EffL 6-12 29.01.2013 8:28 Uhr Seite 296

The Revival of Modern Agricultural Biotechnology by the UK Government: What Role for Animal Cloning?

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A renaissance of modern agricultural biotechnology to achieve food security is occurring in the UK, where animal cloning is moving centre stage. By establishing limited regulation and labelling and, therefore, limited controls on cloned animals, their progeny, and their derived foods, the UK favours the development of the technology. However, this regime reduces information for consumers and their freedom of choice. The new approach contrasts with a growing tendency to accommodate consumer preferences when regulating – as demonstrated by the positions endorsed by individual EU institutions – which weakens the legitimacy and the effectiveness of the UK regulatory intervention.

I. Introduction

The United Kingdom (UK) former Agriculture Minister Jim Paice declared in January 2012 at the Oxford Farming Conference that:

> 'We can keep the cosy image of Buttercup in the field producing a few litres a day and the bucolic farmer leaning on his gate. We can sentimentalise farmers as small players in a market dominated by supermarkets at home and multinational conglomerates abroad. Or: we can set this industry [farming] on fire and take the opportunities, and face the reality that those opportunities provide; [...] proud to still be producing most of the food for our people and ready to play our part in the Foresight challenge to feed the world'.[1]

This attitude reflects the new governmental approach towards new technologies.[2] Modern agricultural biotechnology must play a central role in sustainable intensification to attain food security.[3]

Since the Coalition Government took power in May 2010, it has been offering its backing and support to modern agricultural biotechnology and its industry. The former Secretary of State for Environment, Food and Rural Affairs, Caroline Spelman has made repeated calls for a green global economy where natural resources, science and technology play central stage.[4] More importantly, within the following days of the establishment of the Coalition Government, the Department for Environment, Food and Rural Affairs (DEFRA) authorised a field trial of a GM potato in Nor-

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1 Former Agriculture Minister Jim Paice, "Jim Paice's Speech at the Oxford Farming Conference 2012", 4 January 2012, available on the internet at <http://www.defra.gov.uk/news/2012/01/04/jim-paice-speech-oxford-farming-conference-2012/> (last accessed on 20 November 2012). In September 2012, the UK Prime Minister David Cameron, reshuffled his government and the current Agriculture Minister is David Heath.

2 From the outset, the market prospects that could provide modern agricultural biotechnology to the UK economy are underlined.

3 Genetic modification and animal cloning are part of modern agricultural biotechnology. The purpose of animal cloning is to be used as an assisted reproductive technology for breeding animals and to use the sexually-reproduced offspring of clones for food production.

4 See for instance, former Environment Secretary Caroline Spelman, "Caroline Spelman's Speech at the Oxford Farming Conference 2012", 4 January 2012, available on the internet at <http://www.ofc.org.uk/files/ofc/papers/caroline-spelman.pdf> (last accessed on 20 November 2012). Also, in May 2010 Caroline Spelman declared that she favoured GM foods 'in the right circumstances' as 'GM can bring benefits in food to the marketplace'. See Juliette Jowit and JohnVidal, "Environment Secretary Caroline Spelman Backs GM Crops", The Guardian, 4 June 2010. The current Environment Secretary is Owen Paterson.

EffL 6-12 29.01.2013 8:28 Uhr Seite 297

folk.[5] Also, in September 2011, DEFRA issued its consent to an application from Rothamsted Research to carry out a trial of a GM wheat resistant to aphids.[6] Indeed, the Government has reinforced its willingness to commercialise GMOs.

Genetic modification is not the only technology to be favoured by the new government's position, animal cloning for food production also benefits from it.[7] Both animal cloning and GMOs could potentially in the long-term offer a possible solution for food crises and shortages and play a determining role in achieving food security. Nonetheless, GMOs and animal cloning are contested because of the scientific uncertainty that surrounds them and the potential risks they raise. In relation to GMOs there are mainly two types of concerns: first, there is the question of the unknown long term effects of consuming GM crops/foods on humans (allergic reactions); and second, they can have effects on the environment per se (superweeds and reduction of biodiversity).[8] Concerning animal cloning, the overall success rate of the cloning procedure is still low. The cloning efficiency of cattle, namely the percentage of viable offspring born from transferred embryo clones, is around 10%; and that of pigs around 6%.[9] Animal cloning could lead to a reduction in the genetic diversity of farmed animals.[10] It can further push the evolution of genes in a single direction and new traits could be missed. The European Group on Ethics in Science and New Technologies (EGE) also concluded that 'considering the level of suffering and health problems of surrogate dams and animal clones, it had doubts as to whether cloning for food was justified'.[11] It did not see any convincing arguments to justify the production of food from clones and their offspring.[12] Despite such controversy, in 2008, the European Food Safety Authority (EFSA) concluded that meat and milk from clones and their progeny were safe even though 'the health and welfare of a significant proportion of clones [...] have been found to be adversely affected, often severely and with a fatal outcome'.[13]

The regulation of new technologies is not unproblematic for states. Over the past decades, as a 'scientization of risk' has occurred, risks are frequently being defined and measured according to scientific principles – as demonstrated by the EFSA opinion.[14] Scientific principles are widely dominant which can lead to the marginalisation of other relevant considerations. Risk has multiple dimensions; it has implications and meaning beyond scientifically quantified expressions of magnitude and effect. Risk is 'not [only] a matter of simple probabilities to be rationally calculated by experts and avoided in accordance with the cold arithmetic of

5 It may be noted that consent had also been granted shortly before the election for a similar trial of GM blight-resistant potatoes at the University of Leeds. See DEFRA, "Part B Consents Granted to Release Genetically Modified Organisms", 3 February 2012, available on the internet at <http://archive.defra.gov.uk/environment/quality/gm/regulation/registers/consents/index.htm> (last accessed on 20 November 2012). In the UK, DEFRA is the main government department on the environmental safety of GMO releases and also considers wider issues surrounding the use of GM crop technology, while the Food Standards Agency leads on the safety of GM food and feed, and responsible for novel foods more generally.

6 DEFRA, "Genetic modification (GM)", 28 September 2012, available on the internet at <http://www.defra.gov.uk/environment/quality/gm/> (last accessed on 20 November 2012).

7 When relevant, references will be made to GMOs. Comparisons between the more established genetic modification and the less established animal cloning and their derived products create a good opportunity to look for progression.

8 For more on GMOs and their regulation, see for example, Maria Lee, *EU Regulation of GMOs: Law, Decision-making and New Technology* (Cheltenham: Edward Elgar 2008); Theofanis Christoforou, "The Regulation of Genetically Modified Organisms in the European Union: the Interplay of Science, Law and Politics", 41 *Common Market Law Review* (2004), pp. 637 *et sqq.*; and Helle Anker and Margareth Grossman, "Authorization of Genetically Modified Organisms: Precaution in US and EC Law", 4 *European Food and Feed Law Review* (2009), pp. 3 *et sqq*.

9 EFSA, *Update on the state of play of Animal Health and Welfare and Environmental Impact of Animals derived from SCNT Cloning and their Offspring, and Food Safety of Products Obtained from those Animals* (2012), at p. 18. See also 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* (2008), at p. 18.

10 National Standing Committee on Farm Animal Genetic Resources, "Statement on Cloning of Farm Animals", June 2011, available on the internet at <http://archive.defra.gov.uk/fangr/documents/100914-cloning-statement.pdf> (last accessed on 20 November 2012). The National Standing Committee on Farm Animal Genetic Resources was set up in 2008 to advise on implementation of the UK National Action Plan on Farm Animal Genetic Resources and to provide technical advice on policy matters relating to the conservation and sustainable use of farm animal genetic resources.

11 European Group on Ethics in Science and New Technologies, *Opinion No 23 on the Ethical Aspects of Animal Cloning for Food Supply* (2008), at p. 45.

12 Ibid.

13 EFSA, *2008 Opinion of Animal Cloning*, *supra* note 9, at p. 32.

14 See, e.g., Ulrich Beck, *Risk Society: Towards a New Modernity* (M. Ritter tr; London: Sage 1992), at p. 56.

EffL 6-12 29.01.2013 8:28 Uhr Seite 298

cost-benefit analysis'.[15] Rather, risk is 'part of the modern human condition, woven into the very fabric of progress'.[16] There is a close relationship between science, risk and society. Science is not self-sufficient and is to be seen in context. Science and technology both embed and are embedded in social practices, identities, and institutions.[17] Consequently, decision-makers, when regulating new technologies, have to balance the differing views of stakeholders (public, politicians and scientists) over risks and how these should be regulated as well as which factors should be relevant. Animal cloning and its derived foods are the prime example of such disagreement – as will be observed in this article.

Because of the new UK pro-biotech stance, changes are noticeable in the UK policy on animal cloning and its resulting foods. As will be seen, the government prefers relatively light regulation and few labelling obligations, which impacts on consumer information and their ability to take informed decisions. Such a policy could create regulatory issues in relation to the risks created by cloning as a new technique; its compatibility with the European Union (EU) policy and law; and, its impact on consumer choice. As identified by Brownsword, regulatory interventions should be legitimate and effective to achieve specific regulatory purposes.[18] If they fulfil both conditions, regulators are proceeding in 'the right kind of way'.[19] Keeping this in mind and the fact that the new policy could raise regulatory issues, this article will try to determinate whether the new regulatory framework for animal cloning for farming purposes fulfil such conditions.

This article will explore the policy of the Coalition Government on modern agricultural biotechnology before focussing on the position on animal cloning including cloned foods and their labelling. It will further analyse whether such an approach is in line with the EU institutions by analysing the collapse of the review of the 1997 Novel Foods Regulation. Finally, the extent to which consumer preferences should be taken into account by regulators will be assessed.

II. The UK Approach: Modern Agricultural Biotechnology is the Way Forward

The 2011 Foresight Report on The Future of Food and Farming: Challenges and Choices for Global Sustainability from the Government Office for Science identifies food security as a governmental priority as well as sustainability.[20] Food security and sustainable agriculture are closely interconnected as a sustainable agricultural production and a sustainable food chain can help fighting and tackling hunger.[21] In order to achieve such priorities, the *Foresight Report* calls for the appraisal of modern biotechnology as it is capable of delivering resilient high levels of productivity.[22]

15 Sheila Jasanoff, "Technologies of Humility: Citizen Participation in Governing Science", 41 *Minerva* (2003), pp. 223 *et sqq*., at p. 224.

16 Ibid.

17 Sheila Jasanoff, "The Idiom of Co-production", in Sheila Jasanoff (ed), *States of Knowledge: The Co-production of Science and the Social Order* (London: Routledge 2006), pp. 1 *et sqq*., at p. 3.

18 Richard Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford: OUP 2008).

19 *Ibid* 9.

20 The Government Office for Science, *Foresight Report on The Future of Food and Farming: Challenges and Choices for Global Sustainability* (2011), at p. 5. The report defines sustainability as implying 'the use of resources at rates that do not exceed the capacity of the earth to replace them' that is 'a system or state where the needs of the present and local population can be met without diminishing the ability of future generations or populations in other locations to meet their needs and without causing harm to the environment and natural assets' See respectively p. 72 and 204. See also, DEFRA, "Caroline Spelman Speech to Food and Drink Association on 'Secure and Sustainable Food – The Rio+20 Challenge", 24 May 2012, available on the internet at <http://www.defra.gov.uk/news/2012/05/24/caroline-spelman-speech-to-food-and-drink-association-on-secure-and-sustainable-food-the-rio20-challenge/> (last accessed on 20 November 2012).

21 See for instance, European Commission, "Fighting hunger", 3 October 2012, available on the internet at <http://ec.europa.eu/europeaid/what/food-security/index_en.htm> (last accessed on 20 November 2012); European Commission, "Food waste", <http://ec.europa.eu/food/food/sustainability/index_en.htm> (last accessed on 20 November 2012); Michael Cardwell, "European Union Agricultural Policy and Practice: the New Challenge of Climate Change" 13 Environmental Law Review (2011), pp. 271 *et sqq*., at p. 271. The Foresight report defines sustainable intensification as 'the pursuit of the dual goals of higher yields with fewer negative consequences for the environment' for three reasons: (i) that there is relatively little new land for agriculture; (ii) that more food needs to be produced; and (iii) that food production must become sustainable. Foresight Report, *supra* note 20, at p. 73.

22 Ibid 88 and167. See also, Paice's Speech at Oxford Farming Conference, *supra* note 1, where Jim Paice describes sustainable intensification as 'using less and producing more'.

EffL 6-12 29.01.2013 8:28 Uhr Seite 299

As GM crops and animal cloning are identified as having the potential to feed more people than ever before, partnerships between research, technology and knowledge transfer should be increased to favour modern agricultural biotechnology.[23] Currently, the UK government spends £400 million a year on agricultural science, such as research into crop and livestock genetics to increase the competitiveness of UK farming and to contribute to 'tackling global food security'.[24] Therefore, favouring the development of modern agricultural biotechnology also has economic justifications.

The DEFRA stance is based on and informed by the report: it identified food sustainability and security as some of its main aims and modern agricultural biotechnology, with its economic potential, as a solution to such challenges. For instance, in his speech as DEFRA chief scientific adviser at the 2012 Oxford Farming Conference, Bob Watson confirmed that new technologies such as livestock genomics and GMOs are central to DEFRA policy on food and farming.[25] This is also exemplified by recent speeches of Caroline Spelman where the goals are a 'green and growing economy' where the biotech industry plays a determining role.[26]

The governmental priority to use GMOs and animal cloning for farming purposes seems, nonetheless, to be underpinned by scientific uncertainty and concerns. It appears, however, that the government is aware of the potential risks and concerns created by modern agricultural biotechnology but has made a policy decision to trade an element of biodiversity for increased production and economic growth to achieve food security and more importantly a 'green and growing economy'.

Because technological innovations command enormous rewards in the marketplace, economic considerations are often considered enough to 'drive science through the pipeline of research and development into commercialization'.[27] This is confirmed in the words of Beck who states that 'the first priority of techno-scientific curiosity is *utility for productivity*'.[28] Economic growth is a legitimation of the policy on modern agricultural biotechnology.

This pro-biotech stance recalls the 2002 European Communication on 'Life Sciences and Biotechnology – A Strategy for Europe' where even though the Commission states that there is a choice to be made for the EU between being proactive or passive, it is pretty clear that, for the Commission, there is only one policy choice: the EU must play an active role in the development of modern agricultural biotechnology.[29] The strategy remains a 'necessary policy objective' reinforcing competitiveness.[30] It seems contrary to the concept of co-production, which attaches science, facts and policy together with culture, values and other social dimensions,[31] as it fails to take into account consumer views. Similar aspirations permeate the UK position. It appears to follow the impetus of the Strategy for Europe, where fostering technological innovation and re-building a strong economy are the priorities rather than considering the public perspective.

23 Foresight Report, *supra* note 20, at p. 88.

24 Spelman's Speech at Oxford Farming Conference, *supra* note 4. See also Foresight Report, *supra* note 20, at p. 34.

25 Bob Watson, "Bob Watson's Speech at the Oxford Farming Conference 2012", 4 January 2012, available on the internet at <http://www.ofc.org.uk/files/ofc/papers/bob-watson.pdf> (last accessed on 20 November 2012).

26 See, DEFRA, "Caroline Spelman Speech at Planet Under Pressure Conference", 26 March 2012, available on the internet at <http://www.defra.gov.uk/news/2012/03/26/caroline-spelman-speech-planet-under-pressure-conference/> (last accessed on 20 November 2012); Andrew Sparrow, "Caroline Spelman Interview: 'It's in Our Interests to be Green and Growing'", The Guardian, 15 June 2012; and Fiona Harvey, "Drought May Be New Norm for UK, Says Environment Secretary", The Guardian, 21 February 2012.

27 Michael Aaron Dennis, "Reconstructing Sociotechnical Order: Vannevar Bush and US Science Policy" in Sheila Jasanoff (ed), *States of Knowledge: The Co-production of Science and the Social Order* (London: Routledge 2006), pp. 225 *et sqq*., at p. 228.

28 Beck, *Risk Society*, *supra* note 14, at p. 60.

29 Commission Communication on 'Life Sciences and Biotechnology – A Strategy for Europe' (Strategy for Europe) COM(2002) 27, at p. 3: 'Europe is faced with a major policy choice: either accept a passive and reactive role, and bear the implications of the development of these technologies elsewhere, or develop proactive policies to exploit them in a responsible manner, consistent with European values and standards. The longer Europe hesitates, the less realistic this second option will be'.

30 Marine Friant-Perrot, "The European Union Regulatory Regime for Genetically Modified Organisms and its Integration into Community Food Law and Policy" in Luc Bodiguel and Michael Cardwell (ed), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (Oxford: OUP 2010), pp. 79 *et sqq*., at p. 79.

31 Jasanoff, "Co-production", *supra* note 17, at p. 3.

EffL 6-12 29.01.2013 8:28 Uhr Seite 300

III. The UK Policy on Animal Cloning and its Derived Foods

DEFRA and the Food Standards Agency (FSA) have given a green light for the use of animal cloning in farming. The current policy is based on a narrow definition of a 'cloned food' which, as a consequence, excludes products from the offspring of clones from such a definition. This leads to the limited labelling of cloned foods as only the products from clones themselves could be labelled – and not the foods from the offspring. As will be shown, these three policy components again demonstrate the economic motivation behind the policy.

1. No Ban on Animal Cloning

For the UK government a ban on animal cloning, use of clones and food from clones would be disproportionate in terms of food safety and animal welfare.[32] DEFRA reached such a conclusion after reviewing the latest advice from the EFSA and from the national Advisory Committee on Novel Foods and Processes (ACNFP).[33] Another UK advisory body, the National Standing Committee on Farm Animal Genetic Resources, found similar conclusions.[34] In its statement, the National Standing Committee, nonetheless, alerts breed societies and breeders to take steps to 'minimise inbreeding and to ensure sufficient diversity within breeds to ensure their future "genetic health"' as diversity is the basis of breed improvement.[35] Therefore, the committee warns against a major drawback of using animal cloning as it could lead to a reduction of the gene pool. Such a danger, however, is not expressly mentioned in any FSA or DEFRA document. The Foresight report is, however, more nuanced, as it warns against the human and environmental safety of any new technology to be rigorously established before its use.[36]

Yet again, the government focuses on economic considerations. It also shows that a precautionary approach has not been adopted by the government. The precautionary principle modifies the role of scientific data in cases of scientific uncertainty. It directs to a decision to act or not to act and helps determine which measures should be adopted. It also looks at non-scientific conceptions of risk.[37] The precautionary principle has become a tenet of

32 DEFRA, "Cloning of Farmed Animals", 30 August 2011, available on the internet at <http://www.defra.gov.uk/food-farm/animals/cloning/> (last accessed on 20 November 2012) and Hansard (House of Commons) Vol.527, Part 147, Col.2W.

33 See EFSA, "Update on the State of Play of Animal Cloning", 17 September 2010, available on the internet at <http://www.efsa.europa.eu/en/efsajournal/pub/1784.htm> (last accessed on 20 November 2012) and FSA, "Cloned Meat is Safe – Hypothetically Speaking", 25 November 2010, available on the internet at <http://www.food.gov.uk/news/newsarchive/2010/nov/acnfcloned> (last accessed on 20 November 2012). The ACNFP is an independent body of scientific experts that advises the FSA on any matters relating to novel foods and carries out safety assessments of any novel food submitted for approval under the Novel Foods Regulation.

34 National Standing Committee, "Statement on Cloning of Farm Animals", *supra* note 10.

35 *Ibid*.

36 Foresight Report, *supra* note 20, at p. 167. In the conclusions of the report, a more cautious approach seems to be given to new technologies, such as GMOs and animal cloning, to think very carefully about the impact of such technologies on the public, farmers and other stakeholders along the food chain.

37 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 OJ 2001 L 106/1; Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed OJ 2003 L 268/1; 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 OJ 2003 L 268/24. At the European level, the precautionary principle is a cornerstone of EU environmental law and policymaking: Article 191(2) Consolidated Version of the Treaty on the Functioning of the European Union (TFEU) OJ 2008 C 115/47. A full analysis of the role of precautionary principle is outside the scope of this article. For a detailed examination of the role of the precautionary principle, see, e.g., Nicolas De Sadeleer, *Environmental Principles: From Political Slogans to Legal Rules* (Oxford: OUP 2007); Timothy O'Riordan, James Cameron and Andrew Jordan, *Re-interpreting the Precautionary Principle* (London: Cameron and May 2001); Elizabeth Fisher, Judith Jones and René von Schomberg, *Implementing the Precautionary Principle: Perspectives and Prospects* (Cheltenham: Edward Elgar 2006); David Freestone and Ellen Hey, *The Precautionary Principle and International Law: The Challenge of Implementation* (The Hague: Kluwer Law International 1996); Elen Stokes, "The Role of Risk Assessment in Precautionary Intervention: A Comparison of Judicial Trends in the EC and WTO" 4 *Journal for European Environmental Planning Law* (2007), pp. 455 *et sqq*.; Naomi Salmon, "A European Perspective on the Precautionary Principle, Food Safety and the Free Trade Imperative of the WTO" 27 *European Law Review* (2002), pp. 138 *et sqq*.; Nicolas de Sadeleer, "The Precautionary Principle in EC Health and Environmental Law" 12 *European Law Journal* (2006), pp. 139 *et sqq*.

EffL 6-12 29.01.2013 8:28 Uhr Seite 301

the regulation of modern agricultural biotechnology.[38] This is demonstrated by the regime existing for GMOs and their derived foods, which put in place pre-market authorisation, mandatory labelling and traceability. The European Court of Justice has defined the precautionary principle in the Artegodan case 'as a general principle of Community law requiring the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests'.[39] Non-economic considerations can be the basis of regulation. Therefore, the food safety issues, long-term concerns, consumer worries and animal health and welfare issues raised by animal cloning seem to call for the application of the precautionary principle. The principle is, nevertheless, playing a marginal role in the regulation of animal cloning in the UK. The UK assumes the safety of cloned foods as demonstrated by the ACNFP and the EFSA opinion and therefore chose to give preference to economic considerations rather than consumer concerns.

In relation to animal welfare, the government declared that 'the welfare of all farmed animals, including clones and their descendants, is already protected by current welfare legislation'.[40] Animal cloning for farming purposes appears, however, to be contrary, for example, to paragraphs 28 and 29 of Schedule I to the Welfare of Farmed Animals (England) Regulations 2007 which provides that: '[n]atural or artificial breeding or breeding procedures which cause, or are likely to cause, suffering or injury to any of the animals concerned, must not be practised'[41] because of the issues of animal welfare and suffering that it raises. Therefore, based on those regulations the UK government could have banned animal cloning.[42]

Embracing modern agricultural biotechnology, as it favours the development of new industry and reinforces scientific innovation in the UK economy, emerges as a commercial imperative. There appears to be only one policy option: taking a leading role in modern biotechnology.

2. A Narrow Definition of Cloned Foods

The regulation of cloned foods falls under Regulation (EC) No 258/97 concerning Novel Foods and Novel Food Ingredients (Novel Foods Regulation) – as there is no national law specifically dealing with novel foods.[43] Cloned food would fall most naturally under category (e) of Article 1 (2) of the Novel Foods Regulation.[44] Under this regulation, meat and milk derived from cloned animals and their progeny could potentially require pre-market authorisation and labelling.[45]

Since the emergence of cloned foods, and until May 2011, the FSA position in relation to cloned foods was that 'products from the offspring of cloned animals, like those from cloned animals themselves, should be considered as novel foods'.[46] They would therefore have to undergo the procedure exiting under the Novel Foods Regulation. In

38 See for instance, Zeynep Kivilcim Forsman, "Community Regulation of Genetically Modified Organisms: a Difficult Relationship Between Law and Science" 10 *European Law Journal* (2004), pp. 580 *et sqq*., at p. 583. The key case on the precautionary principle and modern agricultural biotechnology is the Greenpeace v. France case. See Case C-6/99, Association Greenpeace France and Others v. Ministère de l'Agriculture et de la Pêche and Others [2000] ECR I-1676. For, De Sadeleer, the Greenpeace v. France case 'implicitly confirmed that recourse to the precautionary principle could put a stop to the free circulation of GMOs'. See, De Sadeleer, "The Precautionary Principle in EC", *supra* note 37, at p. 144.

39 Joined cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00 and T-141/00 Artegodan GmbH and Others v. Commission of the European Communities [2002] ECR II-4945, at para. 184. See also Communication from the Commission on the Precautionary Principle COM(2000) 1.

40 DEFRA, "Cloning of Farmed Animals", *supra* note 32 and Hansard (House of Commons) Vol.527, Part 147, Col.2W.

41 Schedule I to the Welfare of Farmed Animals (England) Regulations 2007, SI 2007/2078, at para. 28. Paragraph 29: 'Animals may only be kept for farming purposes if it can reasonably be expected, on the basis of their genotype or phenotype, that they can be kept without any detrimental effect on their health or welfare'. Those regulations implement Council Directive 98/58/EC of 20 July 1998 concerning The Protection of Animals Kept for Farming Purposes, OJ 1998 L 221/23.

42 As will be analysed in the next section, the EU institutions had 'agreed' on a ban on animal cloning.

43 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning Novel Foods and Novel Food Ingredients OJ 1997 L 43/1.

44 Novel Foods Regulation, *supra* note 43, Article 1 (2)(e): 'foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use'. The Novel Foods Regulation will be analysed further in section IV.1.

45 Ibid Articles 5 and 8.

46 FSA, "Cloned offspring novel food, says Agency", 18 January 2007, available on the internet at <http://www.food.gov.uk/news/newsarchive/2007/jan/clonedoffspring> (last accessed on 20 November 2012).

EffL 6-12 29.01.2013 8:28 Uhr Seite 302

May 2011, the FSA changed its position in relation to the offspring of clones. It declared that it was adopting a similar position to the position taken by the European Commission that 'there are no food safety grounds for regulating foods from the descendants of cloned cattle and pigs, food obtained from the descendants of clones of cattle and pigs does not require authorisation [or mandatory labelling] under the novel foods regulation'.[47] This is in line with DEFRA and Jim Paice's positions and is now government policy.[48]

The existing policy does not subject the product of the descendants of cloned animals to any specific pre-market authorisation, labelling or traceability – contrary to the regime that exists for GMOs and their resulting foods. Therefore, fewer requirements will be imposed on farmers and other food processors, which could increase potential trade and competitiveness. The FSA also specified that this policy modification would appear to accommodate businesses willing to market such foods, even though the FSA was not in a position to assess the scale of this possible impact.[49] Economic reasons are, yet again, used to justify this liberal approach. Therefore, increased growth and competitiveness are the regulatory purposes of this new policy on animal cloning and are used as a legitimation for this relaxed position.

This change in policy would seem possible as the terms '[novel foods] obtained by traditional breeding practices' under Article 1(2)(e) of the Novel Foods Regulation can be interpreted in two ways according to the FSA.[50] On the one hand, it can mean that the regulation applies to the progeny of a cloned animal as the offspring would not exist without the original non-traditional breeding practice, that is cloning. Descendants should thus not be regarded as 'obtained by traditional breeding practices' and should therefore go through an authorisation process and be labelled. On the other hand, the legislation can also be interpreted to apply only to food from cloned animals themselves and not to the progeny as the latter is 'obtained by traditional breeding'. Therefore, foods from the offspring of clones would not have to be authorised or labelled as they would fall outside the scope of the Novel Foods Regulation.[51] This second interpretation is the one now adopted by the government which means that currently meat and milk from the offspring of clones could end up on the food shelves without being pre-authorised or require any specific labelling as they would be considered as similar to any other conventional food. This limits to a huge extent the capacity of consumers to take informed decisions.

3. The Limited Labelling of Cloned Foods

Under the general labelling requirements of the 1996 Food Labelling Regulations, all foods must be marked or labelled with 'particulars of the place of origin or provenance of the food if failure to give such particulars might mislead a purchaser to a material degree as to the true origin or provenance of the food'.[52] Therefore, not labelling the correct provenance of the food – that is where the food originates i.e. its cloned animal origin – could be a misdescription of the food, which would lead to mislabelling and deceiving consumers. Moreover, under the regulation consumers are misled if there is the omission of an indication of physical conditions or treatment.[53] This specifically refers to the nature of the food, its method of manufacture or production and cloning constitutes such a process.

47 FSA, "Meat and milk from cloned animals", 7 December 2010, available on the internet at <http://www.food.gov.uk/news/newsarchive/2010/dec/boardcloning> (last accessed on 20 November 2012). See also, FSA, "'Novel' Status of Food from Descendants of Cloned Cattle and Pigs", available on the internet at <http://www.food.gov.uk/policy-advice/novel/cloned/> (last accessed on 20 November 2012). Such a position was adopted after the views of interested parties was received, even though many responses dealt with the concerns over food safety, animal welfare and consumers' values.

48 DEFRA, "Cloning of Farmed Animals", *supra* note 32 and Hansard (House of Commons) Vol. 527, Part 147, Col. 2W.

49 FSA, "Meat and milk from cloned animals", *supra* note 47.

50 The two interpretations were put forward by the FSA in its letter to stakeholders to seek their views on a potential change in its interpretation of the Novel Foods Regulation in respect of food from the descendants of cloned cattle and pigs. FSA, "Letter to Interested Parties on the Food from the Descendants of Cloned Animals", 13 January 2011, available on the internet at <http://www.food.gov.uk/multimedia/pdfs/cloningletterjan11.pdf> (last accessed on 20 November 2012). See also, DEFRA, "Cloning of Farmed Animals", *supra* note 32. For more on the regulation of cloned foods at EU level, see, e.g., Ludivine Petetin, "Clone Wars? The Challenges of Cloned Food in EU, US and WTO Law" 11 *Environmental Law Review* (2009), pp. 246 *et sqq*.

51 The Novel Foods Regulation will be further developed in section IV.

52 The Food Labelling Regulations 1996, SI 1996/1499, regulation 5(f).

53 Ibid regulation 11 and schedule 2.

EffL 6-12 29.01.2013 8:28 Uhr Seite 303

Therefore, not describing that a food comes from a cloned animal or its progeny could arguably create a mislabelling of the food because of its misdescription.

DEFRA and the FSA are satisfied with the potential pre-market authorisation for cloned foods and their labelling under the Novel Foods Regulation but not for the food deriving from the offspring of clones.[54] For the FSA the mandatory labelling of meat and milk obtained from the descendants of cloned cattle and pigs is unnecessary and disproportionate.[55] DEFRA added that 'mandatory labelling of meat or milk products derived from animals with a clone in their ancestry would be unenforceable and impractical' as there is 'no traceability system that can be applied to either imported or home produced products from descendants of clones' and that 'the cost of introducing such a system [...] cannot be justified'.[56]

The argument that there is no method for the identification and traceability of farm animals produced by different breeding practices may be questioned. First, the fact that it might be currently impossible to determine by examination or testing which breeding practices were used to obtain a specific animal could change in the future as scientific innovations become more robust. Second, a system of identity preservation, traceability and labelling could be established. For example, as a consequence of the BSE crisis, Council Regulation (EC) No 820/97 and Regulation (EC) No 1760/2000 established a regime of individual traceability of cattle by means of individual identification of animals with 'double ear tag', 'holding register', 'cattle passport' and 'computerised database'.[57] Third, a recent Commission proposal amending Regulation (EC) No 1760/2000 recommends the simplification of information obligations by introducing bovine electronic identification to improve the existing systems of cattle identification.[58] This new system which allows the tracking of individual animals and their ancestors could be used and adapted in husbandry to limit the issues of the current non-traceability of cloned animals and their progeny. Fourth, fully traceable systems have been put in place for voluntary labelling schemes in supermarkets. For instance, organic and fair-trade products rely on recordkeeping to document the origin of animals and foods as well as controls and inspections. Thus, it seems that the tracing and labelling of cloned animals, their progeny and their derived products could be achieved if there was sufficient effort and willingness to do so.

The reasons above given by the FSA and DEFRA demonstrate that not labelling the products from the offspring of clones is based purely on economic considerations, including promoting the competitiveness of the UK biotechnology industry and promoting economic growth, rather than consumer choice. In contrast, DEFRA generally acknowledges that food labelling allows consumers to receive accurate information and to make informed choices.[59] However, not labelling cloned foods reduces consumer information and choice. Moreover, the lack of mandatory labelling and traceability, and therefore of monitoring could have a negative impact on consumer confidence in the food supply – as it did, for example, in the United States of America after the StarLink™ incident.[60]

The government overlooks the fact that consumers may want to see effective labelling of products from clones and their offspring. Other reputable bodies, such as the Government Office for Science and the Royal Society, focus more on taking

54 Hansard (House of Commons) Vol.527, Part 147, Col.2W.

55 DEFRA, "Cloning of Farmed Animals", *supra* note 32.

56 Ibid and Hansard (House of Commons) Vol.527, Part 147, Col. 2W.

57 Council Regulation (EC) No. 820/97 establishing a System for the Identification and Registration of Bovine Animals and regarding the Labelling of Beef and Beef Products OJ 1997 L 117/1and Regulation (EC) number 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a System for the Identification and Registration of Bovine Animals and regarding the Labelling of Beef and Beef Products and repealing Council Regulation (EC) number 820/97 OJ 2000 L 204/1.

58 Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1760/2000 as regards Electronic Identification of Bovine Animals and Deleting the Provisions on Voluntary Beef Labelling COM(2011) 525 final, at p. 1.

59 DEFRA, "Food labelling", September 2011, available on the internet at <http://www.defra.gov.uk/food-farm/food/labelling/> (last accessed on 20 November 2012). See more generally: European Commission, White Paper on Food Safety COM(1999) 719 final at p. 32; Caoimhin Macmaolain, *EU Food Law: Protecting Consumers and Health* (Oxford: Hart 2007); Paul Weirich (ed), *Labeling Genetically Modified Food: the Philosophical and Legal Debate* (Oxford: OUP 2007).

60 StarLink™ is a variety of Bt corn. It was only allowed for commercialisation as animal feed because a small number of people might develop an allergic reaction to the Bt protein used in StarLink™. However, it was subsequently found in food destined for consumption by humans. See In re StarLink Corn Products Liability Litigation 212 F Supp 2d 828 (ND Ill 2002).

EffL 6-12 29.01.2013 8:28 Uhr Seite 304

into account the views of the public.[61] They adopt a more nuanced view: pro-science but with a much greater emphasis on consumer stance. Also, it might appear that the government is now in danger of repeating the experience with GMOs. Similar examples could be found at EU level in relation to the regime for GMOs and their resulting foods as well as the ban on recombinant bovine somatotropin (rBST).[62]

The governmental approach towards the regulation of animal cloning and cloned foods is in opposition with the political momentum existing in the EU institutions, momentum which is, at least in principle, more respectful of consumer preferences and concerns as well as animal welfare – as will be now seen.

IV. The Failure of the Novel Foods Proposal

Although at present no specific authorisation procedure exists for regulating food from cloned animals, cloned foods fall under category (e) of Article 1 (2) of the Novel Foods Regulation, as mentioned earlier.[63] The Novel Foods Regulation creates a harmonised procedure for the placing on the market within the EU of novel foods. Nonetheless, by 2006, an explanatory document had described why the Novel Foods Regulation had to be modified:[64] first, to clarify the legislation after the removal of GM food from the scope of the regulation (as Regulation (EC) No 1829/2003 on Genetically Modified Food and Regulation (EC) 1830/2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products produced from Genetically Modified Organisms regulate GM food and feed and their labelling[65] now regulate GM foods); second, to create a more favourable environment for innovation for the food industry; third, to facilitate internal and external trade; and, fourth, to allow consumers to benefit from a wider choice of safe novel foods. The second and third reasons clearly show, once again, the economic and commercial considerations behind such a desired change in the law. These considerations are, nevertheless, put into a social context where consumers are considered. However, the document fails to mention that the concept of substantial equivalence, on which the Novel Foods Regulation is based, created huge controversy, controversy which also needed to be remedied.

During the review of the Novel Foods Regulation, the position of the EU political institutions shifted. Two main elements emerged as central to the negotiations of the Novel Foods Proposal: a ban on animal cloning for food consumption and the labelling of cloned foods. Nonetheless, cloned foods currently fall under the scope of the Novel Foods Regulation, as its review failed in March 2011.

1. The Novel Foods Regulation and the Concept of Substantial Equivalence

The Novel Foods Regulation defines novel foods, as foods that 'have not hitherto been used for human consumption to a significant degree within the Community'.[66] When this regulation was enacted, both GM and cloned foods fell under its scope.

Substantial equivalence is the criterion by which the evaluation of novel foods will be weighed when an applicant notifies the placing on the market to the national competent authority.[67] Substantial equivalence relies on the comparative analysis of conventional and biotech foods. It is a procedure

61 See for example, Foresight Report, *supra* note 20, at p. 167 and p. 172; The Royal Society, "Report on Reaping the Benefits: Science and the Sustainable Intensification of Global Agriculture" (2009), at p. 51.

62 See the European Communities – Measures Concerning Meat and Meat Products WT/DS26/AB/R, WT/DS48/AB/R, 16 January 1998 (panel), at para. 10, where the European institutions relied on EU consumer anxieties to ban the use of rBST.

63 Novel Foods Regulation, *supra* note 43, Article 1 (2)(e).

64 Explanatory document: Revision of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning Novel Foods and Novel Food Ingredients (31 May 2006) 2.

65 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed OJ 2003 L 268/1 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 OJ 2003 L 268/24.

66 Novel Foods Regulation, *supra* note 43, Article 1(2).

67 Ibid Article 5. The OECD developed the concept of substantial equivalence. See OECD, *Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles* (OECD 1993); FAO/WHO, *Expert Consultation on Biotechnology and Food Safety* (FAO/WHO 1996).

EffL 6-12 29.01.2013 8:28 Uhr Seite 305

which has two implications: first, it assesses the safety of biotech foods; and, second, if substantial equivalence is established, biotech foods are regulated in the same manner as conventional foods.

Article 3(1) deals with the scope of the regulation: on the one hand, if a novel food is 'substantially equivalent' to an existing food, it falls under the scope of the 'simplified procedure' existing under Article 3(4). Under the regulation, substantial equivalence can be established by two means: either a food is considered to be substantially equivalent to an existing food on the basis of available and generally recognised scientific evidence; or substantial equivalence is based on the opinion of a competent food assessment.[68] On the other hand, if a novel food is not substantially equivalent to an existing food, pre-authorisation is required and the food must undergo an 'initial' safety assessment and may then proceed to an EU decision in certain circumstances.[69]

Under the Novel Foods Regulation, if novel foods, such as cloned foods, are substantially equivalent to conventional foods, they would reach the market without any specific requirements.[70] Currently, following the EFSA risk assessment, cloned food could then benefit from the 'simplified procedure' under Article 3(4) as the EFSA declared 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'.[71] Thus, no case-by-case risk assessment would be needed for cloned food to enter the EU market and no specific labelling would be required under this regulation – contrary to the authorisation of GM foods. However, because of its vagueness and its regulatory consequences, the concept attracted criticism.

Substantial equivalence suffers from the important failing that the concept has never been properly defined – as can be observed in the Novel Foods Regulation. In particular, there is no definition of 'substantial' and, consequently, no certainty about when two foods cease to be substantially equivalent. It is very subjective: 'no standardized objective tests for determining equivalence and measuring substantiality exist'.[72] This results in a decision not to require labelling, facilitating trade but limiting consumers' freedom of choice considerably. Yet, for many consumers, any products derived from modern agricultural biotechnology are perceived to be 'fundamentally different from their conventionally produced counterparts', regardless of their substantial equivalence.[73] Following these concerns and the *Monsanto* case, substantial equivalence was removed from the regulation of GM foods by the establishment of the Food and Feed Regulation and Regulation 1830/2003.[74] Pre-market authorisation and mandatory labelling of GM foods as well as their traceability are now required. Such obligations constitute big differences between the systems now in place for cloned and GM foods.

2. A Ban on Animal Cloning

In January 2008, the European Commission adopted a proposal to revise the Novel Foods Regulation. Cloned food would likely have fallen under the definition of novel food in Article 3(2)(a)(ii) which stipulated that 'novel food means food of plant or animal origin when to the plant and animal is applied a non-traditional breeding technique not used before 15 May 1997'. The proposal aimed to simplify the existing framework by creating a centralised EU-level procedure for the assessment and

68 Novel Foods Regulation, *supra* note 43, Article 3(4): 'By way of derogation from paragraph 2, the procedure laid down in Article 5 shall apply to foods or food ingredients referred to in Article 1 (2) (b), (d) and (e) which, on the basis of the scientific evidence available and generally recognized or on the basis of an opinion delivered by one of the competent bodies referred to in Article 4 (3), are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein'.

69 Ibid Article 4.

70 Ibid Article 8.

71 EFSA, Opinion on Animal Cloning 2008, *supra* note 9, at p. 31.

72 Thomas O. McGarity, "Seeds of Distrust: Federal Regulation of Genetically Modified Plants" 35 *University of Michigan Journal of Law Reform* (2002), pp. 403 *et sqq*., at p. 429. See also, Erik Millstone, Eric Brunner and Sue Mayer, 'Beyond Substantial Equivalence' 401 *Nature* (1999), pp. 525 *et sqq*., at p. 526.

73 Naomi Salmon, "What's 'Novel' About It? Substantial Equivalence, Precaution and Consumer Protection 1997–2004" 7 *Environmental Law Review* (2005), pp. 138 *et sqq*., at p. 142.

74 The concept of substantial equivalence and its deficiencies were at the heart of the 2003 *Monsanto* case which deals with GM foods. Case C-236/01, Monsanto Agricoltura Italia SpA and Others v. Presidenza del Consiglio dei Ministri and Others [2003] ECR I-8105. For a comment of the case, see Ruby R. Fernandez, "Monsanto and the Requirement for Real Risks in GM Food Regulation" 28 *International & Comparative Law Review* (2006), pp. 335 *et sqq*.

EffL 6-12 29.01.2013 8:28 Uhr Seite 306

pre-market authorisation of novel foods and therefore established a 'one door-one key' procedure potentially facilitating the sale of cloned foods in the European market – as it exists for GM foods.[75] More importantly, substantial equivalence would have been removed from the regulation.

During the first reading of the initial proposal before the European Parliament in 2009, the Members of the European Parliament declared their position in favour of the removal of cloned foods and their offspring from the scope of the proposal and the banning of cloning for farming purposes.[76] For the European Parliament, cloned foods should be dealt with in a specific regulation.[77] It reinforced its position by referring, first, to the incompatibility of animal cloning for farming purposes with Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes, in particular Articles 20 and 21, and second to the EGE opinion on animal cloning.[78] During the second reading of the proposal before the European Parliament in July 2010, MEPs reiterated their objection.[79]

The European Parliament seems alert to popular influence and to consider what the European public wants.[80] Such a result could be attributed to the role of the Parliament's Committee on the Environment, Public Health and Food Safety (ENVI Committee). The ENVI Committee is one of the most influential committees in EU policy decisions.[81] One of its main priorities, with environmental and public health policy, is to look at EU citizens' concerns in food safety legislation and policy, and in particular provide 'better information for consumers, e.g. through clearer and unambiguous labelling of products.'[82] Through its activism, the committee promotes key public concerns and shapes the public agenda, which subsequently impact on the European Parliament's policymaking.[83] In the case of animal cloning and its derived products, it is clearly obvious that the committee has taken on board consumer concerns.[84] It constitutes, therefore, one of the means to channel consumer preferences and for them to be expressed.

In 2009, the Council also declared that animal cloning for farming purposes and its derived products should be banned and that a specific legislation on cloning would be desirable to address the various aspects of the cloning issue.[85] In October 2010, the Commission aligned itself with the other two European institutions and changed its earlier position. It proposed to suspend temporarily the use of animal cloning for food consumption and their derived foods, with a review clause after five years.[86] It could be argued that banning cloned foods undermines consumer choice. However,

75 Proposal for a Regulation of the European Parliament and of the Council on Novel Foods, COM(2007) 872 – 2008/0002 (COD) (2008), at p. 7 and Articles 1 and 19.

76 European Parliament Legislative Report adopted on 25 March 2009, P6_TA-PROV(2009)03-25, Provisional Edition PE 422.707: European Parliament legislative resolution of 25 March 2009 on Proposal for a Regulation of the European Parliament and of the Council on Novel Foods, COM(2007) 872 – 2008/0002 (COD) (2008), P6_TA-PROV(2009)0171.

77 Ibid Preamble (16).

78 Council Directive 98/58/EC of 20 July 1998 concerning The Protection of Animals Kept for Farming Purposes, OJ 1998 L 221/23. Article 20: 'Natural or artificial breeding or breeding procedures which case or are likely to cause suffering or injury to any of the animals concerned must not be practised. This provision shall not preclude the use of certain procedures likely to cause minimal or momentary suffering or injury, or which might necessitate interventions which would not cause lasting injury, where these are allowed by national provisions'. Article 21 'No animal shall be kept for farming purposes unless it can reasonably be expected, on the basis of its genotype or phenotype, that it can be kept without detrimental effect on its health or welfare'. See also, EGE, *Opinion on the Ethical Aspects of Animal Cloning*, *supra* note 11.

79 European Parliament Legislative Resolution of 7 July 2010 on the Council Position at first Reading for adopting a Regulation of the European Parliament and of the Council on Novel Foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 (11261/3/2009 – C7-0078/2010 – 2008/0002(COD)).

80 See consumer surveys in section V.1.

81 Most of the European Parliament's work is undertaken by the committees, which means that they have a tremendous input into the policymaking process. See Ken Collins and Charlotte Burns and Alex Warleigh, "Policy Entrepreneurs: The Role of European Parliament Committees in the Making of EU Policy" 19 *Statute Law Review* (1998), pp. 1 *et sqq*., at p. 6.

82 Europa, "Environment, Public Health and Food Safety", <http://www.europarl.europa.eu/committees/en/envi/members.html#menuzone> (last accessed on 20 November 2012).

83 Christilla Roederer-Rynning, "From 'Talking Shop' to 'Working Parliament'? The European Parliament and Agricultural Change" 41 *JCMS* (2003), pp. 113 *et sqq*., at p. 113.

84 Opinion of the Committee on the Environment, Public Health and Food Safety on the European Union Strategy for the Protection and Welfare of Animals 2012–2015 (June 2012), suggestion 9.

85 Preamble (6a) Council Political Agreement on the first reading of the Proposal for a Regulation of the European Parliament and of the Council on Novel Foods, COM(2007) 872 – 2008/0002 (COD) (2008) adopted on the 22 June 2009.

86 European Commission, Report from the Commission to the European Parliament and the Council on Animal Cloning for Food Production COM(2010) 585, at p. 14.

EffL 6-12 29.01.2013 8:28 Uhr Seite 307

surveys have shown that consumers do not actively buy GMOs. It can deduced from a broad survey involving ten EU countries between 2006 and 2008 which concluded that consumers are not careful about avoiding GM products as they do not actually look at the label.[87] Genetic modification is not a food characteristic that is sought out by consumers, unlike organic products. Therefore, removing cloned products from supermarket shelves does reduce consumers' decision-making capacity.

The European institutions appear to listen to consumer preferences and to adopt a precautionary approach towards the use of animal cloning for farming purposes – as they did for GMOs. In contrast, the UK government fails to acknowledge that its present policy on animal cloning is on opposition with the European Parliament and the Council as they want a ban on animal cloning while the Commission proposed a temporary suspension. By allowing the technique, the UK appears to be isolated from the EU institutions but also from the public – which raises issues as to the moral legitimacy of the new policy.[88]

As it stands, animal cloning would also seem to be contrary to Article 13 of the Treaty on the Functioning of the European Union (TFEU) which incorporated the Additional Protocol on Protection and Welfare of Animals to the Amsterdam Treaty which recognises that animals are 'sentient beings' and obliges EU Member States to take full account of the welfare requirements of animals when formulating and implementing EU legislation.[89] The EGE confirms this understanding by declaring that it has 'doubts whether infringements of these standards can be justified by the benefits obtained by current procedures in cloning animals for food production'.[90] Moreover, the EU Animal Health Strategy (2007–2013) focuses on issues linked to animal health, such as public health, food safety and animal welfare.[91] Animal cloning for food consumption seems to contravene EU law and policy due to its associated impacts and risks to animal health and welfare. Thus, the UK position might also be contrary to EU provisions, especially as Articles 20 and 21 of Council Directive 98/58/EC were implemented by Paragraphs 28 and 29 of Schedule I to the Welfare of Farmed Animals (England) Regulations 2007.

3. A Lack of Agreement on Labelling

The review process of the proposal, nonetheless, failed at the end of March 2011 as the dialogue between the European Parliament, the Council and the Commission finished in deadlock.[92] The labelling of the offspring of cloned animals, emerged as the most contentious issue and is the reason why the conciliation process failed. The European Parliament supported the mandatory labelling of any products from the offspring of clones and, therefore, a full system of traceability which would have allowed consumer information and choice. The Council only wanted to label fresh meat – which would have excluded cloned milk.[93] As to the Commission, it did not consider the products from the offspring of clones to require mandatory labelling.[94] The UK policy here is in line with the Commission's position. The Council and the Commission argued that it would not have been

87 King's College London, "Do European Consumers Buy GM Foods?" ('Consumerchoice') (2008), at paras. 1–11. The ten EU countries were the Czech Republic, Estonia, Germany, Greece, the Netherlands, Poland, Slovenia, Spain, Sweden and the United Kingdom.

88 As will be observed in section V.

89 TFEU, Article 13. See, in relation to the protection of animal welfare in the EU in both legislation and case law, Rasso Ludwig and Roderic O'Gorman, "A Cock and Bull Story? Problems with the Protection of Animal Welfare in EU Law and some Proposed Solutions" 20 *Journal of Environmental Law* (2008), pp. 363 *et sqq*. This incorporation put an end to the weakness of the status of the protocol, as it had been established in the Jippes Case. See, Case C-189/01 H. Jippes, Afdeling Groningen van de Nederlandse Vereniging tot Bescherming van Dieren and Afdeling Assen en omstreken van de Nederlandse Vereniging tot Bescherming van Dieren v. Minister van Landbouw, Natuurbeheer en Visserij [2001] ECR I-5689), at para. 73. For a comment of the case, see Eleanor Spaventa, "Annotation on Jippes" 39 *Common Market Law Review* (2003), pp. 1159 *et sqq*.

90 EGE, *Opinion on the Ethical Aspects of Animal Cloning*, *supra* note 11, at p. 39.

91 See European Commission, Directorate General for Health and Consumers, "The New Animal Health Strategy (2007–2013): 'Prevention is Better than Cure"', 3 November 2008, available on the internet at <http://ec.europa.eu/food/animal/diseases/strategy/index_en.htm> (last accessed on 20 November 2012).

92 For a useful summary, see Euractiv, "Novel Foods Review Stumbles over Cloning", 29 March 2011, available on the internet at <http://www.euractiv.com/en/cap/novel-foods-review-stumbles-cloning-news-503610?utm_source=EurActiv+Newsletter&utm_campaign=978ddd2130-my_google_analytics_key&utm_medium=email> (last accessed on 20 November 2012).

93 *Ibid*.

94 European Commission, *Report 2010*, *supra* note 86, at p. 14.

EffL 6-12 29.01.2013 8:28 Uhr Seite 308

feasible because of the lack of technology being able to detect the difference.[95] The UK, like the Council and the Commission, fails to consider consumer preferences.

This review has led to a regulatory conundrum, a Catch 22 situation. It demonstrated that disagreements existed at two levels within the EU institutions: first, a disagreement about risks and adequacy of scientific data as shown by the opinions provided by the EFSA and the EGE; and second, a divergence on how to deal with animal cloning and its resulting foods, that is the regulatory solution that should be put in place.

Because the process failed, a new proposal has now to be submitted. Agreeing on another text could take up to three years – as did this process – and could end again in an impasse. At the time of writing, no such proposal has been submitted.[96]

Even though it lacked final agreement, a shift in the negotiating positions occurred during the review. These changes in position show, nonetheless, the growing influence that consumers can have on the decision-making process.

Currently, cloned foods fall under the scope of the Novel Foods Regulation and could not be required to be labelled, which reinstates the use of the principle of substantial equivalence and its inadequacies at the heart of the system. The EU usually adopts a 'better safe than sorry' or precautionary approach to manage the uncertainty created by biotech foods. But in the case of animal cloning, it is currently failing to do so. The European Parliament has prevented a 'weak' legislation, but as a consequence allows a 'weaker' legislation to continue to apply. Effectively, as substantial equivalence leads to the limited labelling of cloned foods and their traceability, if a food safety issue would arise, governmental action would be highly restricted and slow. Also, the real extent of the permeability of cloned foods within the food system could not be assessed.

V. A Meaningful Role for Consumers?

As will be now demonstrated, consumers are resistant towards animal cloning and its derived foods. This can be contrasted with the lack of mandatory labelling, which prevents consumers from knowing what they eat. The new UK policy departs from developments which tend to listen to public perspective. In particular, there is a growing tendency for supermarkets to accommodate consumer preferences in relation to biotech foods. All these elements raise questions as to the legitimacy and effectiveness of the UK regime.

1. Consumer Attitudes

Consumer surveys have demonstrated and confirmed concerns about animal cloning and its derived foods. In a 2008 FSA research on the views of the UK public about animal cloning and their products, results showed that the key areas of concern raised by the public were food safety, the lack of consumer benefits, animal welfare and the lack of trust in the key players involved.[97] Participants felt 'as uncomfortable buying and consuming food derived from the offspring of clones as they would about food derived directly from clones'.[98] More importantly, the survey showed that the UK public favoured a strong regulatory regime to be established where clones and their offspring should be traceable and labelled to enable consumers to make an informed choice; to increase consumer confidence; and to allow the monitoring of such technology.[99] Moreover, UK consumers are not alone in their concerns about animal cloning and its derived foods, as EU surveys have disclosed comparable results. In a 2008 Eurobarometer on Europeans' attitudes towards animal cloning, nine out of ten EU citizens considered it crucial that food products

95 As they advanced similar arguments to the UK, they suffer from the same deficiencies: mandatory labelling and traceability are possible. See section III.3.

96 If the EU regime were modified, the UK policy could potentially be incompatible.

97 Creative Research, "Animal Cloning and Implications for the Food Chain: Findings of Research Among the General Public" (FSA, Survey 2008) (2008), at p. 3. Similar comments were submitted by interested parties in their 2011 responses on the FSA opinion on food from the descendants of cloned animals. FSA, "Food from Descendants of Cloned Animals – Consultation Responses" (2011), at p. 1.

98 FSA, "Survey 2008", *supra* note 97, at p. 16. A 2011 survey, undertaken by the consumer interests organisation Which?, confirmed such results and found that approximately 3 in 5 people declared preferring to buy food that was not produced using cloned animals. Sue Davies, "Consumers: the Most Important Link in the Food Chain", Speech at the Oxford Farming Conference 2012, January 2012, available on the internet at <http://www.ofc.org.uk/files/ofc/papers/sue-davies-ppt.pdf> (last accessed on 20 November 2012).

99 FSA, "Survey 2008", *supra* note 97, at p. 14.

EffL 6-12 29.01.2013 8:28 Uhr Seite 309

from offspring of cloned animals should be labelled.[100] Both UK and EU surveys show that consumers want to know the origin of their foods. They want consumer choice through labelling.

2. Consumers: a Market Force of their Own?

As a result of the failure of the review of the Novel Foods Regulation, at the end of March 2011, six of the UK largest supermarkets pledged to keep meat and milk from cloned animals and their offspring off their shelves.[101] Such a position reflects popular demand: supermarkets are following the preferences and perceptions of consumers – as evidenced in the surveys. Such a de facto ban recalls the (lack of) development of GMOs in the UK, as consumer are resistant to them.[102] A similar ban was put in place and still exists for GMOs and GM foods. It started in 1998 when Iceland removed all GM ingredients from its own labelled products and was then joined by more UK supermarkets.[103] Subsequently, this prevented the GM market from taking off. As stated by Bodiguel and Cardwell, 'sections of the public ... would seem to have influenced the pace at which GMOs are being developed, and also their market penetration'.[104] The impact of banning animal cloning by major retailers will most likely limit the development and commercialisation of animal cloning and their derived products.

In relation to GMOs, in January 2012 the German biotech and chemical company BASF announced the withdrawal of its research and development operations on GM crops in the European market. The main reason was the lack of consumer acceptance for GM plants and foods combined with farmers and politicians' hostility.[105] Along the same line, in February 2012, the biotech company Monsanto declared that it would abandon the sale of GM MON810 maize in France from 2012 because of the opposition from the public and the French authorities. Monsanto deemed that 'favourable conditions for the sale of the MON810 in France in 2012 and beyond are not in place'.[106] These two events show the weight that consumers and their preferences can have on multinationals and their market development. Thus, through various means, consumer preferences tend to be accommodated by different actors. Nonetheless, the UK governmental position is stepping into the opposite direction where economic expansion necessitates the use of modern biotechnology, without fully considering the consequences of such a decision on the public, the animals, their health and the environment.

3. The 'Right Kind Of' Policy

New technologies create a twofold challenge for regulators: the question of the legitimacy and effectiveness of their interventions.[107] The question is whether the regulators are 'doing the right thing', whether their intervention passes moral muster.[108] It was mentioned in this article that the objective of the UK policy on animal cloning was economic growth and that such an objective was a legitimation of the new policy. The legitimacy of regulatory

100 The Gallup Organization, "Europeans' Attitudes Towards Animal Cloning" (October 2008), at p. 41.

101 The supermarkets involved are Tesco, the Co-operative, Marks & Spencer, Sainsbury's, Morrisons and Waitrose. See Sean Poulter, "We Won't Sell Clone Meat Say Supermarkets After Minister Sabotages 'Frankenfoods' Label Plans" The Daily Mail, 31 March 2011.

102 British Science Association, "Populus Survey", March 2012. Such results are very similar to the findings of the 2003 GM Nation report. See, Department of Trade and Industry, "GM Nation? The Findings of the Public Debate" (London: Department of Trade and Industry, 2003).

103 See for instance, GeneWatch UK, "WTO Dispute", 2006, available on the internet at http://www.genewatch.org/sub.shtml?als[cid]=538152 (last accessed on 14 October 2012).

104 Luc Bodiguel and Michael Cardwell, "Genetically Modified Organisms and the Public: Participation, Preferences, and Protest" in Luc Bodiguel and Michael Cardwell (ed), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (Oxford: OUP 2010), pp. 11 *et sqq.*, at p. 36.

105 See Rebecca Trager, "BASF Pulls Out of Europe over GM Hostility", 18 January 2012, available on the Internet at <http://www.rsc.org/chemistryworld/News/2012/January/basf-pull-out-gm-crops-biotech.asp> (last accessed on 20 November 2012). For instance, in May 2012, an organic farmer vandalised the Rothamsted Research GM crop trial site. See Leo Hickman, "GM Crops: Protesters Go Back to the Battlefields", The Guardian, 22 May 2012. Such action shows how the British public is still hostile towards GM technology.

106 Nathan Gray, "Monsanto Scraps GM Maize in France", 1 February 2012, available on the Internet at <http://www.food-navigator.com/Financial-Industry/Monsanto-scraps-GM-maize-in-France> (last accessed on 20 November 2012).

107 Brownsword, *Rights, Regulation, and the Technological Revolution*, *supra* note 18, at p. 9 and 11.

108 *Ibid* 132.

EffL 6-12 29.01.2013 8:28 Uhr Seite 310

purposes is however different. The simple fact that consumer preferences towards animal cloning and cloned foods were ignored by the UK government questions the moral legitimacy of this new policy on animal cloning. According to Brownsword, regulators should operate in an 'evidence-based' manner.[109] In the case of the cloning strategy, it seems that the evidence is pointing to the contrary of the decisions taken.

As to the effectiveness of the animal cloning policy in serving its intended purpose, the regulatory approach seems adequate to improve the development of the biotech industry and therefore favour economic growth by requiring no pre-market authorisation or labelling. As stated by Sunstein, stringent regulation 'might well deprive society of significant benefits'.[110] Concerning the appropriateness of the regulatory approach, however, the fact that no mandatory labelling is required prevents the public from knowing what they eat. The new policy fails to consider the full range of available regulatory instruments, which leads back to the absence of legitimacy of the chosen regulatory purposes. Therefore, as the objectives are not regarded as legitimate, the regulatory intervention lacks effectiveness.

The current 'laissez-faire' regime could have negative effects. Sometimes 'regulators can make things worse by intervening because the intervention produces unintended consequences.'[111] Here, the governmental intervention, more precisely lack of intervention, might lead to unwanted effects, as it did with the StarLink™ incident. Requiring the mandatory labelling of products derived from cloned animals and their descendants appears to be a good compromise: it provides consumers with safe food and the information they desire while still allowing for the technology to develop until it is more efficient and long term risk can be measured.

Finally, Brownsword argues that a regulatory system is put the test if there is no consensus or convergence of views within this system.[112] Very interestingly, in the case of animal cloning and its derived foods (and as is the case for GMOs), a huge majority of the UK public are against such a practice and agree on the mandatory labelling of its resulting products as the lowest common denominator. Even though there is a strong agreement within UK consumers rather than a consensus, this should play a role in the regulation of animal cloning. Consumers should be at the centre of the regulation of biotech foods. If supermarkets are listening to consumer preferences, it seems that the regulators should do the same.

VI. Conclusion

A strong positive approach towards modern biotechnology has been revived by the Coalition Government, where modern agricultural biotechnology through sustainable intensification addresses new threats of food security and sustainability.

The debate over modern agricultural biotechnology, its role in ensuring food security and sustainability and economic growth, and how it should be regulated will continue to grow as the EFSA published at the beginning of 2012 a guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare aspects.[113] This new technology and its resulting foods will raise similar regulatory issues as cloned and GM foods.

This article has identified various issues with the current governmental policy call for the use of animal cloning for farming purposes. Those issues weaken to a tremendous extent the legitimacy and effectiveness of the regulatory intervention. First, animal cloning is promoted without fully considering its negative (environmental) impacts, without establishing appropriate controls, for example in relation to genetic diversity, and without the mandatory labelling of the offspring of clones. Second, economic reasons have been identified to be behind such a policy. A driving force towards technological development, the promotion of animal cloning and its resulting financial benefits has been demonstrated. Third, allowing animal cloning puts the UK apart from the EU political institutions as they agreed, in principle, on a temporary ban of

109 *Ibid* 241.

110 Cass R. Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge: CUP 2005), at p. 29.

111 Brownsword, *RightsRegulation, and the Technological Revolution*, *supra* note 18, at p. 138.

112 *Ibid* 100.

113 EFSA, *Guidance on the Risk Assessment of Food and Feed from Genetically Modified Animals and on Animal Health and Welfare Aspects* (2012).

EffL 6-12 29.01.2013 8:28 Uhr Seite 311

the technology. Fourth, animal cloning for food consumption seems contrary to both UK and EU laws because of the animal welfare issues it raises. Fifth, there is a developing trend to listen and to accommodate consumer attitudes, where consumers emerge as a separate market force. For instance, the EU showed willingness to listen to public views during the review of the Novel Foods Regulation, even if it failed. However, the UK government with this new policy is heading in the opposite direction as consumer information and choice are highly limited.

The regulation of modern agricultural biotechnology involves moral, social, societal and cultural values which should be considered by policy- and decision-makers and should play a decisive role in the decision-making process. A framework respecting such criteria – that combines both social needs and regulatory (including technological development) needs – would endow a new regime with legitimacy and effectiveness. Ignoring consumer preferences, animal health and welfare issues, and environmental impacts could create further constraints and put the UK system in peril.