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Precaution and Equivalence - The Critical Interplay in EU Biotech Foods

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Keywords

Substantial equivalence – Precautionary principle – Biotech food – GM food – Cloned food – Consumer choice

Abstract

Scientific uncertainty surrounds biotech foods. To regulate such foods and to ensure consumer choice and safety, the EU has adopted a precautionary approach based on premarket authorization and mandatory labelling. Despite these regulatory requirements, the controversial concept of substantial equivalence is still present within the existing regimes for GM and cloned foods. The concept uses a comparative analysis of conventional and biotech foods to assess their safety. If substantial equivalence is present, biotech foods are regulated in the same manner as conventional foods. The concept restricts consumer choice and calls into question the safety of such foods because it requires no specific mandatory labelling or traceability and only minimal premarket authorization. The dynamic between substantial equivalence and the precautionary principle is problematic as the two concepts seem contradictory. This situation prevents the existence of an adequate and efficient regulatory environment for EU biotech foods regulation and undermines a comprehensive precautionary approach towards such foods and the EU food system in general.

Introduction

Modern agricultural biotechnologies, such as genetic modification and animal cloning, and their resulting products, have been identified as part of the solution to deliver food security and sustainability through environmental and food applications.¹ Both plant and animal agricultural biotechnologies have similar aims – to produce superior crops or animals by eliminating undesirable traits, passing on desirable ones through successive generations, and improving yield.² For instance, a genetically engineered salmon, the AquAdvantage™ salmon, which can grow to a

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¹ Generally on food security and sustainability issues, see e.g. Commission Communication, “The CAP towards 2020: Meeting the Food, Natural Resources and Territorial Challenges of the Future” COM(2010)672 final; and European Commission, “Sustainable Agriculture for the Future We Want” (2012).

² See e.g. National Academies of Sciences, “Genetically Engineered Crops: Experiences and Prospects” (2016).

mature size in almost half the time of its natural counterpart, has been developed by AquaBounty Technologies and was approved for commercialisation in the US in 2015.³

The EU has opted for the precautionary principle to diminish potential risks created by biotech foods.⁴ Unknown long-term effects of consuming biotech foods on humans, including nutritional differences, new diseases developed in the human gut and allergic reactions⁵ raise uncertainty.⁶ Within EU food law, the central role played by the precautionary principle in cases of scientific uncertainty for foods has forced decision-makers to act carefully and with foresight when making decisions related to biotech foods, and by so doing potentially prohibit such foods from being marketed in the EU.⁷ It would appear that the precautionary principle has become a linchpin in the regulation of biotech foods. Cloned and GM foods are regulated under distinctive regimes. The authorization, labelling and traceability requirements for GM foods are harmonized by two complementary regulations, the Food and Feed Regulation and the Traceability Regulation.⁸ From 1 January 2018, the 2015 Novel Foods Regulation will update the regulatory framework for novel foods,⁹ inclusive of cloned foods, and repeal the 1997 Novel Foods Regulation, which also deals with cloned foods.¹⁰

A careful examination of the biotech regulatory regimes reveals that the older and more controversial concept of substantial equivalence is still present in the regulation of biotech foods.

³ Food and Drug Administration, “FDA Has Determined That the AquaAdvantage Salmon is as Safe to Eat as Non-GE Salmon” (19 November 2015), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm472487.htm> [Accessed 26 May 2017].

⁴ For the purpose of this article, biotech foods are foods resulting from three types of modern agricultural biotechnologies: genetically modified plant organisms (GMOs), animal cloning, and genetically engineered animals (GEAs).

⁵ See e.g. the following US case, *In re StarLink Corn Products Liability Litigation* 212 F Supp 2d 828 (ND Ill 2002).

⁶ See e.g. A. Coghlan, “Enter the Superweed” *New Scientist* (27 August 2005) 17; and L.L. Wolfenbarger and P.R. Phifer, “The Ecological Risks and Benefits of Genetically Engineered Plants” (2000) 290 *Science* 2088.

⁷ The 2002 General Food Law enshrines the first definition of the precautionary principle within EU law and establishes the principle as overarching and applicable in all food safety legislation. See Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the General Principles and Requirements of Food Law, establishing the European Food Safety Authority and laying down Procedures in Matters of Food Safety [2002] OJ L31/1 [hereinafter General Food Law]. For more on the role of the precautionary principle in the EU regulation of foods, see e.g. A. Szajkowska, *Regulating Food Law: Risk Analysis and the Precautionary Principle as General Principles of EU Food Law* (Wageningen: Wageningen Academic Publishers, 2012).

⁸ Respectively Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed [2003] OJ L268/1 [hereinafter Food and Feed Regulation]; and Regulation (EC) 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products produced from Genetically Modified Organisms and amending Directive 2001/18/EC [2003] OJ L268/24 [hereinafter Traceability Regulation].

⁹ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods [2015] OJ L 327/1 [hereinafter 2015 Novel Foods Regulation].

¹⁰ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning Novel Foods and Novel Food Ingredients [1997] OJ L43/1 [hereinafter 1997 Novel Foods Regulation]. When it entered into force, the 1997 Novel Foods Regulation covered genetically modified (GM) foods. Since 2004, GM foods have been removed from its scope and fall under the scope of the Food and Feed Regulation and the Traceability Regulation.

Substantial equivalence was developed in the 1990s as a risk assessment method.¹¹ If substantial equivalence is present between two foods, no other premarket authorization and no specific labelling is required for biotech foods.¹² The concept prevailed at an international level and was subsequently used at a national level. Substantial equivalence swiftly became a pillar of risk regulation for modern agricultural biotechnology and the benchmark standard against which the safety of biotech foods in the EU would be assessed.¹³ The EU embraced the concept in the 1997 Novel Foods Regulation.¹⁴ However, substantial equivalence significantly restricts consumer choice by requiring no specific mandatory labelling and no traceability. It also brings into questions the safety of biotech products if they only undergo minimal premarket authorization. Because of these issues, substantial equivalence is a concept that has been the subject of much criticism.

This article examines the problematic dynamic between the concept of substantial equivalence and the precautionary principle, including the issues of safety and consumer choice. It is argued that both the precautionary principle and substantial equivalence still interplay in the field, despite an apparent and formal departure from substantial equivalence. **The second section assesses how the EU has moved away from the controversial concept of substantial equivalence under the 1997 Novel Foods Regulation to supposedly enshrine the precautionary principle in the framework for biotech foods. The third section argues that there is an unsubstantiated claim of departure from substantial equivalence under the existing regimes for biotech foods. It assesses how the constraints created by substantial equivalence prevent the precautionary principle from playing a comprehensive role in the risk regulation for biotech foods. The fourth section indicates that the dominance of substantial equivalence in the frameworks impacts on consumer safety and choice. The final section concludes that the dynamic but problematic interaction between the precautionary principle and substantial equivalence undermines the EU framework for biotech foods.**

From “Substantial Equivalence” to “Precaution”

The Scientific and Regulatory Roles of Substantial Equivalence and their criticism

¹¹ The Organisation for Economic Co-operation and Development (OECD) wanted to develop a risk assessment method that would liberalize trade in biotech products and favour regulatory harmonization. See OECD, “Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles” (OECD, 1993) 14. The concept was first used in a US document. See FDA, “Statement of Policy: Foods Derived from New Plant Varieties” (1992) 57 Fed Reg 22984. It was then appropriated by the OECD and other international organizations.

¹² See Food and Agriculture Organization (FAO)/ World Health Organization (WHO), “Expert Consultation on Biotechnology and Food Safety” (FAO/WHO, 1996); and FAO/WHO, “Expert Consultation on Foods derived from Biotechnology” (FAO/WHO, 2000).

¹³ For more on risk regulation see *E. Fisher, Risk Regulation and Administrative Constitutionalism* (Oxford: Hart Publishing, 2010); *J. Steele, Risks and Legal Theory* (Oxford: Hart Publishing, 2004); and *C.R. Sunstein, Laws of Fear: Beyond the Precautionary Principle* (Cambridge: Cambridge University Press, 2005).

¹⁴ Art.3(4) 1997 Novel Foods Regulation.

In the 1990s, substantial equivalence became “an internationally recognized standard” to undertake safety assessments.¹⁵ The concept is built on the premise that a conventional food can be used as the “basis for comparison when assessing the safety of human consumption of a food [...] that has been modified or is new”.¹⁶ Substantial equivalence, as a scientific concept, is composed of two elements. First, substantial equivalence is based on an assumption of equivalence and risk between biotech and conventional foods. The aim is not to establish an absolute level of safety, but to ensure with a “reasonable certainty” that no harm to public health and the environment results from new food products.¹⁷ The reasoning is that modern biotechnology does not automatically result in foods which are “less safe than those developed by conventional techniques”.¹⁸ In other words, biotech foods are not risk-free; they simply involve the same types of risks to human health and food safety as conventional foods. The FAO and WHO also confirmed that substantial equivalence was the “most practical approach to address the safety evaluation” of biotech foods.¹⁹ It is part of the safety assessment for biotech foods and this **assessment is framed as a positive scientific approach that favours this type of foods. Nonetheless, it seems bizarre to assume that a novel type of food be considered as safe as a traditional food that would have been consumed for the last hundreds or thousands of years.**

Second, substantial equivalence entails a comparative analysis between biotech and their conventional counterparts.²⁰ It compares the chemical composition between the biotech and the traditional food, as well as the molecular, agronomical and morphological characteristics,²¹ and nutritional (or anti-nutritional) components.²² In the early 2000s, the concept was further refined. The 2000 Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology declared that the concept should be used “to identify similarities and differences”.²³ The aim is to determine if the biotech food presents any new or greater risks in comparison with its traditional counterpart without affecting the health or nutritional status of consumers.²⁴ The frame of this comparative analysis element of substantial equivalence is more neutral and does not favour biotech foods.

Not only is substantial equivalence a scientific assessment but it also plays a role during the regulatory stage of biotech food regulation.²⁵ If biotech foods are substantially equivalent to

¹⁵ Council for Biotechnology Information, “Substantial Equivalence in Food Safety Assessment” (Council for Biotechnology Information, 2001).

¹⁶ OECD, “Safety Evaluation of Foods Derived by Modern Biotechnology” (OECD, 1993) 11. See also FAO/WHO, “Expert Consultation on Foods derived from Biotechnology” (FAO/WHO, 2000).

¹⁷ L.R. Ghisleri and others, “Risk Analysis and GM foods: Scientific Risk Assessment” (2009) 4 European Food and Feed Law Review 235, 247.

¹⁸ OECD, “Safety Evaluation of Foods Derived by Modern Biotechnology” (OECD, 1993) 10.

¹⁹ FAO/WHO, “Expert Consultation on Biotechnology and Food Safety” (1996) 4.

²⁰ OECD, “Safety Evaluation of Foods Derived by Modern Biotechnology” (OECD, 1993) 14.

²¹ Ghisleri and others, “Risk Analysis and GM foods” (2009) 4 European Food and Feed Law Review 235, 241.

²² OECD, “Safety Evaluation of Foods Derived by Modern Biotechnology” (OECD, 1993) 11.

²³ FAO/WHO, “Expert Consultation on Foods Derived from Biotechnology” (FAO/WHO, 2000) 4.

²⁴ Ghisleri and others, “Risk Analysis and GM foods” (2009) 4 European Food and Feed Law Review 235, 247.

²⁵ L. Petetin, “The Revival of Modern Agricultural Biotechnology by the UK Government: What Role for Animal Cloning?” (2012) 7 European Food and Feed Law Review 296, 305.

conventional foods, they are regulated similarly to conventional foods. **Substantial equivalence is “regulatory shorthand for defining those new foods that do not raise safety issues that require special intensive, case by case scrutiny”.**²⁶ The decisive criterion is the end-product rather than the manufacturing process of foods. **The process according to which a food was produced is irrelevant.** A determination of substantial equivalence between biotech and conventional foods reduces the regulatory hurdles at an international level by standardising the risk assessment criteria across countries.²⁷

Substantial equivalence is specifically mentioned under the 1997 Novel Foods Regulation.²⁸ Under the regulation, novel foods, including cloned foods, must undergo premarket authorization before being placed on the market.²⁹ Commentators have argued that even if the word “precaution” is not mentioned in the text of the regulation, the Novel Foods Regulation adopts a precautionary approach by establishing a mandatory premarket approval.³⁰ However, substantial equivalence is the scientific criterion by which the evaluation of novel foods is weighed when an applicant notifies the placing on the market to the national competent authority.³¹ If a novel food is not substantially equivalent to an existing food, the food must undergo an “initial” safety assessment by the competent authority of a Member State, and may then proceed to premarket authorization.³² An authorization decision is required. On the other hand, if the novel food is “substantially equivalent” to an existing food, it falls under the scope of the simplified procedure that exists under Art.3(4). In this instance, applicants would simply have to notify the European Commission of the placing of the food on the market. No specific premarket approval is required to put the novel food on the market. Further, the labelling of novel foods under the scope of the 1997 Novel Foods Regulation is based on the concept of substantial equivalence. Art.8(1)(a) ensures the labelling of a novel food if this food is “no longer equivalent to an existing food”.³³ If a novel food is declared substantially equivalent to an existing food, no specific labelling is required. They are submitted to general labelling requirements.³⁴

Cloned foods, which fall by default under the regulation, could benefit from the simplified procedure under the 1997 Novel Foods Regulation.³⁵ The Commission and national competent

²⁶ H.I. Miller, “Substantial Equivalence: Its Uses and Abuses” (1999) 17 *Nature Biotechnology* 1042, 1042.

²⁷ See OECD, “Safety Evaluation of Foods Derived by Modern Biotechnology” (OECD, 1993).

²⁸ The 1997 Novel Foods Regulation was the first EU regulatory document dedicated to novel foods. It defines novel foods, as foods that “have not hitherto been used for human consumption to a significant degree within the Community” prior to 15 May 1997. See Art.1(2) 1997 Novel Foods Regulation.

²⁹ Art.4 1997 Novel Foods Regulation.

³⁰ See e.g. N. Salmon, “A European Perspective on the Precautionary Principle, Food Safety and the Free Trade Imperative of the WTO” (2002) 27 *European Law Review* 138, 143.

³¹ Art.5 1997 Novel Foods Regulation. See also Petetin, “The Revival of Modern Agricultural Biotechnology by the UK Government” (2012) 7 *European Food and Feed Law Review* 296, 304.

³² Art.4 1997 Novel Foods Regulation.

³³ Art.8(1)(a) 1997 Novel Foods Regulation.

³⁴ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers [2011] OJ L304/18.

³⁵ Cloned foods fall under category (e) of Article 1 (2) of the Novel Foods Regulation. Art. 1 (2)(e) Novel Foods Regulation states that “foods and food ingredients consisting of or isolated from plants and food ingredients isolated

authorities would not be able to prevent applicants from placing their products on the EU market as they only have a reactive regulatory role to play. Cloned foods would not require any specific labelling. One market combining both cloned and conventional foods would be created, which would facilitate the sale of such foods but would reduce consumers' freedom of choice to a large extent as they would not be able to differentiate between a cloned and non-cloned product. The burden of testing the existence of substantial equivalence is in the hands of the manufacturers. The regulation is an example of how substantial equivalence can give "producers carte blanche to do as they please".³⁶ This degree of "self-determination" for the foods produced by the biotech industry leads to self-regulation and raises questions as to the safety of foods placed on the EU market if no independent check is undertaken. **The regulatory and scientific aspects of substantial equivalence and their consequences are visible under the 1997 Novel Foods Regulation.** It must, however, be noted that as of yet no food derived from animal cloning has been placed on the EU market.

Substantial equivalence quickly attracted criticism. Its detractors assert that substantial equivalence suffers from significant failings, both as a scientific and regulatory tool; the most disturbing aspect of the concept being its subjectivity: "no standardized objective tests for determining equivalence and measuring substantiality exist".³⁷ The term "substantial" is not defined so there is uncertainty about when two foods cease to be substantially equivalent. The concept also starts from the erroneous premise that modern agricultural biotechnology does not differ from conventional breeding.³⁸ In particular, the presence of "novelty" in a new plant or animal seems to be in total contradiction with a designation of "equivalence".³⁹ Findings of equivalence also result in concerns. A biotech food which has been declared substantially equivalent to a conventional food will not have undergone a full safety assessment and will not be labelled and therefore be untraceable, thus creating potential food safety problems and significantly limiting consumer choice. **For Ho and Steinbrecher, substantial equivalence is devised to "expedite product approval" with little regard for safety".⁴⁰**

Almost immediately after the 1997 Novel Foods Regulation came into force, the regime started to be affected by comparable criticism that was developed at the time against substantial equivalence. Despite claiming to be precautionary, a rigorous analysis of the text and mechanisms of the 1997 Novel Foods Regulation demonstrate that substantial equivalence is expressly placed

from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use".

³⁶ M.W. Ho and R.A. Steinbrecher, "Fatal Flaws in Food Safety Assessment: Critique of the Joint FAO/WHO Biotechnology and Food Safety Report" (1998) 2 Environmental & Nutritional Interactions 51 (specifically referring to substantial equivalence).

³⁷ T.O. McGarity, "Seeds of Distrust: Federal Regulation of Genetically Modified Plants" (2002) 35 University of Michigan Journal of Law Reform 403, 429.

³⁸ Ho and Steinbrecher, "Fatal Flaws in Food Safety Assessment" (1998) 2 Environmental & Nutritional Interactions 51.

³⁹ McGarity, "Seeds of Distrust" (2002) 35 University of Michigan Journal of Law Reform 403, 429.

⁴⁰ Ho and Steinbrecher, "Fatal Flaws in Food Safety Assessment" (1998) 2 Environmental & Nutritional Interactions 51.

at the heart of the regulation and prevents a truly precautionary approach towards **novel foods, including cloned foods, both in relation to premarket authorization and labelling.** These issues led the Novel Foods Regulation (along with the Council Directive 90/220/EEC⁴¹) to be at the centre of the EU de facto moratorium on the approval of GMOs and their resulting products.⁴² Most EU Member States declared that they were not ready to abandon the moratorium until effective and truly precautionary rules on labelling and traceability were adopted.⁴³ **The 2015 Novel Foods Regulation is a welcome revision to the existing weak regime as the European Food Safety Authority (EFSA) can finally play a proactive role in the premarket authorization of novel foods.**⁴⁴

Precaution Across the Board – At Last

From the early 2000s, the EU updated its regimes for biotech foods. It decided to adopt an actual process approach (as opposed to an end-product approach) when regulating biotech foods as the technological processes behind these foods differ from conventional foods.⁴⁵ The concept of substantial equivalence and the simplified procedure were removed from these regimes as they were considered too contentious and artificial.⁴⁶

The new and “improved” frameworks for biotech foods constituted by the Food and Feed Regulation and the Traceability Regulation for GM foods, and the 2015 Novel Foods Regulation for cloned foods, establish much-awaited, strong precautionary EU procedures. Under these regimes, the premarket approval of biotech foods is required.⁴⁷ These regulations create a single, efficient and transparent EU procedure for biotech food, a “one door-one key” authorization. Independent risk assessment is now centralised and carried out by the competent authority, the EFSA. This is a fundamental step in any biotech food authorization.⁴⁸ This Europeanisation of risk

⁴¹ Council Directive 90/220/EEC of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms [1990] OJ L117/15.

⁴² From 1998 to 2004, Member States’ opposition meant that GMOs and GM foods were not approved. The de facto moratorium was lifted with the entry into force of the Food and Feed Regulation and the Traceability Regulation. The moratorium prompted the World Trade Organization *EC-Biotech* case. See *EC-Biotech: Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R and WT/DS293/R, 29 September 2006.

⁴³ The concerns relating to the 1997 Novel Foods Regulation and substantial equivalence were confirmed in the 2003 *Monsanto* case. This case dealt indirectly with the simplified procedure of the Novel Foods Regulation. See Case C-236/01, *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others* [2003] EU:C:2003:431. See especially para 84.

⁴⁴ Art.10 2015 Novel Foods Regulation.

⁴⁵ H.T. Anker and M. Grossman, “Authorization of Genetically Modified Organisms: Precaution in US and EC Law” (2009) 4 *European Food and Feed Law Review* 13 (specifically referring to GMOs and GM foods).

⁴⁶ The preamble of the Food and Feed Regulation declares that “whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself” and should be abandoned in respect of GM foods. See Recital (6) Food and Feed Regulation.

⁴⁷ Art.5 Food and Feed Regulation and Art.10 2015 Novel Foods Regulation.

⁴⁸ Art.6 Food and Feed Regulation and Art.11 2015 Novel Foods Regulation.

assessment harmonizes science-based regulation⁴⁹ and simplifies the EU decision-making process for biotech foods to avoid another moratorium.⁵⁰ Nonetheless, the centralisation of the risk assessment under the EFSA takes powers away from competent national bodies to assess foods.

Both foods from GM plants and GEAs fall under the scope of the Food and Feed Regulation.⁵¹ The framework established by the Food and Feed Regulation has the merit of regulating similarly a variety of novel processes, i.e. bioengineering of plants and of animals, which create similar risks. Preapproval is necessary for GM foods before entering the EU market and mandatory labelling is required.⁵² Traditionally, the burden of proof lies with the person opposing an activity to prove that it is likely to cause environmental damage or threaten public health. For biotech foods, the precautionary principle shifts the burden of proof and requires the applicant to provide data and prove that their product does not cause excessive adverse effects on health, that is, their food must be safe. This fundamental shift in the burden of proof started with the 2000 Communication on the Precautionary Principle⁵³ and was enshrined in the General Food Law.⁵⁴ The 2000 Communication on the Precautionary Principle specifies that the principle of prior approval (positive list) before placing GM foods on the market is one way of applying the precautionary principle as it shifts the responsibility for producing scientific evidence.⁵⁵ Scientific justification is “not required to ban a product from the market, but to gain access to the market”.⁵⁶ To this extent, the new regime could “only go so far along the road towards an overtly strong

⁴⁹ However, this further integration is not without problems. See e.g. L. Levidow and S. Carr, “Europeanising Advisory Expertise: The Role of ‘Independent, Objective, and Transparent’ Scientific Advice in Agri-Biotech Regulation” (2007) 26 *Environment and Planning C: Government and Policy* 880.

⁵⁰ See European Commission, “Communication Reviewing the Decision-Making Process on GMOs” COM (2015)176 final; and Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of Genetically Modified Organisms (GMOs) in their Territory [2001] OJ L 68/1.

⁵¹ Foods from GEAs are produced through GM techniques which are included in the definition contained in Annex IA, part 1, of Directive 2001/18 and referred to in Art.2(2) of the same directive. See Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and repealing Council Directive 90/220/EEC [2001] OJ L106/1.

⁵² In 2015, the European Commission authorised 17 GMOs for food/feed uses. European Commission, “Commission Authorises 17 GMOs for Food/Feed Uses and 2 GM Carnations” (European Commission, Press release, 24 April 2015). http://europa.eu/rapid/press-release_IP-15-4843_en.htm [Accessed 26 May 2017].

⁵³ European Commission, “Communication from the Commission on the Precautionary Principle” COM(2000) 20. For more on the Communication, see J.D. Graham and S. Hsia, “Europe’s Precautionary Principle: Promise and Pitfalls” (2002) 5 *Journal of Risk Research* 371.

⁵⁴ Art.7 General Food Law.

⁵⁵ European Commission, “Communication from the Commission on the Precautionary Principle” COM(2000) 21. The Communication can be seen as a precursor to the subsequent Food and Feed Regulation and Traceability Regulation. Precaution is also present in the fact that the marketing authorization for GM foods is renewable for ten-year periods. This limitation puts pressure on the industry to further research GM foods and assess new scientific evidence as the authorization can stop or not be renewed. See Art.7(5) Food and Feed Regulation.

⁵⁶ B. van der Meulen, “Science based Food Law” (2009) 4 *European Food and Feed Law Review* 58, 71. This statement can be differentiated from Lee’s argument that “the restriction of a new technology needs to be justified, not its introduction”. See M. Lee, *EU Regulation of GMOs: Law, Decision-making and New Technology* (Cheltenham: Edward Elgar, 2008) 83.

precautionary approach to the regulation of GMOs and their derivative products”.⁵⁷ This reversal of the burden of proof is based on the rationale that applicants gain financially and should bear part of the responsibility for risk assessment as they have access to the data needed.⁵⁸ The EFSA “shares part of the burden [...] through its responsibility to evaluate the applicant’s data”.⁵⁹

Under the 2015 Novel Foods Regulation, novel foods are preapproved and then included in the Union list of novel foods.⁶⁰ This procedure demonstrates the application of the precautionary principle in the new regime.⁶¹ To assess the “novelty” of foods under the regulation, two criteria must be fulfilled. A novel food is “any food that was not used for human consumption to a significant degree within the Union before 15 May 1997”.⁶² It is the “primary element to determine whether a food” falls under its scope.⁶³ The same cut-off date as the 1997 Novel Foods Regulation is used and provides continuity and certainty in the regulatory regime. Additionally, novel food must fall within at least one of the ten categories listed in Article 3 of the new regulation. As a rule of thumb, foods are considered “novel” if they are newly developed, innovative, produced using new technologies and production methods (i.e. cloned food, cultured meat or nanomaterials) or traditionally eaten outside of the EU (i.e. insects).

Critically, the regulation introduces a paradigm shift from “applicant/individual-based” to “generic” authorizations.⁶⁴ Once authorized and added to the EU list a novel food may be placed on the market by any food business operator. This avoids repeated new applications by other companies for the same novel food and should benefit in particular small and medium-sized enterprises.⁶⁵ The new rules are expected to speed up the process to around eighteen months compared to three years under the current rules.⁶⁶

⁵⁷ N. Salmon, “What’s ‘Novel’ About It? Substantial Equivalence, Precaution and Consumer Protection 1997-2004” (2005) 7 *Environmental Law Review* 138, 148. See also T. Christoforou, “The Regulation of Genetically Modified Organisms in the European Union: The Interplay of Science, Law and Politics” (2004) 41 *CML Rev.* 637.

⁵⁸ R. Andorno, “The Precautionary Principle: A New Legal Standard for a Technological Age” (2004) 1 *Journal of International Biotechnology Law* 11, 19.

⁵⁹ Anker and Grossman, “Authorization of Genetically Modified Organisms” (2009) 4 *European Food and Feed Law Review* 13, 17. The independence, transparency and objectivity of the decisions taken by the EFSA experts have been contested. See Levidow and Carr, “Europeanising Advisory Expertise” (2007) 26 *Environment and Planning C: Government and Policy* 880.

⁶⁰ Art.6 2015 Novel Foods Regulation. The publication of the list could be beneficial to consumer information.

⁶¹ Art.10 2015 Novel Foods Regulation.

⁶² Art. 3(2)(a) 2015 Novel Foods Regulation.

⁶³ P. Coppens, “The Revision of the Novel Foods Regulation: Forget about Cloning and Nanotechnology, Let’s Focus on the Scope” (2013) 9 *European Food and Feed Law Review* 238, 246.

⁶⁴ This new procedure for application could create proprietary data issues. See e.g., C. Simpson. “Data Protection under Food Law Post: In the Aftermath of the Novel Foods Regulation” (2016) 11 *European Food and Feed Law Review* 309.

⁶⁵ T. Laaninen, “Updating Rules on Novel Foods to Keep up with Scientific Advances” (European Parliamentary Research Service, Briefing, June 2015).

⁶⁶ European Council and Council of the European Union, “New Rules on Novel Foods get Council’s Approval” (Press Release, 11 November 2015) <http://www.consilium.europa.eu/en/press/press-releases/2015/11/11-novel-foods-new-rules> [Accessed 26 May 2017].

The 2015 Novel Foods Regulation creates a dedicated regime for cloned foods. Cloned foods are specifically mentioned under Art.3(2)(a)(v) and must be authorized before being placed on the market. The new regulation contrasts with the 1997 Novel Foods Regulation where cloned foods could fall under the simplified procedure. The very distinct regulatory structures between cloned and GM foods before the establishment of the 2015 Novel Foods Regulation seemed incoherent, unsustainable and even contradictory as these two types of foods raise similar levels of risk.

Labelling and traceability requirements are another expression of the precautionary principle.⁶⁷ The GM food regulations require the mandatory traceability and labelling of products of GMOs, consisting of or containing GMOs and products for food produced from GMOs.⁶⁸ They allow consumers to know what they are eating. For Lee, the labelling of GMOs in the EU is “a ‘last resort’ response to extreme antipathy to the new technology”.⁶⁹ Indeed, part of the rationale for demanding traceability and labelling is that it should help restore consumer confidence in the food safety system by giving greater information and choice to consumers. The focus of the regulation is to provide information to consumers through the labelling of GM foods and the creation of a “safety net” based on the labelling and traceability of GM foods at every stage of the food chain.

With regards to the labelling requirements for cloned foods, the 2015 Novel Foods Regulation has similar requirements as the 1997 Novel Foods Regulation. Novel foods are subject to general labelling requirements.⁷⁰ The 2015 Novel Foods Regulation does not require the mandatory labelling of all novel foods because it covers both novel food technologies and traditional foods from countries outside the EU. As with the 1997 Novel Foods Regulation, Art.9(3)(b) only requires additional labelling “to inform the final consumer”.⁷¹ **Informing consumers about cloned food could prove a critical element because such foods give rise to specific ethical concerns. Such ethical concerns when regulating cloned foods might be animal health and welfare, or more general concerns about humankind ‘playing God’.**⁷² **Consequently, foods from cloned animals could require additional labelling. Presently, this is the only provision that could allow consumers to know if the food they eat comes from a cloned animal.**

⁶⁷ See e.g. Anker and Grossman, “Authorization of Genetically Modified Organisms” (2009) 4 European Food and Feed Law Review 13, 21. For a view that labelling is a coexistence issue, see Lee, *EU Regulation of GMOs: Law, Decision-making and New Technology* (2008).

⁶⁸ Art.12(1) Food and Feed Regulation, and Art.4 and Art.5 Traceability Regulation.

⁶⁹ See Lee, *EU Regulation of GMOs: Law, Decision-making and New Technology* (2008) 240.

⁷⁰ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 [2011] OJ L304/18.

⁷¹ Art.9(3)(b) 2015 Novel Foods Regulation.

⁷² See Gallup Organization, “Europeans’ Attitudes Towards Animal Cloning” (European Commission, October 2008).

In 2013, the Commission submitted two separate proposals on animal cloning and its derived foods, which would strengthen precaution in relation to such foods. The Proposal for a Directive on Animal Cloning for Farming Purposes would provisionally ban such practices.⁷³ This proposal was complemented by a Proposal for a Directive on Cloned Foods which would temporarily prohibit the placing on the market of these products as well as their importation.⁷⁴ In September 2015, the European Parliament voted to strengthen the Commission's initial proposal on animal cloning both in terms of substance and form. The new act proposes to ban the cloning of all farm animals, their descendants and products (both food and feed) derived from them as well as the imports of reproductive material, clones and their descendants.⁷⁵ Not only does the amended text combine the Commission's proposals into one but, crucially, it changes the legal act into a regulation to allow for direct application rather than a directive, which would require transposition into national legislation. The European Parliament has followed this strong precautionary approach towards animal cloning since 2010.⁷⁶

If these two proposals were passed, cloned foods would not be placed on the EU market. Agreeing on new texts is particularly difficult as the EU, when it comes to biotechnology, has approached "the problem of coordinating differences among its members without erasing them".⁷⁷ As such, there is a vast gap between intention and reality. **On the one hand, EU institutions and consumers favour a ban on animal cloning for food consumption and their resulting products, while on the other hand, these products could be placed on the market without mandatory labelling under the 2015 Novel Foods Regulation.**

There is generally little consensus about what biotech foods regulation should be about and not everyone is satisfied with the establishment of specific frameworks for biotech foods. However, by adopting a prudent and precautionary approach, EU decision-makers have reduced the level of criticism.

Substantial Equivalence by the Backdoor

Despite an apparent removal of substantial equivalence within the regimes for biotech foods and their focus on the precautionary principle, two pathways exist for substantial equivalence to be

⁷³ Proposal for a Directive of the European Parliament and of the Council on the Cloning of Animals of the Bovine, Porcine, Ovine, Caprine and Equine Species Kept and Reproduced for Farming Purposes, COM(2013)892 final.

⁷⁴ Proposal for a Council Directive on the Placing on the Market of Food from Animal Clones, COM(2013)893 final, 6.

⁷⁵ European Parliament/Legislative Observatory, "2013/0433(COD) - 08/09/2015 Text adopted by Parliament, 1st Reading/Single Reading" (8 September 2015)

www.europarl.europa.eu/oeil/popups/summary.do?id=1401503&t=d&l=en [Accessed 26 May 2017].

⁷⁶ Position of the European Parliament adopted at Second Reading on 7 July 2010 with a View to the Adoption of Regulation (EU) No .../2010 of the European Parliament and of the Council on Novel Foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001.

⁷⁷ S. Jasanoff, "Biotechnology and Empire: The Global Power of Seeds and Science" (2006) 21 OSIRIS 273, 290.

reintroduced into the biotech food regimes, through the utilisation of a comparative approach and through gaps in the law.

A Comparative Approach

As observed, one of the two central elements of substantial equivalence is the comparative analysis between biotech and conventional foods. Every determination of substantial equivalence requires the identification of an “equivalent” product, an understanding of the characteristics of the biotech product and the conventional product, and a comparison of the two sets of characteristics, including the assessment of the similarities and differences between biotech and conventional foods. As such, a “comparative approach”⁷⁸ is inherent in the very test of substantial equivalence. This comparative approach is utilised both scientifically and regulatorily in the text of the Food and Feed Regulation and the 2015 Novel Foods Regulation.

Certain articles in the Food and Feed Regulation and the 2015 Novel Foods Regulation state that a biotech food must not be “different from” or “differ from” its conventional counterpart. From a regulatory standpoint, Art.4(1)(c) of the Food and Feed Regulation states that GM foods must not “*differ from* the food which they are intended to replace”.⁷⁹ The regulation also specifies that the application submitted to the EFSA shall be accompanied by “an analysis [...] showing that the characteristics of the food are *not different from* those of its conventional counterpart”.⁸⁰ Additional labelling requirements for GM foods should mention any characteristic or property which renders a food “*different from* its conventional counterpart”.⁸¹ The decisive criterion for additional labelling of GM foods is based on a comparative approach. Under the Food and Feed Regulation, both the premarket authorization and labelling are underpinned by this comparative approach. For cloned foods, Art.7(c) of the 2015 Novel Foods Regulation asserts that where a novel food is intended to replace another food, the novel food to be authorized must “*not differ from* that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer”.⁸² The premarket authorization of novel foods is also based on a comparative approach.

From a scientific stance, Article 6(3)(e) of the Food and Feed Regulation, which deals with the opinion of the EFSA, stipulates that “the authority examines the information and data submitted by the applicant to show that the characteristics of the food are *not different from* those of its conventional counterpart”.⁸³ Similarly, under the 2015 Novel Foods Regulation, when undertaking

⁷⁸ H.A. Kuiper and others, “Substantial Equivalence - An Appropriate Paradigm for the Safety Assessment of Genetically Modified Foods?” (2002) 181 *Toxicology* 427, 427 (emphasis added).

⁷⁹ Art.4(1)(c) Food and Feed Regulation (emphasis added).

⁸⁰ Art.5(3)(f) Food and Feed Regulation (emphasis added).

⁸¹ Art.13(2)(a) Food and Feed Regulation (emphasis added). See also M. Friant-Perrot, “The European Union Regulatory Regime for Genetically Modified Organisms and its Integration into Community Food Law and Policy” in L. Bodiguel and M. Cardwell (eds), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (Oxford: Oxford University Press, 2010) 79.

⁸² Art.7(c) 2015 Novel Foods Regulation (emphasis added).

⁸³ Art.6(3)(e) Food and Feed Regulation (emphasis added).

a safety assessment for novel foods the EFSA considers if the novel food is “*as safe as* food from a comparable food category” and if it “*does not differ from* that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer”.⁸⁴ **This comparative approach also includes an “as safe as” approach. Further, the emphasis is placed on health of the consumer, ignoring wider harm (including arising from the process of production), and ignoring “ethical harm”.**

In its 2008 risk assessment of cloned foods, the EFSA concluded that there was “*no indication that differences* exist in terms of food safety between food products from healthy cattle and pig clones and their progeny, compared with those from healthy conventionally-bred animals”.⁸⁵ The EFSA employs a “not differing from” approach, that is a comparative approach to reach such a conclusion. The EFSA comparisons are made on two levels: first, with conventionally bred animals; and, second, with other assisted reproductive technologies.⁸⁶ Such a comparative analysis impliedly led to cloned foods being declared substantially equivalent to conventional foods.⁸⁷

As noted, novel foods, including cloned foods, only require additional labelling to inform the final consumer under the 2015 Novel Foods Regulation. Interestingly, the (absence of) equivalence between a novel and conventional food is the criterion for labelling.⁸⁸ As cloned foods have been declared equivalent to conventional foods by the EFSA, they will likely not require labelling. Under both Novel Foods Regulations, cloned foods can be released onto the markets with identical labelling requirements as conventional foods because they are deemed to be substantially equivalent to existing foods. **Therefore, the new regulation is not as precautionary as originally thought and overall appears as weak when failing to regulate comprehensively cloned foods.**

The EFSA itself validates substantial equivalence when assessing the safety of foods from GEAs. Although there is no application for premarket authorization for GEAs in the EU yet, the EFSA published in a proactive manner a Guidance on GEAs to establish a harmonized practice⁸⁹ and thereby reinforced its role as European scientific assessor. Most importantly, the guidance noticeably states that substantial equivalence is part of the comparative safety assessment of foods

⁸⁴ Art.11(2) respectively (a) and (c) on the opinion of the EFSA, 2015 Novel Foods Regulation (emphasis added).

⁸⁵ EFSA, “Final Scientific Opinion on the Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals” (EFSA, 2008) 31 (emphasis added).

⁸⁶ L. Petetin, “Clone Wars? The Challenges of Cloned Food in EU, US and WTO Law” (2009) 11 Environmental Law Review 246, 250.

⁸⁷ For a contrasting analysis that foresees an approval system for cloned foods, see M. Weimer, “The Regulatory Challenge of Animal Cloning for Food – The Risks of Risk Regulation in the European Union” (2010) 1 European Journal of Risk Regulation 31.

⁸⁸ Art.9(3)(b) 2015 Novel Foods Regulation states that additional labelling is required to “inform the final consumer of any specific characteristic [...], which renders a novel food no longer equivalent to an existing food or of implications for the health of specific groups of the population”.

⁸⁹ EFSA, “Scientific Opinion on the Guidance on the Risk Assessment of Food and Feed from Genetically Modified Animals and Animal Health and Welfare Aspects” (EFSA, 2012) 7. The guidance develops risk assessment guidelines for foods from GEAs and indicates how to evaluate risks for food safety. See also EFSA, “Genetically Modified Animals” (2017) www.efsa.europa.eu/en/topics/topic/gmanimals.htm [Accessed 26 May 2017].

from GEAs.⁹⁰ Similarly, at an international level, in its Guideline for the Conduct of Food Safety Assessment of foods derived from GEAs, the Codex Alimentarius Commission (CAC) declares that the safety assessment of foods derived from GEAs relies on the concept of substantial equivalence as part of the process to identify similarities and differences between the new food and its conventional counterpart.⁹¹ It seems that foods from GEAs revive the concept of substantial equivalence.

Interestingly, the 2003 CAC principles on the risk assessment of foods derived from GM plants includes a safety assessment designed to identify whether a “hazard, nutritional or other safety concern is present” and compares a biotech food and its conventional counterpart by focussing on determination of similarities and differences.⁹² Both CAC safety assessments involve a comparative analysis which rely on the same elements. If the CAC switches between the comparative approach and substantial equivalence in its guidance documents, it most likely means that these concepts are treated as interchangeable. The foundation of both documents is substantial equivalence.

Substantial equivalence or comparative approach, if it is indeed different, means that a biotech food is as safe as an existing food. There is, however, still nothing in this comparative approach on how different a biotech food has to be to make it not comparable to a conventional food. There is no specification as to when a difference becomes too great: what if the foods satisfy most criteria but there is a huge difference in respect of one criterion. It is only in the case where there is no comparator that a comprehensive safety assessment will be undertaken. On this point, the CAC Guideline for Foods from GEAs states interestingly that, when no comparator can be selected, “a comparative safety and welfare assessment cannot be made, and thus a comprehensive safety and nutritional assessment of the products from the GM animal should be carried out”.⁹³ This appears worrying in relation to the actual reliability and safety of the assessments undertaken when a comparator exists. The comparative approach is still limited and insufficient both scientifically and regulatorily. This comparative risk assessment is inadequate and undermines the precautionary approach towards biotech as it (re)introduces substantial equivalence and its deficiencies into the regulatory regimes. This is confirmed by Ghisleri and others who explained that the EU risk assessment methodology for GM foods, as well as those of other countries, is still based on the concept of substantial equivalence.⁹⁴ **More in depth assessments of biotech foods are needed.**

⁹⁰ EFSA, “Scientific Opinion on the Guidance on the Risk Assessment of Food and Feed from Genetically Modified Animals and Animal Health and Welfare Aspects” (EFSA, 2012) 7.

⁹¹ “The concept of *substantial equivalence* is a key step in the safety assessment process”. “The expected endpoint of such a [safety] assessment will be a conclusion regarding whether the new food is *as safe as* the conventional counterpart”. See Codex Alimentarius Commission, “Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals” (CAC, 2008) 3 and 4 (emphases added).

⁹² Codex Alimentarius Commission, “Principles for the Risk Analysis of Foods Derived from Modern Biotechnology” (CAC, 2003) 10.

⁹³ Codex Alimentarius Commission, “Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals” (CAC, 2008) 15.

⁹⁴ Ghisleri and others, “Risk Analysis and GM foods” (2009) 4 *European Food and Feed Law Review* 235, 241-247.

For Anker and Grossman, substantial equivalence no longer applies in the EU and GM foods can only be marketed following a full risk assessment,⁹⁵ but this has proved to be only controversial and artificial. Levidow and others suggest renaming substantial equivalence as the “comparative approach”. They argue that the concept was demoted for two main reasons: to focus on differences between a biotech food and its non-biotech counterpart, and to no longer be used to justify the claim that a risk assessment is unnecessary.⁹⁶ Nonetheless, it has been shown that, contrary to what Levidow and others argue, the concept has not been “recast” to play a diminished role but to strengthen its centrality in the assessment of biotech foods and to substantiate its status at the heart of biotech food regimes both as a scientific and a regulatory concept. The EU has not in reality moved away from the concept of substantial equivalence.

Gaps in the Law

Various loopholes present in the regulatory regimes for GM and cloned foods have led to the reappearance of equivalence in the premarket authorization and labelling of biotech foods. These loopholes establish an assumption of substantial equivalence of risk, and therefore of safety, between biotech and conventional foods. Under the Food and Feed Regulation, food and feed “manufactured with the help of a genetically modified processing aid” are excluded from the scope of the regulation.⁹⁷ This means that products obtained from animals fed with GM feed and their resulting products, including milk, meat and eggs, are not subject to authorization, labelling or traceability requirements. **It is assumed that these foods are “as safe as” existing foods.** Animals fed with GM feed and their resulting foods are substantially equivalent to animals fed with non-GM feed even though the animals that produced these foods are a result of different production processes, that is, they ate different types of feed. Animals fed with GM feed become like a Trojan horse since animal feed accounts for a large proportion of imports of GM crops.⁹⁸ This loophole facilitates exports of GM feed into the EU.

The 2015 Novel Foods Regulation, like its 1997 predecessor, does not require the approval, labelling and traceability of foods that derive from the descendants of cloned animals or imports of reproductive material from cloned animals.⁹⁹ Such foods or imports fall outside the definition of a novel food. **The products from the offspring of cloned animals bear the assumption that**

⁹⁵ Anker and Grossman, “Authorization of Genetically Modified Organisms” (2009) 4 European Food and Feed Law Review 13, 17.

⁹⁶ L. Levidow and others, “Recasting ‘Substantial Equivalence’: Transatlantic Governance of GM Food” (2007) 32 Science, Technology and Human Values 24, 58.

⁹⁷ Recital (16) Food and Feed Regulation.

⁹⁸ See e.g. International Service for the Acquisition of Agri-biotech Applications, “Global Status of Commercialized Biotech/GM Crops: 2015” (2015). 60% of the feed used in the EU is imported and imports come mainly from countries where cultivation is dominated by GMOs. See also European Commission, “Communication Reviewing the Decision-Making Process on GMOs” COM (2015)176 final 5.

⁹⁹ A recent research has shown that “every year around 30 to 40 tons of bull sperm enter the EU from the US for the purpose of cattle breeding”. See Testbiotech, “Cloned bulls and the implications of CETA” (EUBusiness, 10 February 2017), <http://www.eubusiness.com/Members/testbiotech/cloned-bulls> [Accessed 26 May 2017].

they are equivalent, i.e. they are “as safe as” conventional foods. Practically, this means that the possibility for a consumer to see any food labelled as deriving from a clone is extremely limited as it is expected that only the descendants of clones will be used in the food supply chain. Similarly, food from the offspring of GEAs is not mentioned in the Food and Feed Regulation. Therefore, they are also considered to be “as safe as” conventional foods. The premarket authorization and labelling of such foods are unregulated. This is interesting as in contrast foods from GEAs would be preauthorized and labelled.

The 0.9 per cent labelling threshold for approved GM foods appears as another pathway for substantial equivalence to infiltrate in the food chain and limit the precautionary approach towards such foods. The labelling of foods with materials which contain, consist of or are produced from authorized GMOs in a proportion no higher than 0.9 per cent of the food ingredients are exempted from any labelling obligation, provided their presence is considered to be adventitious or technically unavoidable.¹⁰⁰ **Similarly as in the *Monsanto* case, small amounts of residues present in the foods do not prevent GM foods from being equivalent to conventional food.¹⁰¹ GM residues are deemed safe and not requiring further safety assessment or labelling.** This gap in labelling and traceability rules prevent the burdening of the industry but sacrifice consumer information.

The gaps in the regulatory regimes emphasise the role of substantial equivalence, and in particular its first element that is the assumption of equivalence and risk. Certain biotech foods are assumed to be “as safe as” existing foods and because they are assumed to be safe they are unregulated. These loopholes undermine the credibility of the whole EU labelling system and reinforce the Trojan horse analogy. By looking more closely at the text and the practicalities of EU regulations, substantial equivalence is still at the heart of the regulatory process, thus revealing its pervasiveness. It plays a hidden and decisive role. **Overall, the comparative approach and the gaps in the regulatory regimes indicate that the scientific and regulatory elements of substantial equivalence are still present today in the regulations.**

Framing regulations and assessments on substantial equivalence and its assumption that biotech foods are equivalent to conventional foods might have been appropriate in the early development of modern agricultural biotechnology but to still rely on it today appears to be problematic – first, because of its application to new technologies (which did not exist thirty years ago when the concept emerged) and their associated risks; second, the limited requirements it establishes, which diminish a precautionary approach towards biotech foods; and third, the growing consumer opposition and the limited options available to citizens to express their concerns in the regulatory regimes.

The dominance of equivalence impacts on consumers

¹⁰⁰ Art.12(2) Food and Feed Regulation.

¹⁰¹ *Monsanto* case, para 84. The case appears to have created a presumption that even if there are GM residues in the foods, these foods are not prevented from being substantially equivalent to conventional foods.

The artificial approval and labelling of biotech foods establishes weak regimes, which could lead to potential safety problems. As observed, there appears to be a presumption that even if there are GM residues in the foods, these are not prevented from being substantially equivalent to conventional foods and they are safe to eat.¹⁰² The situation seems to be “less protective of human health given the uncertainty of the effects of transgenic proteins present in novel food”.¹⁰³ This is to say nothing of the wider potentially harmful environmental impacts associated within the production of GM residues’.

Although the labelling and traceability rules that exist under the Food and Feed Regulation, the Traceability Regulation and the 2015 Novel Foods Regulation have a positive effect in facilitating informed choice for consumers, the presence of substantial equivalence sustains the misinformation of consumers and their inability to truly choose between conventional and biotech foods. As noted, because cloned foods are deemed to be equivalent to conventional foods, they likely will not require labelling. This situation appears to contradict the preamble of the 2015 Novel Foods Regulation which states that the use of novel foods “should not mislead the consumer”.¹⁰⁴ Under the Food and Feed Regulation and the Traceability Regulation, consumers are not guaranteed access foods free from GMOs; at best, they are offered “food which is ‘without GMOs’, in the sense that any cross-contamination is light”.¹⁰⁵ The presence of GM residues below 0.9 per cent does not prevent these foods from being substantially equivalent to conventional foods and from requiring no labelling. The “real choice” available to the consumer is limited by gaps in the labelling obligations.¹⁰⁶ Consumers are most likely unaware of the existing loopholes and may think that they are eating foods which are 100 per cent GM-free which means that they are being misled.¹⁰⁷ It seems contrary to consumer demand for “objective information” and “clear labelling” as stated in the preamble of the Food and Feed Regulation.¹⁰⁸

The regulatory uncertainty created in the framework for biotech foods contrasts with the certainty of the outcomes of surveys on biotech foods which show the opposition of consumers towards such foods. For many EU consumers, GM foods are different from their conventional counterparts, irrespective of their equivalence.¹⁰⁹ Consumer resistance is even stronger in the case of cloned foods as the health and welfare of animals are at issue and they raise further emotional and ethical aspects. The vast majority of EU citizens agree that animal cloning is morally wrong.¹¹⁰

¹⁰² See Food and Feed Regulation and *Monsanto* case.

¹⁰³ R.R. Fernandez, “Monsanto and the Requirement for Real Risks in GM Food Regulation” (2006) 28 *International & Comparative Law Review*, 335, 344 (specifically referring to the *Monsanto* case).

¹⁰⁴ Recital 20 and Art.7(b) 2015 Novel Foods Regulation. There is a similar statement in Art.3(1) 1997 Novel Foods Regulation.

¹⁰⁵ M. Friant-Perrot, “The European Union Regulatory Regime for Genetically Modified Organisms and its Integration into Community Food Law and Policy” in L. Bodiguel and M. Cardwell (eds), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (Oxford: Oxford University Press, 2010) 79, 94.

¹⁰⁶ Lee, *EU Regulation of GMOs: Law, Decision-making and New Technology* (2008) 141.

¹⁰⁷ This appears contrary to Art.4(1)(b) Food and Feed Regulation.

¹⁰⁸ Recital (21) Food and Feed Regulation.

¹⁰⁹ The majority of EU consumers wants to know whether their food was produced using GMOs. See Gaskell and others, “Europeans and Biotechnology in 2010: Winds of change?” (European Commission, October 2010) 8.

¹¹⁰ Gallup Organization, “Europeans’ Attitudes towards Animal Cloning” (European Commission, October 2008) 10.

Surveys reveal a willingness to question modern agricultural biotechnology. Positive attitudes towards the mandatory labelling of foods derived from animal cloning, GEAs and GM plants are strengthening.¹¹¹ EU consumers want to know what they eat and call for transparency, traceability and labelling in foods. For them, the processes involved in modern agricultural biotechnology are not equivalent and so differ, as do their derived foods.

The 2000 White Paper on Food Safety puts consumers and consumer information at the centre of EU policy by stating that consumers have the “right to expect information on food quality and constituents that is helpful and clearly presented, so that informed choices can be made”.¹¹² Labelling is one of the main tools for consumer protection and information. As stated by Macmaolain, as consumers have become increasingly concerned about food ingredients, it is not surprising that the area of EU food law that leads to the most contention is food labelling.¹¹³ Labelling is a “crucial component of GM regulation, enabling choice on the basis of a criterion that would not otherwise be visible to purchasers”.¹¹⁴ The same is applicable to cloned foods. Consumers are unable to truly choose between biotech and non-biotech products and are arguably misled. The absence of accurate consumer choice and information for biotech foods can be sharply distinguished from the EU system of rules and principles aimed at protecting and improving the information of consumers,¹¹⁵ and could result in consumer ignorance, as well as potential consumer deception.

Further, biotech foods generally fall under the scope of inherited statutes. **This situation calls into question the adequacy of the existing frameworks for biotech foods to address issues of risk and consumer information.** The Food and Feed Regulation does not expressly mention that it covers foods from GEAs as its establishment predates the advent of such foods. Foods from GEAs are regulated by an existing regime which was not designed to deal with the specific issues raised by this new type of food. **To a similar extent, when foods derived from animal cloning came to the fore in 2008, they were regulated by a structure (the 1997 Novel Foods Regulation) that was not designed for these products and had been criticised for almost a decade. The Food and Feed Regulation and 1997 Novel Foods Regulation focus on food of plant origin, not of animal origin. Food of animal origin raise distinctive issues, like animal health and welfare and ethics, which are not considered under these regimes.** This is also true

¹¹¹ See Gaskell and others, “Europeans and Biotechnology in 2010: Winds of change?” (European Commission, October 2010). For instance, nine out of ten EU citizens considered it crucial that food products from the offspring of cloned animals be labelled. See Gallup Organization, “Europeans’ Attitudes Towards Animal Cloning” (European Commission, October 2008) 41.

¹¹² European Commission, White Paper on Food Safety COM(1999) 32. See also European Commission Directorate-General for Press and Communication, “From Farm to Fork: Safe Food for Europe’s Consumers” (Office for Official Publications of the European Communities 2004) 14; and European Commission, “The European Union Explained - From Farm to Fork: Safe and Healthy Food for Everyone” (Office for Official Publications of the European Union, 2014).

¹¹³ C. Macmaolain, *EU Food Law: Protecting Consumers and Health* (Oxford: Hart Publishing, 2007) 77.

¹¹⁴ Lee, *EU Regulation of GMOs: Law, Decision-making and New Technology* (2008) 141.

¹¹⁵ This system applies to all products (including foods) made available to EU consumers. Consumer protection together with an “informed consumer” policy is central to EU law and policy. See Art.169 TFEU.

to a certain extent for the 2015 Novel Foods Regulation. The regulation mentions animal welfare and ethical concerns but only in relation to animal testing.¹¹⁶ There is no reference to the use of animals for farming purposes.¹¹⁷ The regulations constitute the regulatory net for biotech foods.

It is generally assumed that new technologies should trigger a new set of rules and a new framework should be created. However, foods from GEAs indicate that often the new technology “inherits”¹¹⁸ the “regulation of a previous innovation rather than benefiting from suitably updated legislation”, even if the new technology creates its “own specific risks and uncertainties in relation to scientific, environmental, safety or human health impacts”.¹¹⁹ **This is confirmed by Lee who argues that “it should not be assumed that a new technology can be assessed using the tool that proved effective for the last technology”.¹²⁰ Inherited laws are utilised to regulate new types of foods. The expansive application of biotech food regulations to different technologies, which did not exist when the regulations were drafted, limits the effectiveness of the regimes and proves overall to be problematic.** Newer, more precautionary frameworks are needed.

Substantial equivalence should not be present in the regulation of biotech foods as it reduces consumer choice and safety. From the viewpoint of the consumer, biotech foods are not substantially equivalent and the regulators should accommodate this. Nonetheless, moving away from substantial equivalence would be costly for producers and manufacturers as they would bear the regulatory burden of proving the safety of their products, the costs of labelling and traceability (including segregation and identity preservation). But, more importantly, this is an acceptable price to pay as such a new system would, first, improve safety as appropriate assessments would be made; second, establish clarity and simplicity in the system; and third, accommodate consumer preferences which would restore consumer confidence as the regime would be more transparent (which could be a benefit for producers). In the end, the entity producing the biotech food would bear the burden – which does not seem unreasonable.

Conclusion

It is often thought that the EU adopts a “better safe than sorry” or precautionary approach to manage the uncertainty created by biotech foods through the establishment of specific regimes for GM and cloned foods, which include premarket authorization, mandatory labelling and traceability. However, this precautionary approach is limited by the role played by substantial equivalence and the way it underpins the existing regimes.

Both the precautionary principle and substantial equivalence still interplay in the field, despite an apparent and formal departure from substantial equivalence. Substantial equivalence

¹¹⁶ Recital 32 2015 Novel Foods Regulation.

¹¹⁷ Even before its entry into force, the 2015 Novel Foods Regulation is already too weak a regime.

¹¹⁸ E. Stokes, “Nanotechnology and the Products of Inherited Regulation” (2012) 39 *Journal of Law and Society* 93, 99. See also E. Stokes and D.M. Bowman, “Looking Back to the Future of Regulating New Technologies: The Cases of Nanotechnologies and Synthetic Biology” (2012) 2 *European Journal of Risk Regulation* 235.

¹¹⁹ L. Petetin, “Frankenburghers, Risks and Approval” (2014) 2 *European Journal of Risk Regulation* 168, 179.

¹²⁰ Lee, *EU Regulation of GMOs: Law, Decision-making and New Technology* (2008) 12.

was refined or recast into a comparative approach, which is utilised as the basis in biotech food policy and regulation. Substantial equivalence is at the heart of the 1997 Novel Foods Regulation and there is only an apparent “deletion” of the concept in the 2015 Novel Foods Regulation, the Food and Feed Regulation and the Traceability Regulation. These newer regimes indicate that the concept of substantial equivalence plays a decisive, underlying role in both the regulation and the assessment of biotech foods.

It has been established that substantial equivalence is no longer suitable to regulate biotech foods because of its focus on the end-product rather than the manufacturing process. Approval procedures and their reliance on substantial equivalence raise issues regarding the adequacy of the existing regimes in effectively regulating biotech foods, especially in relation to safety assessment. Limited labelling and traceability requirements for biotech foods due to substantial equivalence result in incomplete information being given to the public and limited consumer choice, which can deceive and mislead them. The various regulations for biotech foods, especially for foods from cloned and GE animals, demonstrate the problems raised by grafting new technologies on inherited frameworks.

Despite its failings and insufficiencies, substantial equivalence constitutes today embedded regulatory practice within biotech food regimes. The continued dependence on the concept of substantial equivalence (although not always obvious and straightforward) prevents the regulatory regimes for biotech foods from being truly precautionary. The intricate dynamic between substantial equivalence and the precautionary principle is a peril that undermines biotech food regulation and the EU food system. **The EU needs to act proactively in building a reliable and effective regulatory environment to establish premarket approval, comprehensive labelling, segregation and traceability requirements, which would recognise consumer concerns and allow the public to take informed choices as to the foods they eat.** As new modern agricultural food biotechnologies develop, so should the scientific assessments of these foods and their associated regulatory regimes.

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