance of maize Bt11 to glufosinate ammonium

Again for both votes, the representative from Sweden chose to lodge individual statements, once again nearly identical to each other and nearly identical to the statements in the original committee meeting:

> "The Swedish government is of the view that an holistic approach to the use of the substance is important. The political assessment is that glufosinate-ammonium is such a toxic pesticide that a NO-vote is warranted in order to contribute to an Union strategy for a non-toxic environment in the European Union."

The breakdown of votes was perhaps as predictable as it was inevitable. On both the Bt11 and 1507 strains of genetically modified maize, the appeals committee once again reached the result of "no opinion." Groups opposed to GMOs expressed unhappiness at the results of the meeting. "When he was elected, Commission President Juncker promised more democratic decision-making. This vote leaves no doubt that approving these GMO crops would break that promise," and "A majority of governments, parliamentarians and Europeans oppose them, and two thirds of European countries ban GMO cultivation on their lands."[101]

July Approval Announcement

The European Commission regularly releases news briefings detailing significant activities throughout the day. Two announcements in 2017 refer to the approval processes of the GMOs in question. On 4 July 2017, the commission announced the approval of "maize Bt11 × 59122 × MIR604 × 1507 × GA21" and "maize DAS-40278-9"; the announcement stated, in relatively

[101] Chow, Lorraine, "16 European Nations Vote Against GMO Crops," *EcoWatch,* March 27, 2017, https://www.ecowatch.com/eu-nations-vote-against-gmo-crops-2332080511.html.

simple terms, that "These GMOs had received "no opinion" votes from the Member States in both the Standing and Appeal Committees and the Commission adopted the pending decisions."[102] This announcement is of little note on its own. Of significance, however, is the change that transpired between the 4 July announcement and the release on 22 December 2017 announcing the "renewal of maize 1507" among some others. "These GMOs had received "no opinion" votes from the Member States both in the Standing and the Appeal Committees and the Commission therefore **had to** adopt the pending decisions" (emphasis added).[103] While the phrase "had to" may not be forceful in itself, when paired with the ongoing context of Jean Claude Juncker's personal and professional frustrations with the EU comitology process and the inability to stop the approval of GMOs, to which Mr. Juncker has a longstanding record of opposition,[104] and when also contrasted with the typically dry bureaucratic nature of these announcements, the phrase is telling of growing impatience and a willingness to distance the mentality of the Commission from the comitological rules that force its hand on this issue. In a quiet room, small sounds can be large disruptions.

The above two chapters detail the nature of the proposed reforms and the regulatory structure and history into which they would be implemented. However, despite having been proposed beginning in 2015, they have still not gained sufficient support for passage. The follow sections will detail the arguments in favor of their passage as well as those against.

[102] "European Commission – Daily News 04 / 07 / 2017," European Commission, http://europa.eu/rapid/press-release_MEX-17-1908_en.htm.
[103] "European Commission – Daily News 12 / 22 / 2017," European Commission, http://europa.eu/rapid/press-release_MEX-17-5421_en.htm
[104] "personally not a supporter of GMs." Dave Keating, "All eyes on Juncker for GM crops decision," *Politico, Europe Edition*, March 5, 2015. Additionally under Juncker's Prime Minstership of Luxembourg, the principality banned cultivation of several GMOs – "Le Luxembourg interdit la pomme de terre OGM "Amflora," *Greenpeace*, (June 16, 2010), https://www.greenpeace.fr/le-luxembourg-interdit-la-pomme-de-terre-ogm-amflora/ Retrieved November 7 2018.

Chapter III: Democratic Legitimacy and the Need for Reform

The Democratic Deficit

The single most pressing argument for the institution of the comitological reforms and a subsequent decentralization of European policy on GMO regulation is that doing so would help alleviate the so-called "Democratic Deficit" that has plagued Europe since before the inception of the European Union. Though there is, as Jensen (2009) notes in a literature review of the subject, a great deal of heterogeneity about the nature of or existence of Europe's democratic deficit (depending on conflicting definitions of both "democratic" and "legitimacy"), ultimately "the European Union (EU) is widely believed to harbor a democratic deficit" of some kind.[105] The general idea of the deficit is that European institutions are largely devoid of democratic legitimacy, implemented by agreements among heads of state and hidden behind several layers of bureaucratic abstraction from the daily practices of the civic and political life of the average European; many EU decisions are made by unelected ministers or representatives.

An additional layer to the concept of the democratic deficit is the idea that the deficit grows the farther an institution gets from direct popular input or control – thus the unelected EU Commission and its regulatory agencies exhibit a greater democratic deficit than the directly elected EU Parliament or the national governments of Member States. One avenue of response to the idea of the democratic deficit is "subsidiarity" – the principle in which rules should be propagated at the lowest level at which they can be effective.[106] For example, if a regulation can

[105] Thomas Jensen, "The Democratic Deficit of the European Union," *Living Reviews in Democracy* (2009), https://www.ethz.ch/content/dam/ethz/special-interest/gess/cis/cis-dam/CIS_DAM_2015/WorkingPapers/Living_Reviews_Democracy/Jensen.pdf
Joachim Blatter et al., "Democratic Deficits in Europe: The Overlooked Exclusiveness of Nation-States and the Positive Role of the European Union," *Journal of Common Market Studies* 55, no. 33 (2017): 449-467.
[106] Andreas Follesdal, "Survey Article: Subsidiarity," *The Journal of Political Philosophy* 6, no. 2 (1998): 190-218.
European Parliament Website, "The Principle of Subsidiarity," http://www.europarl.europa.eu/factsheets/en/sheet/7/the-principle-of-subsidiarity, Retrieved 6 November 2018.

be adequately administered at the level of Member States, it should be so, and not unnecessarily appropriated to a higher, less democratic, EU authority.

In recent years, to the institutional tinder of the democratic deficit was added the gasoline of cultural populism. In the lead up to the 2016 Brexit vote, British Foreign Secretary and prominent "leave" proponent Michael Gove declared that the British people were "tired of experts," a position that echoes the phrasing of William Easterly's The Tyranny of Experts. Though writing about economic development in impoverished countries rather than in Western Europe, Easterly nonetheless provides a concise formulation of the problem with the "technocratic illusion" [107]:

> By this technocratic illusion, the technical experts unintentionally confer new powers and legitimacy on the state as the entity that will implement the technical solutions. The economists who advocate the technocratic approach have a terrible naïveté about power—that as restraints on power are loosened or even removed, that same power will remain benevolent of its own accord.

Easterly's formulation articulates a view about expertise in a way that can be seen to have implications for Europe's democratic deficit: if power is zero-sum, then giving power over to the experts, bureaucrats, and regulators ("expert cultures," to use Habermas's term) means taking that power away from the average European citizen (living in the non-expertized "life world").[108] This technocratic perspective, and opposition to it, were evidenced during the most frenetic period of the refugee crisis, when a highly formulaic Commission plan for refugee resettlement quotas (even incorporating formulas based on things like GDP and population) sparked populist ire for the fact that they seemed to ignore social, cultural, and political particularities of would-be host countries

[107] Leighton Andrews, "How can we demonstrate the public value of evidence-based policy making when government ministers declare that the people 'have had enough of experts'?" *Palgrave Communications* 3, 11 (2017).
William Easterly, *The Tyranny of Experts* (New York: Basic Books, 2013).
[108] Jürgen Habermas, *Theory of Communicative Action, Vol. I: Reason and the Rationalization of Society* (Boston: Beacon Press, 1985).

– "The EU has shown itself to be limited in the face of a crisis [the refugee crisis] that revolves around identity concerns more than economic issues."[109] These ideas, all together, effectively contributed to a majority of referendum voters opting to leave the EU.[110] One need hardly look further for proof that such anti-expert and anti-EU sentiments, left unaddressed, pose an existential threat to the integrity of the European Union. It cannot be taken for granted, however, that questions of food and GMO policy necessarily translate into an issue of EU legitimacy. What, exactly, is the connection between the two?

GMOs and the Legitimacy Crisis

A large body of historical data sets the precedent that there is a strong relationship between the GMO issue and legitimacy. First, a similar situation has arisen before, when "by the late 1990s the EU GMO regulatory framework had lost legitimacy."[111] At that time, "the prevailing diagnosis in European policy circles was that the level of public trust in both food safety and food safety institutions had seriously declined and that institutional frameworks needed improving in order to restore public trust and social legitimacy."[112] The response was that "at the level of the European Union and also in a number of EU-Member States food safety institutions were subjected to review and reform."[113] These reforms, in total, moved substantially away from the technocratic, expert-

[109] "Relocation and Resettlement: EU Member States Urgently Need to Deliver," European Commission, http://europa.eu/rapid/press-release_IP-16-829_en.htm.
Uri Friedman, "The Mathematical Equations That Could Decide the Fate of refugees," *The Atlantic* (September 9, 2015).
Quote from James Caporaso, "Europe's Triple Crisis and the Uneven Role of Institutions: The Euro, Refugees, and Brexit," *Journal of Common Market Studies*, (2018): 14.
[110] Idem.
Steve Fuller, "Brexit as the Unlikely Leading Edge of the Anti-Expert Revolution," *European Management Journal*, 35 (2017): 575-580.
[111] Skogstad 902.
[112] Marion Dreyer and Ortwin Renn, *Food Safety and Governance: Integrating Science, Precaution, and Public Involvement* (Berlin Heidelberg: Springer-Verlag, 2009), 3.
[113] Ibid.

driven manner of regulatory decisionmaking to a more open model in which greater emphasis was given to legitimacy of process, appearance, and democratic legitimacy. During the 2000 European Parliament debate on EU directives for the handling of End-of-Life Vehicles, MEPs were happy to directly link inaction on the environmental matter to a loss of legitimacy for the body: several members "made the case that the EP's reputation and rule as a protector of the environment was at stake."[114]

Further, Kurzer and Cooper demonstrate the direct relation between the GMO problem and the democratic deficit, concluding that movement on GMOs demonstrates that in some regards the democratic deficit is not insurmountable to collective European civil society action, but in other regards "comitology operates without significant input from citizens and thereby exemplifies the lack of popular representation and participation at the EU level."[115]

Finally, and most directly, are the arguments of Jean-Claude Juncker himself. When, in the 2015 Plenary Meeting on GMOs of the European Parliament, Commission President Juncker proposed the comitological reforms, he stated plainly the connection to the legitimacy of the EU: "This situation creates tensions. It is highly **unsatisfactory** as it contributes to a climate of distrust against the European Union and its Institutions" [bolding in original text].[116]

To say, however, that the democratic deficit must be alleviated and therefore the comitological reforms must be enacted would be a leap in logic without first establishing a key point: why and how will these comitological reforms help assuage the democratic deficit? To answer that question, Jürgen Habermas provides a regulatory philosophical framework that helps

[114] Smith 116-117.
[115] Kurzer and Cooper 103-106.
[116] Juncker, "Opening speech on GMOs - Plenary meeting," Speech, European Parliament, Strasbourg October 28, 2015.

to make sense of this issue, providing a strong argument that democratic reforms of regulatory procedure may be both useful and necessary for alleviating the Democratic Deficit.

Habermas's Regulatory Frameworks

Jürgen Habermas has, for decades, propounded a path that the European Union would need to follow in order to secure legitimacy in the eyes of the European populace. He summarizes the "political orientations that would have to stand at the beginning of the path leading to a democratically legitimized decision on the future of Europe":

- The deepening of the monetary union into a political union
- The joining of "fiscal, budgetary, and economic policy"
- The lessening of the "legitimacy deficit" of "all international organization founded on treaties between states." This crisis of legitimacy is "exacerbated further by the fact that the negotiations are conducted out of the public eye."[117]

Habermas warns, "the only way that they [EU Member States] can maintain their social welfare model of society and the diversity of their national state cultures is through concerted action."[118] Since these steps were promulgated in 2013, the crisis of European legitimacy, and thus the need for the implementation of these steps, has only deepened.[119] Habermas notes that "What currently unite European citizens are the Eurosceptical mindsets that have become more pronounced in all of the member countries during the crisis." To illuminate the European Union's regulatory trajectory, Habermas provides a useful typology of different regulatory frameworks, thus laying

[117] Jürgen Habermas, *The Lure of Technocracy* (Cambridge: Polity Press, Cambridge, 2013), 13-17.
[118] Idem 17.
[119] For examples, see the 2016 Brexit Referendum, 2017 French Elections, 2018 Italian Elections, and the rise of populist nationalist parties throughout the EU. In a 2018 Eurobarometer poll, when asked about the rise of new parties that "protest[] against the political establishment," 56% of respondents agreed that "We need a real change and this is what these parties and movements can bring." In the same poll, 42% of Europeans felt that "things are going in the wrong direction in the EU" – a decrease from 54% in 2016, but an increase from 36% in 2014. Eurobarometer, "Democracy on the Move: European Elections – One Year to Go," Eurobarometer Survey 89.2 of the European Parliament (2018), http://www.europarl.europa.eu/pdf/eurobarometre/2018/oneyearbefore2019/eb89_one_year_before_2019_eurobarometer_en_opt.pdf

out a well-defined path towards legitimate comitology that the Juncker administration, whether intentionally or not, is already trying to walk.

Deliberative Frameworks

There are several frameworks for understanding the nature and impact of technology assessments, and regulatory policies more broadly. In his 1969 Toward a Rational Society: Student Protest, Science, and Politics, Habermas created a typology of regulatory regimes.[120] The two dominant models, according to Habermas, Decisionistic and Technocratic, represent dominant forms found throughout the EU and in various regulatory bodies, but are broadly incompatible models.

The technocratic model is one "wherein objective science is seen to directly inform policy making"[121], and assumes a general social gravitation towards empirical truth and sees regulation as merely a process of factfinding. "In technocracy, science becomes the dominant institution, because science is believed to identify the 'one best way'."[122] Habermas critiques this model for its undemocratic nature: "the reduction of political power to rational administration can be conceived here only at the expense of democracy itself."[123] He contrasts it with the decisionistic model which places emphasis on the chiefly sociopolitical choices that regulators must make based on policy goals. Owing some of its initial formulation to German law scholar Carl Schmitt (who developed decisionistic theory)[124], modern decisionism emphasizes the perceptions of legitimacy of decisions, rather than any empirically optimal content of the decisions themselves.

[120] Jürgen Habermas, *Toward a Rational Society: Student Protest, Science, and Politics*, trans. Jeremy Shapiro (Boston: Polity Press, 1991).
[121] Dreyer and Renn 29.
[122] Ibidem.
[123] Habermas (1969), 68.
[124] Paul Hirst, "Carl Schmitt's Decisionism," in *The Challenge of Carl Schmitt*, ed. Chantal Mouffe (New York: Verso, 1999).

Figure 2 – The Technocratic Model (Dryer and Renn, p. 30, from Millstone et al. 2004)

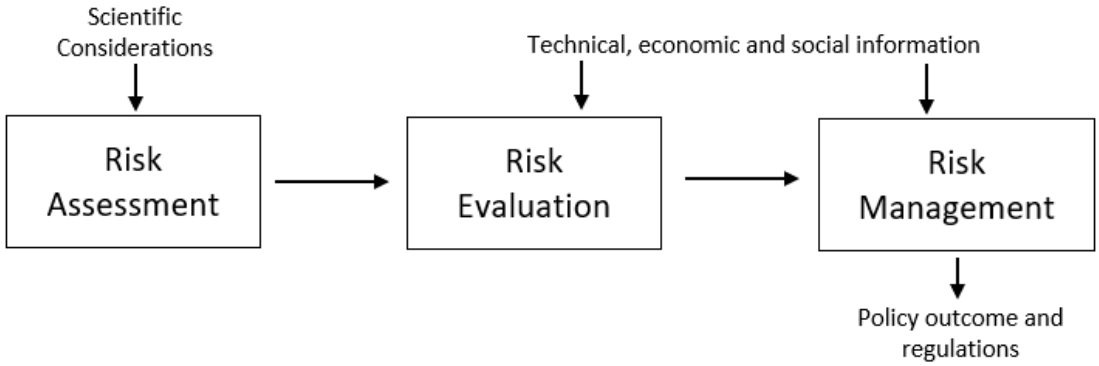

Figure 3: The Decisionistic Model (Dryer and Renn, p. 30, from Millstone et al. 2004)

To elaborate, "in the decisionistic model, politics defines values and goals, and science should deliver instrumental knowledge to achieve the goals."[125] Dreyer and Renn describe the decisionistic model as "less naïve" than the technocratic model in that it "recognised that policy making required inputs other than science in order to inform decisions, and that other legitimate factors (such as those relating to socio-political and economic objectives) needed to be taken into account in addressing risks." However, by Habermas's own typology, "the decisionistic model, however much it approximates the actual procedures of scientized politics, is inadequate according to its own theoretical claims," i.e. that publicly legitimized decisions will ultimately deliver the greatest public good. Habermas elaborates on the critique in that as modern societies are not direct democracies, ultimately "decisions themselves, according to the decisionistic view, must remain

[125] Harald Heinrichs, "Advisory Systems in Pluralistic Knowledge Societies: A Criteria-Based Typology To Assess And Optimize Environmental Policy Advice," in *Democratization of Expertise? Exploring Novel Forms of Scientific Advice in Political Decision-Making,* eds. Sabine Maasen and Peter Weingart (Dordrecht, Netherlands: Springer, 2005).

basically beyond public discussion" and that "democratic choice takes the form of acclamation" of elected officials "rather than public discussion" of the actual decisions at hand.[126] As Habermas elaborates, "everything feared by Carl Schmitt in fact happened: the sovereign power of the king has been dissolved, disembodied, and dispersed in the communication flows of civil society, and it has at the same time assumed the shape of procedures, be it for general elections or the numerous deliberations and decisions of various political bodies."[127]

Nevertheless, the appearance of public input and democratic legitimacy matters. Increasingly, policymakers "have recognised the potential value of deliberation to a healthy democratic society. Two-way collaborative engagement in its various forms is considered by some in academic and policy circles to be a kind of 'gold standard' for decision-making (Felt and Fochler 2008); and this has led to a number of key actors within these academic and policy circles to champion the cause of public engagement as an inherently good or fair thing to practice."[128] Habermas also takes a very different, perhaps consequentialist, tack against Gove's and Easterly's tyranny of the "Expert" in Toward A Rational Society, arguing that "expert-driven positivism was used by military-industrial groups as a cloak to limit public debate and reserve decisions to an agenda which they dominated under the guise of technocracy" – another strong argument in favor of the democratization of these regulatory procedures.

Habermas, then, although critiquing Decisionism as having the potential for vapidness, nonetheless would seem to prefer it to the harmful potentials of elitist technocracy, and his preference for increased European integration encompasses support for increased public

[126] Habermas (1969), 66-67.
[127] Habermas, Jürgen, "'The Political': The Rational Meaning of a Questionable Inheritance of Political Theology," in *The Power of Religion in the Public Sphere*, eds. Eduardo Medieta and Jonathan Vanantewerpen, (New York: Columbia University Press 2011), 27.
[128] Matthew Cotton, *Ethics and Technology Assessment: A Participatory Approach*, (Berlin Heidelberg: Springer-Verlag, 2014), 11.

participation and buy-in, which would most likely initially arise through decisionistic mechanisms – Habermas stresses the importance of democratic norms and a unified *demos* capable participating in the shared political project.[129] Though Habermas proposes some of his own regulatory models (discussed in the conclusion), the dichotomy between technocracy and decisionism remains a primary axis upon which EU regulatory philosophy has moved in recent years.

The EU's Regulatory Trajectory

When the EU began reforming its food safety laws in the 1990s to give greater emphasis to outward appearance and legitimacy, this move bore the hallmarks of a decisionistic model vis-à-vis the technocratic one.

Following the logic of principal-agent dynamics, the European Union and related institutions, though conceived to further the interests of individual member states, are entities with a vested interest in their own survival. From its inception until the early 2000s, the European Commission adeptly crafted and used supranational scientific institutions to expand its remit and cultivate a European network of scientists who could form part of a so-called "constituency for Europe" and thus further the public legitimacy of EU institutions. Having supported the growth of supranational scientific unification for the purposes of both its own political legitimacy and the furthering of European integration and economic competitiveness, however, has not impeded the EU, or specifically the European Commission, from withdrawing support from the scientific community when politically expedient. Institutions such as Participatory Technology Assessment and the EU's particular interpretations of the Precautionary Principle, as well as funding requirements mandating immediate public applicability of scientific advances – all of which have

[129] Habermas, Jürgen, *The Crisis of the European Union: A Response*, Translated by Ciaran Cronin, Cambridge, Polity Press (2012), 7.

come over the critiques of the scientific community - put in place substantial social and political barriers to European scientific advances.[130] Skogstad argues that the EU regulatory regime lost legitimacy in the late 1990s – since that time, EU policy makers have increasingly taken on a precautionary political culture necessary to repair that legitimacy. Skogstad elaborates, however, noting that the "EU regulatory regime incorporated elements of both the precautionary and scientific rationality political cultures in an effort to respond to internal and external accountability standards." [131] As the Juncker Commission mentions in its 2015 Better Regulations pronouncement, the EU is fundamentally a political entity that must make choices based first and foremost on their political consequences, and thus cannot be expected to rest beholden to scientific consensus when it is not politically expedient to do so. Furthermore, the EU's democratic deficit provides even stronger impetus to build political capital and public goodwill. The issue of genetically modified organisms is one that has attracted great antipathy from members of Europe's ecologically- and health-minded constituents, and as a result, heeding the calls for dismissal of Anne Glover, abolition of the post of Commission Science Advisor, and devolution of GMO policy to member state governments represents a clear way to demonstrate both "input" and "output" legitimacy of the EU as a democratic institution; in addition, any act of regulatory devolution holds the possibility of currying favor with Euroskeptics as well.

Whereas the primary EU regulatory framework was technocratic before the 1990s groundswell of public demands for regulatory participation, the EU responded by moving along the spectrum from technocratic in the direction of decisionistic, arriving in the Barroso administration at something perhaps resembling a Habermasian pragmatist regime, a hybrid

[130] See, e.g. Dryer and Renn, 61. or Sally Dalton-Brown, *Nanotechnology and Ethical Governance in the European Union and China*, (Heidelberg New York Dordrecht London: Springer Cham, 2015), 44.
[131] Skogstad 897.

structure in which public input was valued alongside scientific input as evidenced by the presence of Anne Glover as Science Advisor to the EU commissioner.

Why has the Juncker administration engaged in this shift towards a politicization of its regulatory endeavors – a shift that by definition represents and move away of a policy that is nominally "science based" in its regulation of health and safety concerns? Why did Jean Claude Juncker dismiss his science advisor for what many observers contend is based primarily on her opinions relating to GMOs?

Though expert and public consensus may have been divergent since the beginnings of the European Union, this divergence has only recently come to the fore in the discourse of European policymakers. As Habermas himself states, "the European Union owes its existence to the efforts of political elites who were able to count on the passive consent of their more or less indifferent populations as long as the peoples could regard the Union as being also in their economic interests, all things considered. The Union legitimized itself in the eyes of its citizens primarily through the results it produced rather than by fulfilling the citizens' political will."[132] As the low-hanging fruit of European integration came to be exhausted, however, as the Agent escaped the strict and limited desires of the Principals, and as the "constituency for Europe" became large and diverse enough that it began to sprout divisions and differences of opinion, the needs for greater political and social input into the European Union naturally grew. There arose a "a gulf … between the citizens' opinion- and will-formation and the policies actually pursued."[133] This was visible even over the tenure of President Juncker: whereas his earlier addresses and positions called for greater

[132]Habermas (2013), 3.
[133]Idem 4.

institutionalization and "more Europe," subsequent speeches have recognized the need to respond to dissent and difference of opinion on major policy areas.[134]

In its quest for democratic legitimacy and the need to respond to societal pressures and the concerted efforts of political actors, the European Commission has increasingly turned to regulatory structures that include more egalitarian, democratic non-expert participation. A primary example, the Participatory Technology Assessments mentioned in Chapter I, demonstrate the trend. Proponents of the practice cite the general benefits derived from more inclusive evaluation processes, and the fact that a wider panel of stakeholders can present wider perspectives on possible outcomes and externalities of new technologies. Further, the democratic deficit and declining legitimacy in the EU is on the minds of policymakers; the EU therefore has embraced need for more egalitarian participatory democracy.

The trends and debates over the structure and ideology behind GMO regulation came to a head in 2017 with the authorization process of two varieties of GM Maize. The EU Commission's inability to halt the authorization of these GMOs has resulted in several overt demonstrations of frustration, and has led to the Commission to put forward a comitology reform proposal that would be, in short, to shift comitology procedure towards a more Decisionistic regulatory model, one in which "decisions are discussed at the appropriate political level" and that is capable of "ensuring political input." As critiqued by Habermas, this Decisionistic move does little to gain any further public involvement in the decisionmaking process; rather, it merely opens the decisions to slightly

[134] In a 2015 article his 2015 State of the Union called for "more Europe" and Juncker was likened to a "tone-deaf federalist clown," though by 2017 he was calling for "multiple speeds" of European integration.
Peter Foster and Matthew Holehouse, "State of the Union: Europe in the last chance saloon, warns EU president Jean-Claude Juncker," The Telegraph, September 8, 2015, https://www.telegraph.co.uk/news/worldnews/europe/eu/11852158/State-of-the-Union-Europe-in-the-last-chance-saloon-warns-EU-president-Jean-Claude-Juncker.html
Alissa de Carbonnel and Alastair Macdonald, "Juncker says to push for EU at different speeds," Reuters, February 23, 2017, https://www.reuters.com/article/us-eu-future-juncker-idUSKBN1622GJ

greater public scrutiny and public "acclamation"; that is, citizens only feel that they are given a more active voice in the discussions since broader interest groups are involved, when in fact it may merely be the case that a greater variety of experts is involved and contact between decisionmaking and the "life-world" remains minimal.

However, the consequences of this regulatory trajectory run far deeper. Indeed, they cut to the heart of several ongoing dilemmas in regulatory policymaking, and threaten the integrity, competitiveness, and scientific legitimacy of the European Union.

Chapter IV: The Dilemmas of Reform

Two Dimensions of Dilemmas

The Juncker Commission's goals of protecting European health and responding to popular opinion may be substantive and valid reasons for implementing reforms. However, as with many public policy choices, there are tradeoffs that must be accounted for, and the Juncker Commission may be underestimating the negative externalities that are likely to result from the proposed GMO regulatory proposals. The "Regulator's dilemma" proposed by Kapstein refers to the tradeoff that exists between competitiveness on the one hand and safety on the other. "Public officials have been forced to make tradeoffs between domestic regulation on the one hand and international competitiveness on the other;"[135] that is to say, cutting regulatory corners, allowing pollution, and lowering the testing standards of new products can allow companies to maintain lower costs and be more competitive internationally. The different solutions to this dilemma have led to highly divergent regulatory outcomes in the United States and the European Union, for example, with the US by and large opting for a more economically motivated equilibrium, and the EU a more safety-oriented one; "over the last fifteen years, the EU has enacted a number of health, safety and environmental regulations which are more restrictive than their American counterparts," much to the consternation of both parties regarding bilateral trade and regulation.[136]

This regulatory dilemma has not always been a source of great international disagreement; "the successful negotiation of a common standard of adequacy of capital by the G-10 countries was due to the development of consensual knowledge regarding systemic risks, combined with decisive leadership…international coordination reflected the interplay of knowledge and power." However, for the past several decades the EU has been moving toward more restrictive regulatory

[135] Ethan Kapstein, "Resolving the Regulator's Dilemma: International Coordination of Banking Regulations," *International Organization* 42, no. 2 (Spring 1989): 324.
[136] Diahanna Lynch and David Vogel, "The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics," *Council on Foreign Relations Press* (April 5, 2001).

frameworks relative to the United States. To explain this difference in regulatory trajectories and the resulting conflicts of interest of different parties, Smith emphasizes the critical role of court decisions and industry access to regulatory mechanisms, and in addition expands the regulatory dilemma into a "regulatory trilemma" in the EU context in which EU Integration, Economic Competitiveness, and Environmental/Health outcomes represent three points of the trilemma – regulators cannot fully pursue all three at once"[137].

In the following section, several examples will illustrate the ways in which this regulatory trilemma applies to the current case of GMO regulations; specifically the Juncker Commission's plans to move regulation in the direction of greater health and safety-inspired restrictions would come at the cost of both EU integration (threatening the Single Market) and external economic competitiveness (embroiling the EU in a new round of WTO disputes and deterring biotechnology progress).

Moreover, the following examples will illustrate that alongside the regulator's dilemma or trilemma, when public opinion diverges significantly from scientific opinion, there is an entirely different dimension at work: that between public legitimacy on the one hand and scientific legitimacy on the other. In pursuing this regulatory course, the Juncker Commission is willing to sacrifice scientific input and the advice of the scientific community for the sake of political legitimacy – a classic example of a Schumpeterian Public Choice dilemma that illustrates the hot button conflict between technocracy and democracy.

European Integration: The Single Market

One corner of the Regulator's Trilemma is the drive for EU integration; the Juncker Commission's proposals would devalue that goal for the sake of more tightly regulating GMOs.

[137] Smith, throughout.

Although "the Commission suggested that this proposal should be modelled on another EU law, on GMOs intended for cultivation, which entered into force in early April 2015," such a parallel is spurious, for the two processes are substantially different: cultivation takes place entirely within the territory of one country, and physical territory cannot blend into a multinational institution.[138] The Single Market, however, is a multinational institution at the very core of European Union policy. The 1978 European Court of Justice case *Rewe Zentral AG vs. Bundesmonopolverwaltun für Branntwein*, more popularly known as the "Cassis de Dijon" case, established that any national laws that "have effects equivalent to those of quantitative restrictions" are in violation of the EEC Treaty "as they directly affect the establishment or functioning of the common market."[139] As the European Parliament news release noted following the 2015 vote, "whereas cultivation necessarily takes place on a member state's territory, GMO trade crosses borders, which means that a national "sales and use" ban could be difficult or impossible to enforce without reintroducing border checks on imports."[140] Parliament Rapporteur Giovanni La Via recapitulated the nature of the vote: "Today's vote gave a clear signal to the European Commission. This proposal could turn on its head what has been achieved with the Single Market and the customs union."[141] Although it is worth considering that there are currently opt-outs on health and safety grounds in the European Union, it is worth considering that such health and safety exceptions constitute narrow ranges of products, whereas GMO goods represent entire industries and regional products.[142] In 2017, Spain's cultivation of GM crops topped 120,000 hecates, or 1,200 square kilometers; possibly

[138] "Parliament rejects national GMO bans proposal," European Parliament, http://www.europarl.europa.eu/news/en/press-room/20151022IPR98805/parliament-rejects-national-gmo-bans-proposal
[139] "Judgment of the Court of 20 February 1979," EUR-Lex, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61978CJ0120.
[140] Ibid.
[141] Ibid.
[142] "Free movement of goods," European Parliament. http://www.europarl.europa.eu/factsheets/en/sheet/38/free-movement-of-goods

much larger (though there is no data either way) is the scale of EU-wide production of processed foods that may incorporate GM inputs.[143]

Perhaps most significantly, these proposed border controls come at a time when Europe's principle of open borders, and the integrity of the Schengen Area, are under duress due the migration controls imposed during the refugee crisis; in September 2015, a World Economic Forum reported gave consideration to the question "is this the end of Schengen?" with many other scholars and commentators sharing in the concern.[144] Several Member States have imposed migration-related border controls continuing at least through November 2018.[145] A one-two punch of migration controls along with customs and Single Market restrictions would be a serious blow to the integrity of the principle of the EU's Four Freedoms – free movement of goods, services, capital, and persons. If movement of persons can be restricted in a migration crisis, and movement of goods can be restricted for health concerns, would it not be justified to impose capital controls in the event of a new financial crisis, or to halt recognition of foreign professional licensing in order to ensure quality services for consumers? Simply put, norms and precedents matter (to wit: the internal Schengen controls were initially proposed as temporary emergency measures but have now been in effect for three years), and restriction of movement of persons alone is already

[143] ISAAA, 83

[144] Stephanie Thomson, "Is this the end of Schengen?," *World Economic Forum* (September 16, 2015), https://www.weforum.org/agenda/2015/09/is-this-the-end-of-schengen/.
Cyrille Fijnaut, "The Refugee Crisis: The End of Schengen?," *European Journal of Crime, Criminal Law, and Criminal Justice* 23, no. 4 (November 2015): 313-332.

[145] "Temporary Reintroduction of Border Controls," European Commission, Last Updated November 11, 2018, https://ec.europa.eu/home-affairs/what-we-do/policies/borders-and-visas/schengen/reintroduction-border-control_en. Several controls were set to expire November 11, 2018, but others continue until at least December: "Member States' Notification of the temporary reintroduction of border control at internal borders pursuant to Article 25 et seq. of the Schengen Borders Code," European Commission, https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-we-do/policies/borders-and-visas/schengen/reintroduction-border-control/docs/ms_notifications_-_reintroduction_of_border_control_en.pdf. Retrieved November 11 2018.

precipitating a crisis of faith in the European project; adding to it with a restriction in the Single Market could be highly deleterious to European integration.

Economic Competitiveness: The WTO and Biotech Investment

A second point on the Regulator's Trilemma is the drive for economic competitiveness; unfortunately, this, too would take a blow for the sake of increasing GMO regulations. In addition to the endogenous factors compelling the Commission not to undertake the reforms, there is an exogenous reason: the negative consequences of trade protectionism. While the precautionary principle and democratic legitimacy may be sufficient reasons from an EU perspective to allow member states to prevent the marketing of GMOs on their territories, international actors tend to view things differently. From the perspective of the WTO, trade protectionism is about ends, not means. The question of trade protectionism has little to do with the reasons countries or trade blocs may put certain policies into place, but rather those policies have effects: a health-related policy, not backed by sufficient scientific evidence, that has the effect of serving as a trade barrier is as much a trade barrier as a tariff explicitly conceived as such.[146]

Through its Dispute Settlement mechanism, the World Trade Organization arbitrates international trade disputes brought before it by complainants. Though the European Commission's proposed reforms are neither approved nor tested, there is little need for idle speculation on the matter of a WTO verdict on their potential trade-limiting effects; indeed, the WTO has already ruled on such a case. In 2003, the United States, supported by Canada and

[146] "US – Poultry (China)," World Trade Organization, One-page summary last updated November 8, 2010. https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds392sum_e.pdf

Argentina, lodged an official complaint with the WTO alleging that the European Communities "has applied a moratorium on the approval of biotech products…the approvals moratorium has restricted imports of agricultural and food products from the United States." The complaint further held that "the member States maintain a number of national marketing and import bans on biotech products even though those products have already been approved by the EC…The national marketing and import bans have restricted imports of agricultural and food products from the United States."[147] Though the European Communities "categorically denied the existence of such a moratorium," the panel ultimately found that such a moratorium indeed existed, and accepted the parties' requests to work outside the WTO framework toward a mutually agreeable solution.[148] However, although some loosening of EU regulatory framework has occurred, the dispute has not been officially closed; as of the most recent update to the dispute, dated July 10, 2018, "the European Union remains ready to continue its discussions with the United States with the goal of resolving this dispute and related issues."

The ongoing WTO dispute, the possibility of renewed WTO complaints by the United States and other exporters of GMO agricultural goods, and the demonstrated willingness of the United States (under the Trump administration) to implement tariffs on the EU, all serve as significant inducements for the EU to loosen its *existing* regulatory stance on GMOs and other biotech products. The possibility of this regulatory framework being reformed in a way that would not loosen but rather *tighten* the regulatory process and serve as an even more impenetrable trade barrier should be examined with the utmost caution. A regulatory regime that would effectively

[147] "Dispute Settlement DS291: European Communities — Measures Affecting the Approval and Marketing of Biotech Products," World Trade Organization, Retrieved September 2018. https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm,.
[148] Ibid.

devolve the approval process for GMOs to Member State governments would create a host of new possible disputes between countries such as the United States and individual EU members states.

Beyond the WTO angle, an increasing restriction in GMO sales in production would be disastrous for the EU's competitiveness in the biotech sector and jeopardize the EU's "Europe 2020" goal of transitioning to a knowledge based economy. To put this in a global perspective, Chinese investment in biotechnology is soaring, with $5.1 billion invested in US biotech firms in the first half of 2017, and the Chinese biologics market expected to grow 16% by 2021, compared to only 6% for Europe and 9% for the United States.[149] The number of biotechnology firms in Europe is only 71% that of the United States, despite a larger overall population and economy. Although the connection with GMO policy is difficult to demonstrate directly, it is worth noting that the plurality (33%) of those firms are located in GMO-friendly Spain, despite its contributing only one tenth of the EU's total population and a fraction of the overall GDP of the EU.[150] In short, Europe's biotech sector is dangerously close to falling further behind the leadership of American, Chinese, and other firms. Or, as scathingly encapsulated by a agricultural industry group, "The EU regulatory system is increasingly based on hazard and the precautionary principle rather than risk, in contrast to regulatory bodies in other regions. This has resulted in fewer crop protection products and GM seed varieties being available to farmers in the EU, as opposed to other regions such as the USA and Brazil. This situation also makes the region less attractive as a focus for private

[149] Investment figure: Tom Hancock, "Chinese investment into US biotech start-ups soars," *Financial Times* (July 1, 2018).
Growth figure: "China's Biotech Revolution," UBS Chief Investment Office, https://www.ubs.com/global/en/wealth-management/chief-investment-office/our-research/discover-more/2017/china-biotech.html, retrieved August 2018.
[150] Firm figures: "Biotechnology Indicators," OECD, https://www.oecd.org/sti/inno/keybiotechnologyindicators.htm
GDP and Population figures: "World Bank Data Tool," World Bank, https://data.worldbank.org/.

companies' research and development."[151] More generally, there is a perception that Europe is slipping away from leadership in science and technology, with increasingly stringent restrictions on telecommunications or private data recently. "You see in Europe the idea that technology's *against* us, and we should resist this rather than embrace it. A very negative spirit, which I think is a good example of how adventure has disappeared from the European psyche," surely not an attitude conducive to economic growth and competitiveness.[152]

The Second Dimension: Public Choice

The above sections demonstrate how a more restrictive regulatory regime for GMOs would be harmful on the grounds of both EU integration and global economic competitiveness. The comitological and regulatory reforms proposed by the Juncker Commission aim to solve a cluster of related problems. Aside from resolving the committee deadlocks that have gripped EU GMO regulatory proceedings for years, the reform would also respond to the pressure of interest groups and the expressed opinions of large portions of the European populace regarding GMOs, as well as set a precedent of increased democratic and participatory input in health and safety regulations, helping to alleviate some elements of the EU's longstanding democratic deficit. Those goals, namely the last, are highly important for the continued legitimacy of European institutions, and steps must be taken to resolve them before discontent festers and environmental groups and green parties find common cause with Euroskeptic nationalists.

[151] AgbioInvestor, "The challenges facing agriculture and the plant science industry in the EU," https://www.europabio.org/sites/default/files/Agbioinvestor-report-press-releaseF_0.pdf.
[152] Bruno Maçães, "Bruno Maçães on the Spirit of Adventure," interview with Tyler Cowen, *Conversations with Tyler*, Mercatus Center at George Mason University, September 26, 2018, 14:57.

However, there are numerous reasons why the reforms have not been implemented, and indeed would result in several difficulties if implemented in their present form. First, scientific opinion diverges significantly from popular opinion on the matter of the safety of genetically modified foods, setting the conditions for a so-called Schumpeterian "public choice dilemma." Second, by allowing internal prohibitions on the sale of GMOs, the EU risks sacrificing economic competitiveness in biotechnology, as encapsulated in the so-called Regulator's Dilemma – a position that continues to be prohibited by WTO rulings in an ongoing trade dispute with the United States. Further, devolution could represent a watershed moment of using subsidiarity to avoid a compromise solution at the EU Commission level, threatening to undo decades of regulatory harmonization and EU-wide standardization. Even the fundamental principle of the Single Market could be under threat if GM products are allowed to be blocked from the market in some EU countries and not others, with the specter of a WTO dispute involving several European countries. When combined with the previous Regulator's Dilemma, this option has major implications for the European Regulation Trilemma as encapsulated by Smith.

The Crisis of Public Choice

The introduction touches on Giovanni Tagliabue's criticism of EU GMO regulatory policy as a Public Choice dilemma. An examination of the concept of Schumpeterian Public Choice explains what Tagliabue means with this so-called dilemma. According to Mitchell (1984), Dennis Mueller delivers the accepted definition of Public Choice: "…the economic study of nonmarket decision making, or simply the application of economics to political science… The basic postulate of public choice, as for economics, is that man is an egoistic, rational, utility maximizer."[153]

[153] William C. Mitchell, "Schumpeter and Public Choice, Part I: Precursor to Public Choice?" *Public Choice* 42, No. 1 (1984): 73-88.

Schumpeter's contribution to the field is pivotal. In the conceptualization of Mitchell, Schumpeter was purely critical of the role of the individual in making optimal decisions on matters of public affairs; whereas in matters of labor or finance in which the individual was forced to place his livelihood or reputation on the line, in formulating opinions on political issues the average person was content to build his beliefs and positions in affective, emotional, and illogical foundations:

> "… the prime minister in a democracy might be likened to a horseman who is so fully engrossed in trying to keep in the saddle that he cannot plan his ride, or to a general so fully occupied with making sure that his army will accept his orders that he must leave strategy to care for itself."[154]

In short, Schumpeter felt that democratic involvement meant that policy decisions became subordinated to political decisions – that responsibility to pleasing the people, remaining in office, and preserving public perceptions in front of people who might not understand the issues was invariably bound to become more important than fine-tuning the perfect policies which might ultimately result in "better" outcomes for the people.

And indeed a rift has opened in recent years between popular conceptions and "elites'" opinions on GM food. In David Toke's "The Politics of GM Food," the editors' note points out that "Over recent years environmental politics has moved from a peripheral interest to a central concern within the discipline of politics."[155] Writing in 2007, Kurzer & Cooper saw the GMO issue in very simple Expert-Populous terms: "While the Commission is keen to normalize the commercialization of biotechnology foods and crops, European consumers refuse to eat/buy products containing genetically modified organisms (GMO) and have effectively closed the market to GMO." [156] What Tagliaube means to say, therefore, in describing GMO policy as a series of

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[154] Joseph Schumpeter, *Capitalism, Socialism and Democracy* Third Edition (New York: Harper & Brothers, 1950), 261-262.

155 David Toke, *The Politics of GM Food: A Comparative Study of the UK, USA, and EU* (New York: Routledge, 2004), ii.

156 Kurzer and Cooper, 103.

Schumpeterian public choice decisions, is that regulators must balance science-driven policy on the one hand and political-driven policy on the other - and then argues that they are balancing in the wrong way.

The Schumpeterian view is a pessimistic one, essentially painting a portrait in which policymakers must choose between what is popular and what they consider to be good policy. This is not to say that such prioritization is irrational; elected officials in democratic societies have every reason to listen to their constituents and respond to their desires. Schumpeter's concern, rather, is the extent to which democratic choice-structures encourage elected leaders to respond to popular desires which may be out of tune with expert consensus or "good policy"; the possibility of a divergence of good policy from popular policy has been recognized by philosophers and politicians since ancient times.[157] However, this dilemma is not without hope for the modern liberal democratic state, and leaves a bright spot of central importance to this investigation. Schumpeter advocated one force in government to counteract the "populist" tendencies of elected political leaders: a strong bureaucracy capable of moderating democratic vicissitudes. "Bureaucracy is the main answer to the argument about government by amateurs …[it] must be strong enough to guide and, if need be, instruct the politicians who head the ministries…It must be a power in its own right."[158] However, the question of the relative power of democratic input versus professional bureaucratic expertise is the crux of the discussion that remains unresolved since the mid-20th century: the choice between technocracy and democracy.

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[157] See Plato, *The Republic* (Athens: Self, ca. 380BCE); Niccolò Machiavelli, *The Prince* (Italy: Antonio Blado d'Asola, 1532); James Madison and Alexander Hamilton, *The Federalist Papers*, (esp. "No. 51") (The Independent Journal, New York Packet, The Daily Advertiser, J & A McLean, 1787-1788); or Alexis De Tocqueville, *Democracy in America (*London: Saunders and Oatley, 1848).
[158] Schumpeter, 293.

The Advocacy Coalition Framework Response

Work on the role of coalitions in policymaking stands counter to such a simplistic and binary division between "elite" and "popular" views, or even between policymakers and constituencies. To the former dichotomy, through coalitions, "elite" and "popular" views exist together in advocacy networks which influence and draw from each other and organize around a particular set of issues. To the second dichotomy, "although brokers and sovereigns are separated analytically, it is often difficult to know where coalitions end and policy-makers begin, since governmental organizations may often appear to hold, and act on, beliefs consistent with those of a particular advocacy coalition."[159] In this case, it is possible that President Juncker, rather than simply "choosing" between a "popular" and an "elite" policy preference, may be allied with or part of the Anti-Biotech coalition (at least on the issue of GMOs) and as such may favor, or may assign greater weight to the arguments for, tighter GMO regulations. However, as discussed in Chapter I, the ACF may not adequately model the relatively apolitical scientific community; in particular, given the clear message and position of national and EU-wide scientific bodies on the subject of GMO regulation, there does exist a sufficiently stark division between the a majority policy preference of EU citizens and a policy preference of the scientific community to model this division as a Schumpeterian Public Choice dilemma. Further, even if coalitional behaviors do dominate the policy preference of both groups, there is still an important matter to be decided: what should the relative weight be between the interests of subject matter experts and non-specialist citizens--or in this case between science or politics?

[159] Cairney, 486

Technocracy Versus Democracy

The struggle between whether science or democracy should have the upper hand in regulatory decisionmaking has only been succinctly laid out in the past few decades. "Jasanoff (1990) talked about how the debate about the role of science in regulation had been polarised between those arguing from a 'democratic' viewpoint who saw scientists as making a distorted contribution to regulatory outcomes and those arguing from a 'technocratic viewpoint' who argued that only scientists made, or should make, regulatory judgements."[160] While this is a new conceptualization, it is only a recent reincarnation of an extremely old debate: that between the wisdom of the crowd and the insight of the Expert. Schumpeter, writing from a rationalist, positivist perspective, had the naive luxury of writing before the onslaught of structuralist constructivism in the mid 20th century. As historian of science Thomas Kuhn demonstrated in his seminal 1970 work On the Structure of Scientific Revolutions, science is and has always been a politicized tool inseparable from the sociopolitical perspectives in which it is implemented. But just as Kuhn demonstrates that the nature of science changes drastically given social, political, economic, and technological contexts, so too must the nature of the political and governmental apparatuses that employ them also change. Whereas even in the mid-20th century, allowing public input into the regulatory decisionmaking process entailed a high bar in terms of access and connections to the forums of such decisionmaking, as well as difficult technological and communicational hurdles in terms of creating nationwide interest groups around narrow regulatory issues, the nature of modern mass communication and civil society allows massive networks of grassroots activism to drive agendas and spread particular viewpoints to a degree that was difficult

[160] Toke, 31.

in earlier decades in Western regulatory states.[161] "Kuhn's discussion of scientific communities also appears to signal an important way in which his 'paradigm' approach may, at first glance, not be compatible with the study of GM crop and food regulatory discourses. This is because the composition of the scientific regulatory committees is designated precisely by the political mechanisms which Kuhn proscribes." [162]

Winterfeldt advocates a diplomatic approach in seeking a unification of scientific knowledge and political decisionmaking. "Science can and should help decision makers by shaping their beliefs. Unfortunately, science is not easily accessible to decision makers, and scientists often do not understand decision makers' information needs." [163]

However, the rift between the two realms of science and policy may be deeper than a simple informational gap. Indeed, "science and democracy operate within distinct value-spheres that are not necessarily consonant with each other."[164] That is to say, scientific evidence is not subject to democracy, and introducing democratic input into scientific questions of truth is not necessarily a productive enterprise likely to arrive at a greater or broader truth. "There are doubts," reasonably, "whether it is possible to combine the scientific and participatory components of the TA [technology assessment] process without weakening the scientific part of it." [165] In his book Ethics and Technology Assessment, the culmination of research work involving funding by both UK and

[161] Josep-Lluís Micó and Andreu Casero-Ripollés, "Political activism online: organization and media relations in the case of 15M in Spain," *Information, Communication & Society* 17 (2014).
Martin Gurri, *The Revolt of the Public and the Crisis of Authority in the New Millennium*, Stripe Press (2018).
[162] Toke, 35.
[163] Detlof Winterfeldt, "Bridging the gap between science and decision making," *Proceedings of the National Academy of Sciences* 110 (August 20, 2013).
[164] Tlili and Dawson.
[165] Michael Decker and Miltos Ladikas, "Optimising the Impact of Future-Oriented Technology Analysis; Methodological Foundations," Seminar, EU-US Seminar: New Technology Foresight, Forecasting & Assessment Methods, Seville (May 13-14, 2004), http://foresight.jrc.ec.europa.eu/fta/papers/Session%201%20Methodological%20Selection/Optimising%20the%20Impact.pdf

EU institutions, professor Matthew Cotton notes that "Though there are those that see PSE [participatory scientific evaluation] as an inherently good thing due to the emphasis on decentralised power structures and civic empowerment, to some critics public participation in technology decision-making leads to control by public sentiment, leading to the detriment of scientifically defined safety"[166] Cotton notes that the emphasis on the "expert" decision-maker is the result of an ideology of "*administrative rationalism*" in which the "role of the expert is placed in primacy in social problem solving, and where social relations of hierarchy are stressed over those of equality of competition"; he concludes, however, that "if science and engineering-based criteria come under attack, this would be detrimental to the success (and safety) of any given design and so, perhaps ironically, citizen involvement would not be in the public interest." Placing the participatory technology assessment at the center of regulatory policy affords scientists a more marginal role influencing what is ultimately a test of perception and rhetoric.

Thus, there exists substantial literature that problematizes the democratization of regulatory decisionmaking, and the EU's increasing resort to such mechanisms may be based on a false "assumption of a 'higher wisdom' of lay knowledge" deriving from particular pluralistic faith in constructivist worldviews, which is arguably incompatible with the structure of scientific decisionmaking. The convergence of unrelated factors in popular discourse and in the collective consciousness can drastically impact the route of participatory regulatory decisionmaking. One particularly stark example was the way in which rbST, a milk production hormone approved for, and in wide use in, the US dairy industry, came into EU regulatory questioning at the same time as the "introduction of milk quotas and widespread concern in Europe with the use of hormones in meat," as a result of which "scientific evaluation gave way to political debate and socioeconomic

[166] Cotton, 11.

imperatives," ensuring that "rbST was never likely to be licensed."[167] To better illustrate the application to GMOs, "The European directive on GMOs (European Communities, 2001, Article 4) states: 'Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs'. The directive leaves open what precisely can be considered as an 'adverse effect on human health and the environment'. The directive also leaves open what could be 'a sufficient demonstration of safety', let alone that it defines the degree of uncertainty which could justify restricted use or a ban of a particular GMO."[168]

Two competing views of the role of democracy in regulatory decisionmaking then seem to dominate, distilled down to differing answers to a central question: does democratic input introduce, or does it prevent the introduction of, political priorities into the scientific evaluation process? Critics of democratic input argue that opening up regulation to participatory technology assessment and political oversight impedes the attainment of purely scientific conclusions: "there, obviously, exist tensions between public legitimization needs (insulating science from policy) and practical action requirements."[169] Proponents of democratic input argue that there may already be unknowable amounts of political and ideologic input going behind closed doors in the regulatory laboratories, and that opening these processes up to democratic scrutiny shines light onto an otherwise surreptitious affair: "The BSE crisis was interpreted as a result, at least partly, of a regulatory regime marked by a non-transparent intermingling of the roles of assessment and management, and of scientific and non-scientific consideration" and "safeguarding scientific

[167] Claire Dunlop, "Up and down the pecking order: what matters and when in issue definition: the case of rbST in the EU," *Journal of European Public Policy* 14, no. 1 (January 2007): 42.
[168] Tickner and Kriebel, 32.
[169] Dreyer and Renn 21.

analysis against distortion by inappropriate policy influences and considerations is intended to re-establish and assure the credibility of risk assessment activities and results on which risk management decisions are to be based."[170]

To recapitulate**, t**he implications of this age-old debate on the current question of comitological and regulatory reform are significant. The proposed reforms would continue an ongoing trend of reducing the role of scientific input vis-à-vis simple political majorities and non-scientific input into regulatory affairs. There are, of course, strong arguments in favor of such a reform, but as demonstrated above there is substantial reason to be wary. To repeat the warning of Cotton, "if science and engineering-based criteria come under attack[…]perhaps ironically, citizen involvement would not be in the public interest."[171] On the other hand, scientists must embrace the idea that "influence requires persuasion and that hierarchies of evidence are not relevant for policy-making" – i.e., science and engineering-based criteria do not legislate themselves.[172]

[170] Idem., 17-18.
[171] Cotton, 11.
[172] Brooks, 13.

Chapter V: Resolutions and Conclusions

Resolutions and Conclusions

The regulation of genetically modified organisms thus poses a quandary for European institutions. On the one hand, a stable and active majority of EU citizens is generally opposed to GMOs, a plurality of member state governments represents their cause, and EU Commission President Juncker has made clear that the status quo is undemocratic and threatens to undermine the legitimacy of European regulatory bodies at a nadir of popularity. On the other hand, the reforms proposed by the Juncker Administration threaten to either dilute scientific input into the regulatory process or to erode the Single Market; and either reform would open European member states to a series of WTO trade disputes that they seem, based on recent historical precedent, likely to lose.

Though the argument in favor or legitimacy is a strong one that must be responded to (to be discussed below), the dangers of enacting the Commission's proposed reforms – flagging economic competitiveness, new trade disputes with close allies at a time of rising geopolitical tensions, and a deepening culture of opening scientific regulatory processes to lay involvement that may increasingly privilege protection over innovation – collectively pose a greater danger to the long-term success of the European project. As the Group of Chief Science Advisors of the European Commission remind us, "there is danger that unless the EU improves the regulatory environment for products of gene-editing, it will be left behind in this field, which could also diminish EU influence on ongoing debates at the international level with respect to specific applications and regulatory processes." Further, as Kurzer and Cooper note, as GMO cultivation and innovation continue across the rest of the world, it may be that the European Union as a net food importer will be forced to pay higher prices for rarer and rarer non-GMO crops, driving the neutral consumer out of any fellow feeling with the anti-GMO coalition, ultimately making the current regime a pyrrhic victory for the coalition.[173] Indeed, based on the

[173] Kurzer and Cooper, 103

complete lack of traction that Commission proposals have received in the EU parliament, with the 2015 "opt-outs" proposal having languished at Parliament's door for three years, the status quo seems to be the most likely outcome for this conflict.[174] Though government must strive generally to respond to popular sentiments and the impact of transparency and multidisciplinary input on the quality of policymaking must not be understated, there are circumstances (such as Brexit) in which citizens may popularly desire something in the short term without fulling understanding or supporting the long-term negative externalities that may result from the feasible implementations thereof; in those circumstances, as Schumpeter conceptualizes, it may fall to apolitical bureaucracies to provide a countervailing opinion in favor of the long-term best interests of the polity. Though the authoritarian possibilities inherent in that perspective are worrisome, so too are the possibilities of a democratic populism that rejects scientific consensus and does not contemplate long-term consequences of policy preferences. The vox populi alone cannot reshape the structure of international trade agreements or alter the results of scientific studies.

However, as discussed in Chapter III, the status quo runs the risk of allowing an ongoing legitimacy crisis to fester (the far-right Alternative für Deutschland has already adopted an anti-GMO position, possible seeking common cause with anti-GMO activists against European regulation) and an outright concession on the part of President Juncker would earn a swift rebuke from the anti-biotech coalition, who have already criticized him for even slight moderation on the issue.[175] Thus, there are some immediate options the Juncker Regime could adopt to increase transparency into the authorization process without actually altering the structure of the process in

[174] Peter Teffer, "Commission and council dig in on GMO opt-outs," *EU Observer* (January 17, 2018), https://euobserver.com/institutional/140583.
[175] "Natur | Agrar | Verbraucher," Alternative für Deutschland, https://www.afd.de/umwelt-agrar-verbraucher/ "Juncker breaks promise to make EU GMO decisions more democratic," *Greenpeace Website* (April 22, 2015), https://www.greenpeace.org/eu-unit/en/Publications/2015/Juncker-breaks-promise-to-make-EU-GMO-decisions-more-democratic/.

a way that reduces the role of scientists: making public the results of comitology proceedings, and altering the requirements of the EFSA safety studies. First, the proposal by the Commission to disclose the vote totals of the committee that oversees GMO authorization should be implemented.[176] By revealing how Member State representatives vote, skepticism at the opaque nature of reform could be alleviated even without having a direct impact on the votes themselves. Second, there is an opportunity to improve the transparency of the EFSA risk evaluation process: by opening to scrutiny or public research the health and environmental studies submitted as part of the application process. As it stands, an entity applying for GMO authorization (namely, a biotechnology company or research institution) submits its own studies on health and safety, which are then scrutinized by the EFSA and the member state acting on behalf of the applicant.[177] Though all such materials are available for viewing on the EFSA website and public commentary is solicited, it is unclear how the commentary is used, if at all. Rather, this process could be democratized or transparentized by requiring public European universities or institutes to conduct peer review processes on all applications, or opening such studies to crowd review. Further, the fact that proprietary company data is sometimes not disclosed in these regulatory proceedings is something that should also be reformed: even if scientific review finds a GMO safe for human consumption, any consumer should have a right to knowledge about the nature and effect of a genetic modification.

If stricter GMO regulations do go into place, however, it merits thinking through how to minimize the unwanted consequences. Though several options exist, a few are immediately salient:

[176] Commission, "Commission Proposes More Transparency".
[177] EFSA, "EFSA's Role in the GMO Regulatory Framework," https://www.efsa.europa.eu/sites/default/files/assets/gmoauthorisation.pdf

softening or scaling back the nature of GMO opt-outs, accepting or finding creative settlements in a WTO dispute, or renegotiating WTO rules regarding GMOs.

First, there is the possibility of the Commission recalibrating its opt-outs proposal to allow member states to ban GMOs on their territories, but limit the ways in which these bans can be enforced so as to minimally impact the functioning of the common market. Stipulations could be created that would prevent border screenings or any other impediment to freedom of movement of goods or persons, limiting enforcement of GMO bans to mild civil actions at the level of individual companies for selling GM products. Though this streamlined proposal might be more palatable to a sufficiently large portion of the Parliament, it runs the risk of incensing new parties, such as free trade advocates, Eurofederalists, and others strong opponents of internal European borders, without placating the anti-biotech coalition to any significant degree. At the very least, such a move would elicit an outcry from major GMO growers such as Spain and Portugal, as well as coalitions of scientists and biotech companies and supporters.

Second, there is the possibility that the commission could eventually pass its proposed comitological reform and continue/resume the moratorium on GMO approvals, come what may from the WTO. Though the likelihood of retaliation and defeat is high (the previous dispute is technically still unsettled; trade negotiators have had larger issues to contend with in recent years), losing a trade dispute is not a fatal blow, and countries routinely find creative settlements that allow both parties to preserve their own priorities. For example, when Brazil won a trade dispute over US cotton subsidies, the Bush administration negotiated a $300 million payment to a Brazilian cotton trade group.[178] The EU commission can decide whether such an economic outlay is balanced by the political gains of a renewed moratorium on GMO approvals.

[178] "United States – Subsidies on Upland Cotton: Notification of a Mutually Agreed Solution," World Trade Organization, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds267_e.htm.

Third, if a reform like the above could be passed, the EU has the possibility of seeking a renegotiation of WTO rules regarding GMOs. Though there is some international traction on this issue, with Russia being one of the largest non-EU supporters of limiting the prevalence of GMOs, international reception of GMOs remains large and growing, with Brazil, China, the US and Canada among the largest proponents, and roughly 190 million hectares (more than the entire arable land area of the US) currently planted with GMOs.[179] Considering the already fraught process of WTO trade round negotiation (the current Doha round has been inconclusive for 17 years), this presents a daunting challenge.

However, the question of GMOs, put into the larger global context, forces us to ask some difficult questions. What should policymakers do when the desires of the people contradict the views of scientists, of international trade law, or of deeply held organizing principles? Posing the question and providing answers are very different prospects, however. In terms of regulatory structure, though, the Technocratic and Decisionistic models may seem to be at opposite ends of a one-dimensional spectrum, there do exist other regulatory structures that integrate public and expert input in different ways. One example is Habermas's synthesis, the Pragmatist model, in which values are assessed in function of their feasibility and scientific knowledge is assessed in function of its sociopolitical implications – essentially a fusion of the other two models.[180] Habermas's model is "a significant theoretical attempt to preserve both rationality and democracy at the level of political decision making that transcends both technocratic and decisionistic theories of rationality"[181] "Pragmatism finally is, according to Habermas, a middle way, in which science

[179] Shawn Dorius and Carolyn J. Lawrence-Dill, "Sowing the seeds of skepticism: Russian state news and anti-GMO sentiment," *GM Crops & Food* 9 (2018): 53-58.
"Global Status of Commercialized Biotech/GM Crops in 2017," ISAAA, https://www.isaaa.org/resources/publications/briefs/53/.
[180] Hennen, Leonhard, "Why do we still need participatory technology assessment?" *Poiesis Prax* (2017): 27–41
[181] Nader Saiedi, "A Critique of Habermas' theory of Practical Rationality," *Studies in Soviet Thought 33* (1987): 1.

and politics have an interdependent, discursive relationship and values and knowledge can be related effectively to each other."[182]

Alternatively, "the *transparent* model […] views scientific and socio-political factors as intertwined throughout the process of policy making and communication, with reciprocal links between science and policy, and recognises the input of various actors at each stage in the process."[183]

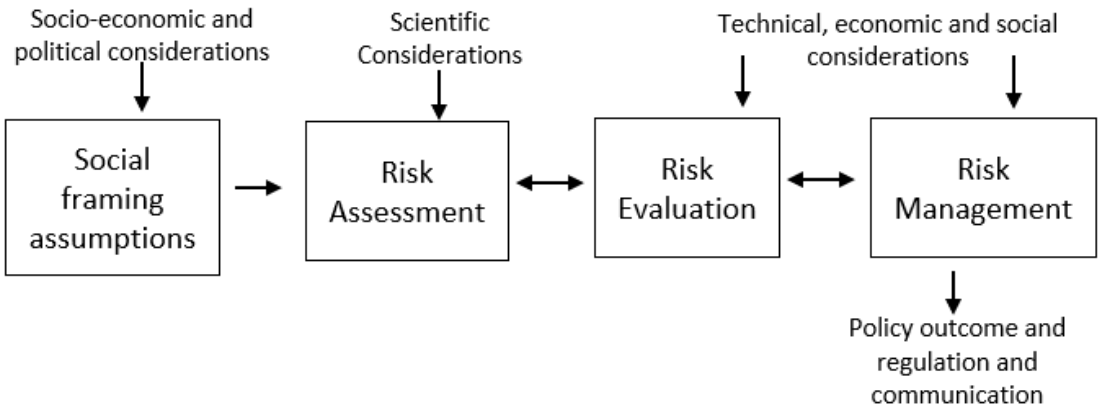

Figure 4: The Transparent Model (Dryer and Renn, p. 31, from Millstone et al. 2004)

In other words, the Transparent model gives both science and democracy their full hearing, equally and in dialog with each other, able to respond and articulate decisions in light of the opinions of the other. The emphasis, as the name would suggest, on "transparency" prevents the accusations of closeted malfeasance that have proven problematic for the technocratic model in the past – while the fact that scientific considerations and input are recurrent prevents the accusations of the politicization of science that seem to detract from the Decisionistic model, and

[182] Heinrichs.
[183] Dryer and Renn, 31.

serves to maximize "input legitimacy." These models are, however, only models, and attempting to integrate their principles into actual comitological proceedings would be easier said than done.

Further, and perhaps most importantly, the literature on Coalitions provides excellent advice on how scientists may go about better translating their views into policy: "'Practitioners who expect their analysis to have an independent and influential role in shaping policy in contexts of this sort are likely to be met with disappointment' […] Researchers must respond to calls for pluralistic and collaborative approaches to knowledge production at the intersection of public health and political science particularly as concerns the policy-making process."[184] This is to say, scientists in public health cannot rest on their laurels and expect the quality of experiments and material data to magically be implemented into policy. Rather, they too must play the game of politics and influence via publicizing data, acquiring allies, and forming coalitions around their science-backed policy views. So, too, must proponents of science-backed policy ally with scientists in understanding, advocating, and disseminating these views.

Implications

The issues raised in this investigation are not likely to dissipate soon. They primarily deal, like this thesis, with two themes: the political institutions of the European Union, and the interaction between science and democracy.

To the former, the GMO issue is one more piece of evidence that the institutions of the European Union are in limbo between the national and the supranational. As Habermas notes, political community, political power, and political culture "come together in a congruent fashion only at the national level" even though the national governments are bound within higher

[184] Brooks, 13

institutions.[185] As evidenced by the intractable division between governments on the policy of GMO regulation, there is a conflict between the policy preferences and discourses that are formed at national levels and the institutional capacity to enact those preferences that exists at a supranational level beyond the immediate reach of the national will-formation. The GMO issue adds to the list of issues, along with migration and border control, Euro interest rates, and others, in which national preferences may differ greatly but a transnational or supranational solution must ultimately be negotiated. Though the status quo may be tenable, it hardly seems preferable to a more decisive answer on the question of sovereignty and policymaking authority. Habermas and other propose that the answer is "more Europe," though populist nationalists counter with a bid for a renationalization of many competencies.

To the latter, science and technology may be developing more rapidly than deliberative democratic structures can keep up. For example, in November 2018 it was revealed that the Japanese minister for cybersecurity does not use computers and is "not familiar with cybersecurity," an incident that recalls the 2006 quote by Ted Stevens, then-chair of the US Senate committee overseeing net neutrality regulations, that "the internet[…]is a series of tubes" – these examples serve to show that the bureaucratic and deliberative structures that elevate individuals to authority over technological regulations may not always (if ever) do so on the basis of familiarity with the technologies in question.[186] This dissonance stands to widen if and as the technological complexity

[185] Habermas (2012), 20

[186] Japan Times, "Japan cybersecurity minister who doesn't use computers says he's also not familiar with cybersecurity," The Japan Times, November 23, 2018. https://www.japantimes.co.jp/news/2018/11/23/national/politics-diplomacy/japan-cybersecurity-minister-doesnt-use-computers-says-hes-not-familiar-cybersecurity/#.XABIaOInZPY.
Ken Belson, "Senator's Slip of the Tongue Keeps on Truckin' Over the Web", The New York Times, July 17, 2006. https://www.nytimes.com/2006/07/17/business/media/17stevens.html.

and specificity of modern regulatory concerns continues to grow. Even before the GMO issue arrives at any kind of lasting settlement, gene editing technologies have already begun entering the public discourse, and an European Court of Justice ruling places them, unwieldily, into the same category as the GMO technology that has existed for decades; even before cryptocurrency caught the attention of regulators the market for then was already in the billions of dollars.[187] And all of these regulatory issues promise to be philosophically and politically puerile compared to questions such as Artificial Intelligence. The theory of Rational Ignorance, commonly associated with Public Choice theory, centers on the idea that there are some things that it is not rational to spend time learning, and therefore that no one should rationally try to become knowledgeable on every topic.[188] Further, work on the relationship between Rational Ignorance and Democracy notes that voters are likely to avoid informing themselves when they feel their impact as a voter is low, and also when they feel they have already made a moral decision on an issue – a set of findings that may make a moral/environmental question like GMOs, in the context of a democratic deficit, particularly subject to irrational choice formation.[189] In 2016 (the last year for which data was available), the number of tertiary degrees awarded in the EU in biology, environmental science, or medicine was roughly a quarter million – a small fraction of the 4.4 million who received degrees of the same level in other fields that year, let alone of the total population coming of age at the same time.[190] While repudiating the implication that only by attaining a degree in biology or related fields can one understand the issue of GMOs, it is clear that the proportion of European

[187] Duncan Rolph, "Is Bitcoin A Safe Bet? A Quick Guide To Cryptocurrency," Forbes, April 23, 2014.
[188] Term coined by Anthony Downs, *An Economic Theory of Democracy* (New York: Harper and Row, 1957).
[189] César Martinelli, "Rational ignorance and voting behavior," *International Journal of Game Theory* 35 (2007): 315-335.
Karine Nyborg, "I don't want to hear about it: Rational ignorance among duty-oriented consumers," *Journal of Economic Behavior & Organization*, 79 (2011): 263-274.
[190] "Graduates by education level, programme orientation, sex and field of education [educ_uoe_grad02]," Eurostat, https://ec.europa.eu/eurostat/web/education-and-training/data/database. Tertiary taken to be all post-secondary.

academic expertise in a field is outmatched by the number of Europeans with strong political feelings on the issue.[191] As the complexity and number of issues affecting the public sphere continues to grow, perhaps the possibility exists that we are entering an age in which a fundamental informational assumption of democracy – that the average citizen can, in a reasonable amount of time, acquire a working proficiency in a variety of subjects of public interest and make informed votes and choices in the matter – is not necessarily true any longer.[192]

Although deliberative democracy may be slow and cumbersome, the answer to this lethargy cannot be the technocratic authoritarianism of the past, for it has the possibility of being even more regressive and reactionary than current regulatory structures. Opaque, slow, behind-closed-doors decisions are not satisfying for the public interest. But online, democratized, non-hierarchical platforms can be innately legitimate and responsive. There are more inclusive technologies and possibilities. In his newest edition of *Revolt of the Public*, former NSA analyst Martin Gurri sees this issue as an ongoing battle between networked, non-hierarchical organizations now have the tools to attack and flatten authority, while the authorities struggle to reclaim legitimacy and rebuild hierarchies, a struggle that calls to mind Habermas. Gurri proposes that was is necessary is a synthesis of these centrifugal and centripetal forces; governments and authorities must figure out ways to embrace or coopt these non-hierarchical mass organizational structures. Some ways in which Gurri's ideas might be realized include the expansion of online democracy platforms such as the Obama Administration's *We the People* project, blockchain tracking on votes and campaign contributions, or online platforms for drafting and crowd-sourcing

[191] And most likely likewise for issues such as immigration, net neutrality, trade barriers, or any number of public policy issues.

[192] A position akin to that discussed in, e.g. Bryan Caplan, *The Myth of the Rational Voter: Why Democracies Choose Bad Policies* (Princeton: Princeton University Press, 2007).

legislation and votes. The legitimacy of scientific and academic work may be improved by Crowd review.

Though the precise nature of the European regulatory and comitological procedure may change in coming months or years, issues like transgenics, gene editing, and other questions of biotechnology have already begun to open new political rifts and regulatory challenges. Further questions at the interface of science and society, such as cybersecurity, artificial intelligence, and others, are likely to pose enormous problems in coming decades as well. Amongst all of these areas, quantitative or qualitative investigation could help reveal how affected interest groups respond to regulatory action in terms of increasing or decreasing faith or perceptions of legitimacy. New structures of participatory input, which take advantage of the mass participatory mechanisms of the internet, may need to be adopted, and blockchain-like mechanisms could show constituents exactly how their input and votes affected final policy outcomes, thereby potentially increasing feelings of buy-in into the system.

However, there are some more difficult and fundamental questions that may arise from this conflict between popular desires and the institutions that constrain them. Do democratic outcomes always equate to the policy outcomes that most benefit the polity, or do voters sometimes vote against their own self interests? To what extent *should* governments respond to popular policy preferences that are difficult to do, or perhaps may not be, from the perspective of governments or experts, the best course of action?

But as with all new technological advances, society must remain vigilant to the potential misuses of these tools. Though the exact balance must vary from society to society and issue to issue, it is important to maintain some balance between popular desires and specialist expertise –

for the perils of too much technocracy are well known, but the perils of too much populist democracy may just be beginning to reveal themselves.

Works Cited

AgbioInvestor. "The challenges facing agriculture and the plant science industry in the EU." https://www.europabio.org/sites/default/files/Agbioinvestor-report-press-releaseF_0.pdf.

Alternative für Deutschland. "Natur | Agrar | Verbraucher." https://www.afd.de/umwelt-agrar-verbraucher/

Andrews, Leighton. "How can we demonstrate the public value of evidence-based policy making when government ministers declare that the people 'have had enough of experts'?" *Palgrave Communications* 3, no. 11 (2017). https://doi.org/10.1057/s41599-017-0013-4

Batra, Karen. "EU's Anti-Science Comitology Reform Threatens Innovation." *Biotechnology Innovation Organization*, February 14, 2017. https://www.bio.org/press-release/eu%E2%80%99s-anti-science-comitology-reform-threatens-innovation

Berthoud, Barbara. *The Precautionary Principle in EU Risk Regulation: A Matter of Priorities*. Hamburg: Anchor Academic Publishing, 2014.

Bio-Based Industries. "About BBI JU." https://bbi-europe.eu/about/about-bbi.

Blatter, Joachim, Samuel David Schmid, and Andrea C. Blättler. "Democratic Deficits in Europe: The Overlooked Exclusiveness of Nation-States and the Positive Role of the European Union." *Journal of Common Market Studies* 55, no. 33 (2017): 449-467.

Bonny, Sylvie. "Why are most Europeans opposed to GMOs? Factors explaining rejection in France and Europe." *Electronic Journal of Biotechnology* 6, no. 1, (April 15, 2003), http://ejbiotechnology.info/index.php/ejbiotechnology/article/view/v6n1-4/573

Brooks, Eleanor. "Using the Advocacy Coalition Framework to understand EU pharmaceutical policy." European Journal of Public Health 28, no. 3 (2018): 11-14.

Bruno Maçães. "Bruno Maçães on the Spirit of Adventure." Interview with Tyler Cowen. *Conversations with Tyler*. Mercatus Center at George Mason University, September 26, 2018: 14:57.

Caplan, Bryan. *The Myth of the Rational Voter: Why Democracies Choose Bad Policies*. Princeton: Princeton University Press, 2007.

Caporaso, James. "Europe's Triple Crisis and the Uneven Role of Institutions: The Euro, Refugees, and Brexit." *Journal of Common Market Studies* (2018): 1-17.

Chow, Lorraine, "16 European Nations Vote Against GMO Crops," *EcoWatch*, March 27, 2017. https://www.ecowatch.com/eu-nations-vote-against-gmo-crops-2332080511.html

Cotton, Matthew. “Ethics and Technology Assessment: A Participatory Approach.” *Studies in Applied Philosophy, Epistemology and Rational Ethics* 13. Berlin Heidelberg: Springer – Verlag, 2014.

Dalton-Brown, Sally. *Nanotechnology and Ethical Governance in the European Union and China.* Cham, Switzerland: Springer, 2015.

De Carbonnel, Alissa and Alastair Macdonald. “Juncker says to push for EU at different speeds.” Reuters, February 23, 2017. https://www.reuters.com/article/us-eu-future-juncker-idUSKBN1622GJ

De Tocqueville, Alexis. *Democracy in America*. London: Saunders and Oatley, 1848.

Decker, Michael and Miltos Ladikas. “Optimising the Impact of Future-Oriented Technology Analysis; Methodological Foundations.” Seminar. *EU-US Seminar: New Technology Foresight, Forecasting &Assessment Methods*. Seville, Spain. May 13-14, 2004. http://foresight.jrc.ec.europa.eu/fta/papers/Session%201%20Methodological%20Selection/Optimising%20the%20Impact.pdf

Deutsche Welle. “Nineteen EU Countries Seek GMO Opt-Out.” *Deutsche Welle*, October 4, 2015. https://www.dw.com/en/nineteen-eu-countries-seek-gmo-opt-out/a-18760718

Dorius, Shawn and Carolyn J. Lawrence-Dill. “Sowing the seeds of skepticism: Russian state news and anti-GMO sentiment.” *GM Crops & Food* 9 (2018): 53-58.

Downs, Anthony. *An Economic Theory of Democracy*. New York: Harper and Row, 1957.

Dreyer, Marion and Ortwin Renn. *Food Safety and Governance: Integrating Science, Precaution, and Public Involvment*. Berlin Heidelberg: Springer-Verlag, 2009.

Dunlop, Claire, “Up and down the pecking order: what matters and when in issue definition: the case of rbST in the EU,” *Journal of European Public Policy* 14, no. 1 (January 2007): 39–58.

EASAC. “European Academies inform MEPs on GMO legislation.” EASAC, October 24, 2014. https://easac.eu/news/details/european-academies-inform-meps-on-gmo-legislation/

Easterly, William. *The Tyranny of Experts*. New York: Basic Book, 2013.

EFSA Website. “EFSA’s Role in the GMO Regulatory Framework.” https://www.efsa.europa.eu/sites/default/files/assets/gmoauthorisation.pdf

EFSA Website. “Principles.” http://www.efsa.europa.eu/en/aboutefsa and http://ec.europa.eu/food/safety/general_food_law/principles/index_en.htm

Ehmke. Tanner.“Why the EU's GMO Vote Matters to Farmers.” *AgWeb*, October 20, 2015. http://www.agweb.com/article/why-the-eus-gmo-vote-matters-to-farmers-naa-tanner-ehmke/

EU Commission. “Better regulation for better results - An EU agenda.” Final communication from the commission to the European Parliament et al. May 19, 2015. ec.europa.eu/smart-regulation/better_regulation/documents/com_2015_215_en.pdf

EUR-Lex European Parliament Website. “The European Commission.” Retrieved November 11, 2018. http://www.europarl.europa.eu/factsheets/en/sheet/25/the-european-commission

EUR-Lex. “Judgement of the Court–Case 120/78, ECLI:EU:C:1979:42.” European Court of Justice. Issued February 20, 1979. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61978CJ0120

EUR-Lex. “Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory” COM/2015/0177 final - 2015/0093 (COD). April 22, 2015. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52015PC0177

Eurobarometer. “Biotechnology – Report.” *Special Eurobarometer* 341 / Wave 73.1 – TNS Opinion & Social. Eurobarometer Survey 73.1 of the European Parliament, 2010. ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_341_en.pdf

Eurobarometer. “Democracy on the Move: European Elections – One Year to Go.” *Eurobarometer Survey* 89.2 of the European Parliament, 2018. http://www.europarl.europa.eu/pdf/eurobarometre/2018/oneyearbefore2019/eb89_one_year_before_2019_eurobarometer_en_opt.pdf

European Biotechnology. “European Biotechnology Science and Industry Guide.” https://european-biotechnology.com/euro-guide-2019.html

European Commission Health and Food Safety Directorate-General. “Summary Report of the Standing Committee on Plants, Animals, Food and Feed Held in Brussels On 27 March 2017.” March 27, 2017. https://circabc.europa.eu/w/browse/8440f2ea-e2ad-4ce2-b520-d2f3b03f8c22

European Commission Health and Food Safety Directorate-General. “Summary Report of the Standing Committee on Plants, Animals, Food and Feed Held in Brussels On 17 March 2017.” January 17, 2017. https://ec.europa.eu/food/sites/food/files/plant/.../sc_plant-health_20170126_sum.pdf

European Commission Press Release. “Appointment of Chief Scientific Advisor.” Modified December 5, 2011. http://europa.eu/rapid/press-release_IP-11-1497_en.htm

European Commission Press Release. “Comitology: Commission proposes more transparency and accountability in procedures for implementing EU law.” Retrieved November 6, 2018. http://europa.eu/rapid/press-release_IP-17-264_en.htm

European Commission Press Release. "Relocation and Resettlement: EU Member States Urgently Need to Deliver." Brussels, March 16, 2016. http://europa.eu/rapid/press-release_IP-16-829_en.htm

European Commission. "Key Enabling Technologies." http://ec.europa.eu/programmes/horizon2020/en/area/key-enabling-technologies.

European Commission. "Comitology Procedure Reforms: Questions & Answers." Uploaded February 14, 2017. http://europa.eu/rapid/press-release_MEMO-17-273_en.htm

European Commission. "Comitology." Retrieved November 2018. https://ec.europa.eu/info/implementing-and-delegated-acts/comitology_en.

European Commission. "European Commission – Daily News 04/07/2017." *European Commission Daily News*. July 4, 2017. http://europa.eu/rapid/press-release_MEX-17-1908_en.htm

European Commission. "European Commission – Daily News 12 / 22 / 2017," *European Commission Daily News*. December 22, 2017. http://europa.eu/rapid/press-release_MEX-17-5421_en.htm

European Commission. "GMOs: EU Decision-making process explained." Accessed November 21, 2018. https://ec.europa.eu/food/plant/gmo/authorisation/decision_making_process_en

European Commission. "Temporary Reintroduction of Border Controls." Last Updated August 9, 2018. https://ec.europa.eu/home-affairs/what-we-do/policies/borders-and-visas/schengen/reintroduction-border-control_en.htm

European Court of Justice. "Judgement of the Court. Case C-111/16. September 13, 2017." European Court of Justice. Issued September 13, 2017. http://curia.europa.eu/juris/document/document_print.jsf;jsessionid=9ea7d2dc30d692a45d3ac71e48c3834cb31c14de1ec4.e34KaxiLc3qMb40Rch0SaxyMbxj0?doclang=EN&text=&pageIndex=0&part=1&mode=DOC&docid=194406&occ=first&dir=&cid=230658

European Parliament. "Free movement of goods." October 2018. http://www.europarl.europa.eu/factsheets/en/sheet/38/free-movement-of-goods

European Parliament. "Parliament rejects national GMO bans proposal." Released October 22, 2015. http://www.europarl.europa.eu/news/en/press-room/20151022IPR98805/parliament-rejects-national-gmo-bans-proposal

European Parliament. "Technopolis Report" (IP/A/STOA/FWC/2008-096/LOT8/C1). Released April 2014. http://www.europarl.europa.eu/RegData/etudes/etudes/join/2012/488798/IPOL-JOIN_ET(2012)488798_EN.pdf

European Parliament. "The Principle of Subsidiarity." Retrieved November 6, 2018. http://www.europarl.europa.eu/factsheets/en/sheet/7/the-principle-of-subsidiarity

European Union Website. “European Commission.” Retrieved November 5, 2018. https://europa.eu/european-union/about-eu/institutions-bodies/european-commission_en

European Union Website. “European Council.” Retrieved November 5, 2018. https://europa.eu/european-union/about-eu/institutions-bodies/european-council_en

European Union. “DIRECTIVE (EU) 2015/412 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 March 2015.” Official Journal of the European Union, 68 no. 1 (March 13 2015). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L0412&from=EN

Eurostat. “Graduates by education level, programme orientation, sex and field of education[educ_uoe_grad02].” Last Updated August 15, 2018. https://ec.europa.eu/eurostat/web/education-and-training/data/database

Fijnaut, Cyrille. “The Refugee Crisis: The End of Schengen?” In *European Journal of Crime, Criminal Law, and Criminal Justice* 23, no. 4 (November 2015): 313-332.

Fisher, Elizabeth et al. (authors and editors) *Implementing the precautionary principle: perspectives and prospects*. Northampton, MA: Edward Elgar Publishing, 2006.

Follesdal, Andreas. “Survey Article: Subsidiarity.” *The Journal of Political Philosophy* 6, no. 2 (1998): 190-218.

Foster, Peter and Matthew Holehouse. “State of the Union: Europe in the last chance saloon, warns EU president Jean-Claude Juncker.” The Telegraph, September 8, 2015. https://www.telegraph.co.uk/news/worldnews/europe/eu/11852158/State-of-the-Union-Europe-in-the-last-chance-saloon-warns-EU-president-Jean-Claude-Juncker.html

Friedman, Uri. “The Mathematical Equations That Could Decide the Fate of refugees.” *The Atlantic*, September 9, 2015.

Greenpeace “Le Luxembourg interdit la pomme de terre OGM “Amflora.” Greenpeace, June 16 2010. Retrieved November 7, 2018. https://www.greenpeace.fr/le-luxembourg-interdit-la-pomme-de-terre-ogm-amflora/

Greenpeace. “Juncker breaks promise to make EU GMO decisions more democratic.” Released April 22, 2015. https://www.greenpeace.org/eu-unit/en/Publications/2015/Juncker-breaks-promise-to-make-EU-GMO-decisions-more-democratic/

Greenpeace. “The position of Chief Scientific Advisor to the President of the European Commission.” Retrieved July 7, 2017. http://www.greenpeace.org/eu-unit/Global/eu-unit/reports-briefings/2014/20140722%20NGO%20letter%20on%20EU%20chief%20scientific%20adviser.pdf.

Group of Chief Scientific Advisors. “A Scientific Perspective on the Regulatory Status of Products Derived from Gene Editing and the Implications for the GMO Directive.”

European Commission, November 13, 2018. ec.europa.eu/info/publications/status-products-derived-gene-editing-and-implications-gmo-directive_en.

Guegen, Daniel. "Comitology reform: Doing, undoing, and redoing is still hard work." *Euractiv*, February 16, 2017. https://www.euractiv.com/section/public-affairs/opinion/comitology-reform-doing-undoing-and-redoing-is-still-hard-work/

Gurri, Martin. *The Revolt of the Public and the Crisis of Authority in the New Millennium* (2018 Update). Stripe Press, 2018.

Habermas, Jürgen. "'The Political': The Rational Meaning of a Questionable Inheritance of Political Theology." In *The Power of Religion in the Public Sphere Medieta*, edited by Eduardo and Jonathan Vanantewerpen, 15-33. New York: Columbia University Press, 2011.

Habermas, Jürgen. *The Crisis of the European Union: A Response*. Translated by Ciaran Cronin. Cambridge: Polity Press, 2012.

Habermas, Jürgen. *The Lure of Technocracy.* Cambridge: Polity Press, 2013.

Habermas, Jürgen. *Theory of Communicative Action, Vol. I: Reason and the Rationalization of Society*. Boston: Beacon Press, 1985.

Habermas, Jürgen. *Toward a Rational Society: Student Protest, Science, and Politics.* Boston: Polity Press, 1991.

Hancock, Tom. "Chinese investment into US biotech start-ups soars." *Financial Times*, July 1, 2018. https://www.ft.com/content/7b045aa2-7cef-11e8-bc55-50daf11b720d

Heinrichs, Harald. "Advisory Systems in Pluralistic Knowledge Societies: A Criteria-Based Typology to Assess and Optimize Environmental Policy Advice." In *Democratization of Expertise? Exploring Novel Forms of Scientific Advice in Political Decision-Making*, edited by Sabine Maasen and Peter Weingart. Dordrecht, The Netherlands: Springer, 2005.

Hennen, Leonhard. "Why do we still need participatory technology assessment?" *Poiesis Prax* 9 (2012): 27–41.

Hirst, Paul. "Carl Schmitt's Decisionism." In *The Challenge of Carl Schmitt*, edited by Chantal Mouffe. New York: Verso, 1999.

ISAAA. "Global Status of Commercialized Biotech/GM Crops in 2017" ISAAA Brief No 53-2017. Retrieved October 2018.https://www.isaaa.org/resources/publications/briefs/53/

Jensen, Thomas. "The Democratic Deficit of the European Union." *Living Reviews in Democracy*, (2009). https://www.ethz.ch/content/dam/ethz/special-interest/gess/cis/cis-dam/CIS_DAM_2015/WorkingPapers/Living_Reviews_Democracy/Jensen.pdf

Juncker, Jean-Claude. “Opening speech on GMOs”. Speech. European Parliament. Plenary meeting. Strasbourg, October 28, 2015. https://ec.europa.eu/commission/commissioners/2014-2019/andriukaitis/announcements/opening-speech-gmos-plenary-meeting-28102015-european-parliament-strasbourg_en

Juncker, Jean-Claude. “Political Guidelines as Candidate for President of the European Commission.” Strasbourg, July 15, 2014. https://ec.europa.eu/commission/publications/president-junckers-political-guidelines_en

Juncker, Jean-Claude. “State of the European Union.” Speech. September 9, 2015. https://ec.europa.eu/commission/sites/beta-political/files/state_of_the_union_2015_en.pdf

Kapstein, Ethan. “Resolving the Regulator’s Dilemma: International Coordination of Banking Regulations.” *International Organization* 42, no. 2 (Spring 1989): 323-347.

Keating, Dave. “All eyes on Juncker for GM crops decision.” *Politico, Europe Edition*. March 5, 2015.

Klüver et al. "EUROPTA." *Cordis, European Commission*. https://cordis.europa.eu/docs/publications/7078/70781441-6_en.pdf

Koenig, Robert. “Research Chief Wants to Make Science Matter.” *Science Magazine* 286, 5447 (December 10, 1999): 2065-2067. http://science.sciencemag.org/content/286/5447/2065

Kurzer, Paulette and Alice Cooper. “Consumer Activism, EU Institutions and Global Markets: The Struggle over Biotech Foods.” *Journal of Public Policy* 27, no. 2 (May-Aug 2007): 103-128.

Lackey, Robert. “Science, Scientists, and Policy Advocacy.” *Conservation Biology* 21, no. 1 (February 2007): 12–17.

Löfstedt, Ragnar. “The precautionary principle in the EU: Why a formal review is long overdue,” *Risk Management* 16, 3 (2014): 137–163.

Löfstedt, Ragnar. “The Swing of the Regulatory Pendulum in Europe: From Precautionary Principle to (Regulatory) Impact Analysis.” Journal of Risk and Uncertainty, 28 no. 3 (May 2004): 237-260.

Louch, William. “MEPs reject 'half-baked' EU Commission GMO opt-out plans,” *The Parliament Magazine,* October 28, 2015. https://www.theparliamentmagazine.eu/articles/news/meps-reject-half-baked-eu-commission-gmo-opt-out-plans

Lynas, Mark. “With G.M.O. Policies, Europe Turns Against Science,” *The New York Times*, October 24, 2015. http://www.nytimes.com/2015/10/25/opinion/sunday/with-gmo-policies-europe-turns-against-science.html

Lynch, Diahanna and David Vogel. “The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics.” *Council on Foreign Relations Press*, April 5, 2001.

Machiavelli, Niccolò. *The Prince*. Italy: Antonio Blado d’Asola, 1532.

Madison, James and Alexander Hamilton. *The Federalist Papers*, (esp. “No. 51”). Various Publishers (The Independent Journal, New York Packet, The Daily Advertiser, J & A McLean): 1787-1788.

Michalopoulous, Sarantis. "Nobel Laureate: EU politicians ignore ‘politically unwelcome’ GMO science.” *Euractiv,* September 27, 2016.

Micó, Josep-Lluís and Andreu Casero-Ripollés. “Political activism online: organization and media relations in the case of 15M in Spain.” *Information, Communication & Society* 17 (2014): 858-871.

Mitchell, William C. “Schumpeter and Public Choice, Part I: Precursor to Public Choice?” *Public Choice* 42, no. 1 (1984): 73-88.

Mratinelli, César. “Rational ignorance and voting behavior.” *International Journal of Game Theory* 35 (2007): 315-335.

Nyborg, Karine. “I don’t want to hear about it: Rational ignorance among duty-oriented consumers.” *Journal of Economic Behavior & Organization*, 79 (2011): 263-274.

OECD Directorate for Science Technology and Innovation. “Key biotechnology indicators.” Most recent data (2015). Last update November 2017. oe.cd/kbi

Orntzeder, Michael and Karen Kastenhofer. “Old problems, new directions and upcoming requirements in participatory technology assessment.” Editorial in *Poiesis Prax 9* (2012): 1–5. DOI 10.1007/s10202-012-0116-3

Ouest France. “Sondage. Les OGM inquiètent de plus en plus les Français.” *Ouest France*, September 27, 2013.

Plato. *Republic*. Greece: Self, ca. 380 BCE.

Randour, François et al. “The Cultivation of Genetically Modified Organisms in the European Union: A Necessary Trade-Off?” *Journal of Common Market Studies* 52, no. 6 (2014): 1307-1323.

Saiedi, Nader. “A Critique of Habermas’ theory of Practical Rationality.” *Studies in Soviet Thought* 33 (1987): 251-265.

Schumpeter, Joseph. *Capitalism, Socialism, and Democracy*, 3rd ed. New York: Harper & Brothers, 1950.

Scott, Joanne and Vos, Ellen. “The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO.” In *Good governance in Europe's integrated market*, edited by Christian Joerges and Renaud Dehousse, 253-286. Oxford: Oxford Scholarship Online, 2002.

Skogstad, Grace. “Contested Accountability Claims and GMO Regulation in the European Union.” *Journal of Common Market Studies* 49, no. 4 (2011): 697-922.

Smith, Mitchell P. *Environmental and Health Regulation in the United States and the European Union.* New York: Palgrave Macmillan, 2012.

Tagliabue, Giovanni. “The EU Legislation on ‘GMOs’ between nonsense and protectionism: An ongoing Schumpeterian chain of public choices.” *GM Crops Food* 8, no. 1 (2017): 57-73.

Teffer, Peter. “Commission and council dig in on GMO opt-outs.” *EU Observer*, January 17, 2018. https://euobserver.com/institutional/140583

Thomson, Stephanie. “Is this the end of Schengen?” *World Economic Forum*, September 26, 2015. https://www.weforum.org/agenda/2015/09/is-this-the-end-of-schengen/

Tickner, Joel and David Kriebel. “The Role of Science and Precaution in Environmental and Public Health Policy.” In *Implementing the Precautionary Principle*, edited by Elizabeth Fisher et al. Cheltenham, UK: Edward Elgar, 2006.

Tlili, Anwar and Emily Dawson. “Mediating Science and Society in the EU and UK: From Information-Transmission to Deliberative Democracy?” *Minerva* 48, no. 4 (December 2010): 429-461.

Toke, David. *The Politics of GM Food: A Comparative Study of the UK, USA, and EU*. New York: Routledge, 2004.

Tosun, Jale. “How the EU Handles Uncertain Risks: Understanding the Role of the Precautionary Principle,” *Journal of European Public Policy* 20, no. 10 (2013): 1517–1528.

UBS Chief Investment Office. “China’s Biotech Revolution.” Retrieved August 2018.https://www.ubs.com/global/en/wealth-management/chief-investment-office/our-research/discover-more/2017/china-biotech.html.

US FDA website. “About Advisory Committees.” Retrieved December 10, 2015. http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/default.htm

Waterfield, Bruno, “Jean-Claude Juncker 'sacks' EU scientific adviser over her pro-GM views,” *The Telegraph*, November 13, 2014. http://www.telegraph.co.uk/news/worldnews/europe/eu/11229774/Jean-Claude-Juncker-sacks-EU-scientific-adviser-over-her-pro-GM-views.html

Winterfeldt, Detlof. “Bridging the gap between science and decision making.” *Proceedings of the National Academy of Sciences*, 110 (August 20, 2013): 14055-14061. https://doi.org/10.1073/pnas.1213532110

World Bank Data Tool. Retrieved September 2018. https://data.worldbank.org/

World Trade Organization. “Dispute Settlement DS291: European Communities — Measures Affecting the Approval and Marketing of Biotech Products.” Retrieved September 2018. https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm

World Trade Organization. “United States – Subsidies on Upland Cotton: Notification of a Mutually Agreed Solution.” https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds267_e.htm

World Trade Organization. “US – Poultry (China). DS392. One-page summary.” November 8, 2010. https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds392sum_e.pdf