

The Regulatory Challenge of Animal Cloning for Food – The Risks of Risk Regulation in the European Union

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In this article I describe and analyse the current regulatory developments at EU level concerning the marketing of foods produced from cloned animals. As they are on the verge of commercialisation in countries outside the EU, especially in the United States, foods from cloned animals are likely to reach the European consumers in the foreseeable future. Yet at the moment there is no specific legal framework that regulates such products in the EU. The European institutions have, however, opened up a debate to determine the appropriate European policy approach towards animal cloning. The recent discussion reveals that the variety of potential yet very uncertain risks associated with animal cloning renders the drafting of suitable legislation difficult. At the same time, Europe's regulation of food risks also entails certain regulatory risks of its own (e.g. risks of political, economic, and legal conflicts within the EU as well as with EU's trade partners). By considering the discussion on animal cloning in the broader context of EU's regulation of genetically modified organisms and of nanotechnology, I identify the legal and political problems of current regulatory options. I argue that such problems should be openly addressed in the regulatory discussion; it is possible for them to be minimised if lessons are drawn from previous regulatory experience.

I. Introduction

The European Union currently faces a public debate on whether, and under what conditions, food produced using animal cloning should be allowed to circulate on the common market. As happened previously with genetically modified food or nanotechnology, also in the case of animal cloning the EU regulators are confronted with a controversial technology which not only raises food safety concerns, but is also likely to have further ethical and socio-economic implications. The variety of potential yet very uncertain risks associated with animal cloning (e.g. risks to public health, environment, animal health and welfare, ethics) makes it difficult for reg-

ulators to design a suitable legal framework: one that would ensure the right balance between risk control and the promotion of technological innovations. Finding such a balance may seem a daunting task in view of negative consumer preferences within the EU, as well as the politicisation of the topic among the European institutions and civil society. Further problems arise regarding the existence and scope of EU legal competence to regulate animal cloning, and therefore regarding the proper allocation of regulatory authority within EU multi-level governance. Moreover, Europe's international trade partners are closely monitoring EU policy developments in this area, as foreign food industries (above all in the United States) are getting ready for the widespread commercialisation and export of food products from cloned animals. Any trade-restrictive EU regulations of such products would therefore endanger future international imports into the Euro-

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pean market, thus creating a potential for new international trade disputes in the World Trade Organisation (WTO).¹

Obviously there are parallels between problems encountered in the case of animal cloning regulation and those encountered in other areas of European risk regulation. Animal cloning, therefore, should be considered in its broader regulatory context. In particular, the ongoing controversy surrounding the EU authorisation of Genetically Modified Organisms (GMOs) teaches us that the regulation of public health and environmental risks also entails regulatory (e.g. political, economic) risks of its own. The EU public authorities appear to be well aware of this. The Commission, therefore, is still hesitant about adopting trade restrictive measures, preferring to wait for further scientific, technological and commercial developments. Such a “wait and see” strategy resembles the Commission approach towards the regulation of nanotechnology, where up until present a specific legal framework is still lacking.² At the same time, EU regulators are contemplating the use of certain existing legislative instruments for both animal cloning and nanomaterials,³ which in turn is likely to raise new legal problems in the application of such instruments. In this article I summarise the EU regulatory discussion on animal cloning for food supply. By analysing the regulatory options and identifying potential problems of their future adoption, I hope to contribute to the current debate.

II. Animal cloning on the verge of commercialisation in the global food market

As often in legal regulation, the devil lies in the details. Understanding the current regulatory developments at EU level and their implications at first requires some contextual information about the technology of animal cloning as well its commercialisation at global level. ‘Animal cloning’ in the sense used in the present regulatory discussion is defined as the reproduction of genetically identical ‘copies’ of an animal through Somatic Cell Nuclear Transfer (SCNT). At present, SCNT is the most commonly used technique for animal cloning, and it allows scientists to create genetic replicas (clones) from adult animals that share the same nuclear gene set as another organism.⁴

The primary commercial use of this technology today and in the near future is in the breeding of farm animals for food production. The benefits of using animal cloning as a breeding technique lie in the potential to produce elite animals to be used in breeding. Thus, the animals to be cloned would be those having traits of interest for farming such as resistance to disease, or characteristics of interest for food production including quantity of milk, quality of meat etc.⁵ The clones themselves have a low probability of entering the food chain. It is rather their progeny that are used for food production, above all for the production of milk or meat products.⁶ ‘Progeny of a clone’ refers to offspring born from it by sexual reproduction, where at least one of the parents was a clone.⁷

- 1 Well known precedents are *EC – Measures Concerning Meat and Meat Products*, Report of the Appellate Body, WTO doc. WT/DS26/AB/R and WT/DS48/AB/R, 16 January 1998; and *EC – Measures Affecting the Approval and Marketing of Biotech Products*, Report of the Panel, WTO doc. WT/DS291, WT/DS292, WT/DS293, 29 September 2006.
- 2 See, however, the Commission announcement in 2009 that it would review all relevant existing legislation within two years to ensure safety of all applications of nanomaterials in products with potential environmental, health, and safety impacts over their life cycle; see European Commission, “Towards a strategic nanotechnology action plan (SNAP) 2010-2015,” Public Consultation available on the Internet at http://ec.europa.eu/research/consultations/snap/consultation_en.htm (last accessed on 8 February 2010); for further comments see Montfort, Jean-Philippe/Indirli, Giovanni/Carrega, Claire-Marie, “Nanomaterials under REACH: Legal Aspects”, *European Journal of Risk Regulation*, in this issue.
- 3 See with regards to food safety the ongoing amendment of Regulation (EC) No 257/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients, OJ 1997 L 43/1; further discussion *infra* at IV; only in the case of nanomaterials see European Parliament and Council Regulation 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; see discussion in Montfort *et al*, “Nanomaterials,” *supra* note 2.
- 4 See in more detail The European Group on Ethics in Science and New Technologies, *Ethical aspects of animal cloning for food supply*, Opinion No 23 from 16 January 2008, p. 6 (hereinafter EGE opinion).
- 5 See EGE opinion *supra* note 4, pp. 12–13.
- 6 See European Food Safety Authority, “Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their offspring and Products Obtained from those Animals,” Scientific Opinion from 15 July 2008, *The EFSA Journal* (2008) 767, pp. 1 *et seq.*, at p. 10 (hereinafter EFSA opinion).
- 7 See EFSA opinion *ibid*, at p. 7.

EU consumer attitudes to cloning for food production, the results of which were published in October 2008. One month earlier, in September, the European Parliament contributed to the debate by issuing a resolution on animal cloning for food supply, in which it demanded a comprehensive ban of the technology. Furthermore, at the beginning of 2008 a legislative co-decision procedure had been initiated by the Commission with the aim of amending Regulation 258/97¹⁷ (known as the Novel Foods Regulation) by including, *inter alia*, food from animal cloning in the scope of this regulation. The outcome of all these processes deserves closer attention, since it indicates the different issues and concerns at stake. Moreover, it provides some ideas about the possible forms of future EU regulation of animal cloning for food supply.

1. EFSA's scientific opinion(s)

On 15 July 2008, EFSA issued its scientific opinion on animal cloning for food supply.¹⁸ EFSA limited its evaluation to cattle and pig clones and their progeny, due to the lack of data for the cloning of other species. Overall, EFSA identified animal health and welfare as the main concern arising from animal cloning through SCNT due to the fact that the technique often still malfunctions. In contrast, EFSA was unable to identify any risks with regard to food safety and the environment.

As regards risks to human health EFSA stated that, based on current knowledge, there is no indication that differences exist in terms of food safety between food products (e.g. meat and milk) from healthy cattle and pig clones and their progeny, compared with those from healthy conventionally-bred animals. However, EFSA also emphasised that there is not enough data at the moment to evaluate whether SCNT has an impact on the immune functions of cloned animals, and therefore on their susceptibility to infection. This raises the question whether and to what extent the consumption of meat and milk from cloned animals or their progeny may also lead to an increased human exposure to transmissible agents. This question remains open, and has been referred back for further research on the immunological competence of clones.¹⁹

EFSA has also found that there are significant animal health and welfare issues for surrogate mothers (dams) and clones that can be more frequent and severe than for conventionally bred animals. Surrogate dams suffer from increased pregnancy failure

and increased recourse to Caesarean section. Further, the mortality and morbidity rate of clones in the early stage of their development is considerably higher than in sexually reproduced animals. However, clones that survive appear to be normal and healthy. As regards progeny EFSA found no indication of any abnormal effects.

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

To conclude, it is worth noting that throughout its opinion EFSA emphasised the uncertainties surrounding the scientific risk assessment of animal cloning at the present stage of technology development. The reasons stated for these uncertainties are: the limited number of studies available, the small sizes investigated and the absence of a uniform approach to allow all the issues relevant to the opinion to be addressed.²⁰ Thus EFSA was unable to provide definitive answers to all the questions addressed to it by the Commission, which is why, in March 2009, the Commission went back to EFSA, asking it to develop its scientific advice further, especially with regard to animal health and welfare of clones. EFSA's second statement was published on 23 June 2009.²¹ Whilst including a number of new publications on SCNT, EFSA overall confirmed the findings and recommendations made in its first risk assessment; at the same time it was still unable to remove all the uncertainties.

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

The EGE adopted its opinion on 16 January 2008. After conducting expert hearings and a public comments round as well as organising a round table

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

18 See EFSA opinion *supra* note 6.

19 See EFSA opinion *supra* note 6, p. 33.

20 See EFSA opinion *supra* note 6, p. 2.

21 See EFSA statement, "Further advice on the implications of Animal Cloning (SCNT)", 23 July 2009, *The EFSA Journal* (2009) RN 319, p. 1 *et seq.*

with representatives from academia, industry, NGOs, civil society and international organisations, the EGE reached the conclusion that doubts existed about the ethical justification for cloning animals for food supply. The Group stated that “*considering the current level of suffering and health problems of surrogate dams and animal clones, the EGE has doubts as to whether cloning animals for food supply is ethically justified. Whether this applies also to progeny is open to further scientific research.*” As a consequence, at present the EGE sees no convincing arguments justifying the production of food from clones and their offspring.²²

3. Public perception – the Eurobarometer on animal cloning

Following the EGE recommendation, the Commission’s DG SANCO launched a Eurobarometer survey to find out more about EU citizens’ attitudes towards animal cloning for food production. The results of the survey, published in October 2008²³, showed that the majority of citizens hold negative views of animal cloning. 84% believe that the long-term effects of animal cloning on nature are unknown; 77% believe that animal cloning might lead to human cloning; 61% think that animal cloning is morally wrong. A majority of interviewees (58%) said that cloning for food production purposes should never be justified. 63% of citizens stated that it was unlikely they would buy meat or milk from cloned animals, even if a trusted source stated that such products were safe to eat. Finally, special labelling for food products from the offspring of clones was favoured by 83% of the interviewees.

Overall, it seems that the issues perceived most problematic by the public are the uncertainty of the

long-term effects of the technology on nature and the moral justification for using animals for cloning for the purpose of food production. Two moral objections seem particularly pressing: the ‘slippery slope’ argument contesting the cloning of animals against the background of immorality of cloning humans; second, the fear that animals would run the risk of being treated like commodities rather than as living creatures with feelings.

4. The European Parliament’s resolution on animal cloning²⁴

The EP’s resolution added a weighty democratic element to the EU orientation debate on the use of animal cloning. Its call to ban every form of commercialisation of the technology, including imports of related products into the EU, was supported by the vast majority of MEPs. 622 voted in favour, 32 against and 25 abstained. The resolution issued a clarion call to the Commission “*to submit proposals prohibiting for food supply purposes (i) the cloning of animals, (ii) the farming of cloned animals and their offspring, (iii) the placing on the market of meat or dairy products derived from cloned animals or their offspring and (iv) the importing of cloned animals, their offspring, semen and embryos from cloned animals or their offspring, and meat or dairy products derived from cloned animals or their offspring, taking into account the recommendations of EFSA and the EGE.*”

5. The Commission’s orientation debate on animal cloning

At one of their weekly meetings in January 2009, the Members of the Commission held an orientation debate to see whether, in the light of the above-described consultations, the EU’s existing regulatory framework was sufficient or whether additional measures designed specifically for animal cloning were required.²⁵

The Commissioners discussed different possible policy options, focussing mainly on three courses of action: (1) not taking any action at present pending further debate at EU level and internationally on the use of cloning for food supply; (2) using the existing EU legal instruments to regulate products derived from animal cloning; and (3) proposing an outright ban of animal cloning for food supply.²⁶ The outcome of this orientation debate was not to

22 See EGE opinion *supra* note 4.

23 See Eurobarometer, “European’s attitudes towards animal cloning”, available on the Internet at http://ec.europa.eu/public_opinion/flash/fl_238_en.pdf (last accessed on 2 February 2010).

24 See European Parliament resolution on the cloning of animals for food supply, 3 September 2008, available on the Internet at <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2008-0400&language=EN&ring=B6-2008-0373> (last accessed on 2 February 2010).

25 See USDA Foreign Agricultural Service, “EC Orientation Debate on Animal Cloning”, GAIN Report Number E41010, 30 January 2009, available on the Internet at www.fas.usda.gov/gain-files/200902/146327190.pdf (last accessed on 2 February 2010).

26 See *ibid.*

take any definitive decisions on a policy approach yet. It seems the Commissioners wanted more time for reflection and for the debate between the Commission, the Parliament and the Council to continue. Also, in March 2009, not long after this orientation debate, DG SANCO asked EFSA for the additional scientific opinion (see above). This may be seen as an indication that the Commission was not satisfied that the available factual evidence formed a sufficient basis for new specific legislative action.

IV. Legislative developments – A new amendment of the Novel Foods Regulation²⁷

It is worth noting that, in parallel to the ongoing debate described above, and half a year before the issue of the EFSA's first scientific opinion on animal cloning, the Commission had already initiated a legislative process, the outcome of which will directly affect the way that food from cloned animals will be regulated in the EU.

In January 2008, the Commission presented a legislative proposal for revision of the Novel Foods Regulation,²⁸ thereby using an existing legislative instrument to regulate food derived from cloned animals.²⁹ The Novel Foods Regulation currently requires a prior authorisation for novel foods: they may only be placed on the common market after having undergone a centralised safety assessment by the EFSA. This Commission proposal is currently at the co-decision stage (which is now the usual ordinary legislative procedure, see Article 294 of the TFEU), and it is worth looking at its content and the modifications by the other institutions, particularly so because the outcome of this legislative process may well clarify the status of food products from cloned animals in the common market; and also because there is currently an ongoing institutional struggle that reflects the possible different ways of treating such products in EU regulation.

It should be noted that, under the current EU legislation, imported food products derived from cloned animals (such as meat or milk) can legally be placed on the common market, being subject only to the general food safety requirements of the Regulation 178/2002.³⁰ However, this does not apply to food derived directly from an animal clone, as such food is today likely to fall under the scope of the Novel Foods Regulation, already in force, with the

consequence that it is submitted to the prior authorisation requirement. According to the present Article 1, para. 2), indent (e) of the Novel Foods Regulation, all food isolated from animals which has not been obtained by traditional breeding and does not have a history of safe food use is considered to be 'novel food' and so requires an additional safety assessment. The new Commission proposal clarifies the status of food obtained directly from cloned animals under this provision, by stating that all foods from animals to which has been applied "a non-traditional breeding technique not used before May 1997,"³¹ such as animal cloning, should fall under the definition of novel foods.

However, even more important for the common market and also for international trade will be those food products which are obtained from a clone's progeny, since such products are likely to present the majority of foods traded or imported into the EU (see above under I.). Here it is interesting to note that the Commission proposal does not also include products from progeny in the future definition of 'novel foods'. Because there is no difference any more between the progeny of clones (created through sexual reproduction with non-clones) and animals obtained through conventional breeding, the former would not be considered as animals to which has been applied "a non-traditional breeding technique."³² Consequently, under the Commission's proposal, products from progeny could still freely circulate on the common market (under the requirements of Regulation 178/2002). This shows that, when presenting its amendment proposal, the Commission only wanted to clarify the legislative status quo rather than change it.

27 See *supra* note 3.

28 Commission Proposal for a Regulation of the European Parliament and of the Council on novel foods, COM (2007) 872 final, available on the Internet at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0872:FIN:EN:PDF> (last accessed on 3 February 2010).

29 Note that another purpose of this amendment is to include foods produced using nanotechnology into the scope of the Novel Foods Regulation, see Commission Proposal, *supra* note 28, point 6) of the preamble.

30 Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 L 31/1.

31 See Commission proposal, *supra* note 28, p. 16.

32 See Commission proposal, *supra* note 28, p. 16.

However, the Commission's proposal has been substantially modified by the other institutions during the course of the co-decision procedure. The European Parliament, in its legislative resolution from the first reading held in March 2009, suggested that foods from cloned animals (both from clones and their progeny) should be totally excluded from the scope of application of the Novel Foods Regulation. Instead, the EP prompted the Commission to submit a legislative proposal effectively banning animal cloning from the food supply chain.³³

At the time of writing, the Council has not yet adopted a common position on the Parliament's amendment to the Commission proposal. However, in June 2009 it approved a political agreement on the draft regulation whereby the Council proposed the inclusion of not only food produced directly from cloned animals but also that produced from their progeny under the scope of the Novel Foods regulation, thereby extending the prior-authorisation requirement to the latter type of products.³⁴

V. Concluding remarks

Animal cloning for food supply is likely to become yet another contested area of EU risk regulation. One of the challenges for EU regulators at the moment is the politicisation of the topic. It has become obvious that animal cloning for food supply transcends food safety concerns. In fact, the most pressing issues identified by the EU expert bodies consulted are

animal welfare and public morals; both issues are to a certain degree intertwined. In addition, there is widespread public aversion among European consumers to food from cloned animals, and neither EU industry nor agriculture are sufficiently advanced in the employment of the technology. As the GMO example shows,³⁵ such a combination provides for a regulatory context that is particularly favourable to non-institutional actors, such as non-governmental organisations, who oppose the use of animal cloning in Europe. It gives them the power to influence regulatory decisions in favour of a strict regulatory framework. It seems too early, though, to predict the outcome of the current EU policy debate. The authorities, in particular the Commission, hesitate over taking trade restrictive measures too quickly. Animal cloning as a breeding technique is still at a development stage promising improvement, and thus also better welfare conditions for the animals in the future. The regulatory developments in the US also seem crucial. The EU would, therefore, be well advised to coordinate its regulatory development with the regulatory authorities of its main trade partner³⁶.

A further difficulty for EU regulation arises with regard to the appropriate legal basis, or EU competence, for enacting legislation in response to the ethical concerns related to animal cloning for food as expressed, *inter alia*, in the EGE expert opinion. Legal regulation on the grounds of public morals is a prerogative of the Member States, and this remains unchanged under the new Lisbon Treaty (see Articles 2 – 6 of the TFEU). Insofar as diverse national regulations on animal cloning would interfere with the functioning of the internal market, the EU would have the competence to approximate the laws in the Member States using the legal basis of Article 114 TFEU (ex Article 95 EC Treaty). Given the complexity of internal market regulation,³⁷ (in particular, its intertwinement with almost all other areas of public regulation), the possibility of using Article 114 also to harmonise the rules on market access for 'cloned' food cannot be dismissed from the outset. Nevertheless, the field of public morals is particularly sensitive politically, so it may be expected that both the Commission and the Member States will be wary of using Article 114 to harmonise national provisions regulating animal cloning on ethical grounds. Finally, the EU also has the powers to legislate for the purpose of protecting animal health and welfare (Article 38 TFEU, ex Article 43 EC Treaty), as indeed

33 See European Parliament legislative resolution of 25 March 2009 on the proposal for a regulation of the European Parliament and of the Council on novel foods, available on the Internet at <http://www.europarl.europa.eu/oeil/file.jsp?id=5583302> (last accessed on 3 February 2010).

34 See Council of the European Union, "Council agrees on new rules for novel foods", Press Release, 22 June 2009 11218/1/09 REV 1 (Presse 188).

35 Cite Pollack, Mark A. and Shaffer, Gregory C., *When Cooperation Fails – The International Law and Politics of Genetically Modified Foods* (Oxford: Oxford University Press 2009), pp. 68 *et seq.*

36 See Alemanno, Alberto, "How to Get Out of the Transatlantic Regulatory Deadlock over GMOs? Time for Regulatory Cooperation", in Swinnen, J. and Vogel, D. (eds) *Cooperating in Managing Biosafety and Biodiversity: California, The United States and the European Union* (Cheltenham: Edward Elgar 2010 forthcoming), available on the Internet at SSRN: <http://ssrn.com/abstract=1419928> (last accessed on 4 February 2010).

37 See Case C-376/98, *Germany v Parliament and Council*; see also Slater, Donald, "The scope of EC harmonizing powers revisited?", 4 *German Law Journal* (2003) No. 2, pp. 137 *et seq.*

it has done in the past. One example is Directive 98/58/EC³⁸ on the protection of animals kept for farming purposes; even today, in theory, this Directive could be used to restrict the use of animal cloning as a breeding technique within the EU.³⁹ However, such a restriction would not solve the issue of international imports of products produced from cloned animals or their offspring outside the EU.

It should be noted that the choice of the correct legal basis for EU legislation on animal cloning is crucial for minimising the risk of its being successfully challenged before the European Courts⁴⁰ in future. On one hand, EU legislative acts can be challenged by EU's institutional actors (see Article 263 II TFEU, ex Article 230 II EC Treaty). One could imagine that a Member State, after having been outvoted during the adoption of the act in the Council of Ministers, might later bring an action before the Court of Justice against the passed legislation while invoking lack of EU competence.⁴¹ On the other hand, the Treaty of Lisbon has extended the possibilities for natural and legal persons to challenge an EU act of general scope. According to the new Article 263 IV TFEU, any person can bring an action against a "regulatory act, which is of direct concern to them and does not entail implementing measures." Therefore, the plaintiff no longer needs to be *individually* concerned by the act in order for his annulment proceeding to be admissible.⁴² Thus, if future EU legislation on animal cloning were to take the form of a self-executing EU regulation (such as the Novel Foods Regulation), producers or importers of foods derived from animal cloning could arguably seek direct judicial protection against it before the European Courts. Problems, however, are likely to arise with regard to the notion of a "regulatory act" (e.g. delegated and implementing acts according to Articles 290 and 291 TFEU as acts of the executive; or even legislative acts according to Article 289 TFEU?), since no definition is laid down in the Treaty. In such cases, one should wait for future case law to shed light on this issue.⁴³

The problem of determining the legal basis brings us to the current process of amendment of the Novel Foods Regulation. The Regulation constitutes an origin-neutral legislative measure, which means that it regulates the market access of all novel food products, including those imported into the EU. Given the positions of the institutions involved in the co-decision procedure and depending on its outcome, three options for dealing with food from cloned animals can be conceived of. First, only food produced

directly from clones will require prior authorisation, including safety assessment, before being placed on the market (Commission proposal). Second, products from clone progeny would also need to be authorised, despite the lack of any nutritional difference of such products compared with food produced from conventionally bred animals (Council). Finally third, animal cloning would fall outside the scope of the Novel Foods Regulation with the possibility of a new legislative measure banning food from cloned animals on the EU market (Parliament).

Apart from the political question of which of the three outcomes would be most desirable, there also is a legal problem with using the Novel Foods framework for regulating animal cloning. The Novel Foods Regulation is based on the EU competence to ensure the proper functioning of the internal market (now Article 114 TFEU), and it has been enacted to harmonise national regulations aiming at the protection of human health. Therefore, the Regulation itself serves the purpose of protecting public health from risks related to novel foods by establishing a common EU safety assessment for such products.⁴⁴ Against this background, the inclusion of food from cloned animals into the Regulation would seem to be at odds with EFSA's opinion, in which the Agency up till now has not been able to identify any risks with regard to food safety or the environment. To take this a step further: according to the positions of both Council and Commission, in the future there would be a case-by-case safety assessment carried out by EFSA for every food product from cloned animals submitted to be authorised in the EU. What

38 OJ 1998 L 221/23.

39 Article 4 of the Directive and its Annex point 20 state that breeding procedures that cause or are likely to cause suffering or injury to any of the animals concerned must not be practiced.

40 Under the new provisions of the Lisbon Treaty, the Court of Justice and the General Court, see Article 251 *et seq.* of the TFEU.

41 See, for example, Case C-301/06 *Ireland v European Parliament, Council*, Judgment of 10 February 2009, OJ 2009 C 82/03.

42 See, as the latest confirmation of the so-called *Plaumann-Formula* of 'direct and individual concern', Case C-50/00 *Union de Pequenos Agricultores* (2002) ECR I-6677.

43 If the EU authorities issued a decision directly addressed to a producer or importer of foods from cloned animals (for example under a prior-authorisation scheme), or which was of direct and individual concern to them, the admissibility of an annulment procedure under Article 263 IV TFEU, following the lines of long standing case law on Article 230 IV EC-Treaty, should not be problematic.

44 See recital (2) of the preamble of Regulation (EC) No. 258/97.

could possibly be the outcome of such individual EFSA risk assessments seeing that the same Agency in previous scientific opinions has been unable to identify any differences in terms of food safety between foods from healthy clones compared with those from healthy conventionally-bred animals? Of course, EFSA's opinions on animal cloning so far have indicated a high degree of scientific uncertainty and lack of data; and it cannot be excluded that risks to food safety would be identified at a later stage. This means, however, that the precautionary principle (Article 191 II TFEU, ex Article 174 II EC Treaty) could eventually be invoked as a justification for the inclusion of food from cloned animals in the Novel Foods Regulation in view of the present insufficiency of scientific evidence. Without going into further detail here, it can be stated that the application of this principle in European risk regulation has until today been impeded by many difficulties,⁴⁵ one of them being its politicisation. The problematic example of EU regulation of GMOs⁴⁶ once again comes to mind: given the strong public opposition to and political contestation surrounding animal cloning at present, the scenario of a *de-facto* moratorium of the same kind as occurred in the Community authorisations of biotech products⁴⁷ can also be imagined for future authorisations of foods from cloned animals under the amended Novel Foods Regulation. The parallels are obvious: a stringent prior-authorisation procedure with individual case-by-case

assessments in which the scientific experts do not identify the existence of risks to food safety and public health, while the Member States – fuelled by strong public opposition from their countries – are reluctant to approve the entry on the market of the contested products, by invoking the precautionary principle. The negative implications of this for international trade would make a new transatlantic WTO dispute a highly likely course of events⁴⁸. All this raises doubts as to whether the Novel Foods Regulation is in fact the appropriate legal framework for regulating foods from cloned animals.⁴⁹

To conclude, the further regulatory developments in European regulation of animal cloning will without doubt raise complex questions with regard to the appropriate policy choice, transatlantic regulatory cooperation, precautionary principle, international trade, and the adequate legal framework, just to name a few considerations. The EU institutions, especially the Commission, seem to be playing for time in view of the early stage of technology development, the scientific uncertainty, and the need for cooperation with international trade partners of the EU. Hope remains that this waiting time will also be used to initiate a broader, more transparent, and balanced public debate on the implications of animal cloning for food supply; and that lessons will be drawn from EU's experience with the regulation of other controversial technologies, in particular, of agricultural biotechnology.

45 See Weimer, Maria, "Applying Precaution in Community Authorisation of Genetically Modified Organisms – Challenges and Suggestions for Reform", *European Law Journal* forthcoming; also as Recon Online Working Paper 2009/14 available on the Internet at <http://www.reconproject.eu/projectweb/portalproject/AbstractRECONwp0914.html> (last accessed on 3 February 2010); Majone, Giandomenico, "Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform", *European Journal of Risk Regulation*, in this issue.

46 Lee, Maria, *EU Regulation of GMOs* (Edward Elgar 2008); Shaffer and Pollack, *When Cooperation Fails*, *supra* note 35.

47 Namely between 1998 and 2004, see Shaffer and Pollack *ibid*, at p. 68.

48 On previous WTO case law and the meaning of precaution under WTO law see Flett, James, "If in Doubt, leave it out? EU Precaution in WTO Regulatory Space", *European Journal of Risk Regulation*, in this issue.

49 Problems of a factual kind can be expected concerning the feasibility of labeling and traceability of food products from cloned animals, which would be a prerequisite for the functioning of the prior-authorisation system. This problem would be particularly acute for foods from clone progeny, which don't seem to show any nutritional difference to conventional food products.