The Cloning of Animals for Farming Purposes in the EU: From Ethics to Agri-food Law

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L’homme n’est pas le seul animal qui pense. Mais il est le seul à penser qu’il n’est pas un animal.
Cécile Lestienne

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I. Introduction

At the end of 2013 the European Commission adopted a “Proposal for a Directive of the European Parliament and of The Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes”1. As this article will show, what is being proposed is a sui generis regulation for a controversial issue2. Both ethical and economic arguments have featured in the fierce debates it has caused3, which in the past were enough to defeat a similar proposal4.

Although this article is primarily focussed on the 2013 proposal5 I shall begin by briefly discussing the current animal cloning regime, which is based on the rules

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5 See footnote 1 in fine.
laid down in Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients and the provisions of Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes. I shall then discuss the Commission’s unsuccessful 2008 proposal concerning animal (and vegetable) cloning, as comparing differences of both form and content between this and the 2013 proposal will no doubt help us to better understand the criteria and rationale behind the latter.

Finally, I shall conclude with a short analysis of the “Proposal for a Regulation of the European Parliament and of the Council on novel foods”\(^9\), which was published on the same day as the Commission’s 2013 proposal. While the article’s main focus and objectives remain those outlined above, this should help the reader gain a broader understanding of the impact of both this Regulation and the Directive which the community legislator may one day adopt\(^10\).

II. Current legislation

1. The pre-market approval procedure - a “new ingredient”

Paragraph 1.1 (“Background of the proposal”) of the Explanatory Memorandum of the Commission’s 2013 proposal\(^11\) recognises that «in food production cloning is a new technique», and goes on to confirm that, under the current legislative framework, food from clones falls under the scope of Regulation


\(^7\) Official Journal L 221, 8/08/1998 p. 23.

\(^8\) See footnote 4 in fine.


\(^10\) Although of course as FERNÁNDEZ MARILGERA., E. reminds us, the proposed texts will no doubt be subject to amendments and additions by the European Parliament and European Council. See FERNÁNDEZ MARILGERA., E. “El nuevo Reglamento relativo a los Novel Foods no puede basarse en criterios políticos sino en sólidos fundamentos científicos a fin de proteger la salud de los consumidores de la UE”, BoDiAlCo, No. 4, 2014, p. 25.

\(^11\) See footnote 1 in fine.
No 258/97\textsuperscript{12} on Novel Food Regulation and is thus subject to pre-market approval based on a food safety risk assessment\textsuperscript{13}.

It should also be noted that there is a limited but valuable body of European Court of Justice (ECJ) case law providing interpretations of this Regulation. Some of the judgements worth highlighting are

“Monsanto Agricoltura Italia SpA” of 9 September 2003\textsuperscript{14}, in which the ECJ stated that article 3.4(1) of Regulation No 258/97 must be interpreted as meaning that the mere presence in novel foods of residues of transgenic protein at certain levels does not preclude those foods from being considered substantially equivalent to existing foods and, consequently, use of the simplified procedure for placing those foods on the market;

“HLH Warenvertriebs GmbH y Orthica BV” of 9 June 2005\textsuperscript{15}, in which it stated that article 1.2 of Regulation No 258/97 «... is to be interpreted as meaning that a food or a food ingredient has not been used for human consumption to a significant degree within the Community if, when all the circumstances of the case are taken into account, it is established that that food or that food ingredient has not been consumed in a significant quantity by humans in any of the Member States before the reference date [15 May 1997]»; and

“M-K Europa GmbH & Co. KG” of 15 January 2009\textsuperscript{16}, according to which the «experience regarding the safety of a food product existing exclusively outside Europe is not sufficient to establish that the product concerned falls within the category of food products ‘having a history of safe food use’ within the meaning of Article 1(2)(e) of Regulation No 258/97»;

Nevertheless, it is evident that even if we rely on a hypothetical and somewhat problematic application by analogy of the case law available, the rules and procedures laid down in the 1997 (!) Directive are neither efficient nor practical enough to regulate animal cloning in the 21\textsuperscript{st} Century\textsuperscript{17}.

\textsuperscript{12} See footnote 7.

\textsuperscript{13} See also paragraph 1.1 of the Explanatory Memorandum of the Commission’s 2013 Proposal.


\textsuperscript{15} Joined cases C-211/03, C-299/03 and C-316/03 to C-318/03, ECR 2005 p. I-5141 (on this sentence see “BOUVERESSE, A. “Relation entre denrée alimentaire et médicament”, Europe, No. 289, 2005,19-20).

\textsuperscript{16} Case C-383/07, ECR 2005 p. I-115 (on this sentence see: “Interpretación de los artículos 1.1, 1.2 y 1.3 del Reglamento n° 258/97 sobre nuevos alimentos, Revista de Derecho Alimentario, n° 44, 2009, 27-31 (text available in the following Internet page, consulted on 24 February 2014: http://aibadaredeco.googlepages.com/crcoaiba2.pdf)]).

\textsuperscript{17} See FERNÁNDEZ MARILGERA, E. op.cit., p. 27, footnote 10.
2. Regulation on the welfare of animals used in agriculture (Directive 98/58/EC\textsuperscript{18})

Elsewhere, Directive 98/58/EC on the protection of animals kept for farming purposes sets \textit{very general minimum animal welfare standards}\textsuperscript{19} for animals used in agriculture: «it does not refer explicitly to cloning, but calls on Member States to avoid unnecessary pain, suffering or injury in farm animals»\textsuperscript{20}. Thus if cloning causes \textit{unnecessary pain, suffering or injury} Member States have to act \textit{at national level} to avoid it\textsuperscript{21}.

III. The Commission’s controversial 2008 proposal\textsuperscript{22}

The \textit{Commission’s 2008 Proposal}\textsuperscript{23} aimed above all to streamline the approval process for novel foods in Regulation No 258/97. However the initiative drowned in a sea of controversy in the ordinary legislative procedure as a result of arguments over various issues ranging from animal cloning for food production to the provisions applicable to nanomaterials, the traditional foods of non-member countries, risk management criteria and the functioning of the novel food approval procedure in accordance with the Treaty on the Functioning of the European Union (Lisbon Treaty). In the end the discussions reached a \textit{stalemate}\textsuperscript{24}: «the Conciliation Committee did not reach a final agreement at its last meeting on 28 March 2011 and the proposal was not adopted by the Union legislator»\textsuperscript{25}.

The \textit{Commission’s 2013 Proposal} itself refers to what happened in paragraph 1.1 of its Explanatory Memorandum, noting that legislators had \textit{attempted} to amend the proposal during the legislative procedure in order to introduce specific

\textsuperscript{18} See footnote 6.

\textsuperscript{19} \textit{Sic} paragraph 1.3 (“Regulatory framework”) of the Explanatory Memorandum of the \textit{Commission’s 2013 Proposal}.

\textsuperscript{20} See paragraph 1.3 of the Explanatory Memorandum of the \textit{Commission’s 2013 Proposal}.

\textsuperscript{21} \textit{Ibidem}.

\textsuperscript{22} See footnote 4 \textit{in fine}.


\textsuperscript{24} \textit{Sic} in the second paragraph of section 1 of the Explanatory Memorandum in the document cited in footnote 9.

\textsuperscript{25} See the second paragraph of section 1 of the Explanatory Memorandum in the document cited in footnote 9.
rules on cloning, but «no agreement was reached on the scope and features of these insertions so that the proposal was abandoned after a failed Conciliation…».

It was in this context that «as a result the Commission was asked to prepare a legislative proposal on cloning in food production based on an impact assessment outside the Novel Food Regulation».

It is worth asking how the regulation of cloning was described in the Commission’s 2008 Proposal. In fact, the proposed text did not mention “cloning” explicitly but rather stated that:

«this Regulation lays down harmonised rules for the placing of novel foods on the market in the Community with a view to ensuring a high level of human health and consumers’ protection, whilst ensuring the effective functioning of the internal market» [article 1 (“Subject matter”)]

and

the «… Regulation [in question should be applied] to the placing of novel foods on the market in the Community» [article 2.1 (“Scope”)];

The aforementioned scope of application excludes food additives, food flavourings, extraction solvents used in the production of foodstuffs, food enzymes, vitamins and minerals, as well as «foods falling within the scope of Regulation (EC) 1829/2003» (article 2.2);

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26 See the Report from the Commission to the European Parliament and the Council on animal cloning for food production [COM(2010) 585, de 19.10.2010], which makes the following proposals: (i) suspend temporarily the use of the technique in the EU for the reproduction of all food producing animals; the use of clones of these animals; and the marketing of food from clones; and (ii) establish the traceability of imports of semen and embryos to allow farmers and industry to set up data bank(s) of offspring in the EU (text available in the following Internet page, consulted on 20 February 2014: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52010DC0585&qid=1402070139063&from=ES).


28 See also paragraph 1.1 of the Explanatory Memorandum of the Commission’s 2013 Proposal.


Finally, cloning - not only of animals - was alluded to in article 3 (“Definitions”):

«2. The following definitions shall also apply:

(a) "novel food" means:

[...]

ii) food of plant or animal origin when to the plant and animal is applied a non-traditional breeding technique not used before 15 May 199731

[...]

As jurisprudence has demonstrated32, article 3.2.a(ii) above is hard to interpret without also reading the following recitals in the proposed text:

«5. The existing definition of novel food should be clarified and updated33 by replacing the existing categories with a reference to the general definition of food in Regulation (EC) No 178/200234 [...].

6. It should also be clarified that a food should be considered as novel when it is applied a production technology which was not previously used35. In particular, emerging technologies in breeding and food production processes, which have an impact on food and thus might have an impact on food safety, should be covered by this Regulation. Novel food should therefore include foods derived from plants and animals, produced by non-traditional breeding techniques36, and foods modified by new production processes, such as nanotechnology and nanoscience, which might have an impact on food. Food

31 Emphasis added by the author.

32 See for example SWINDELLS, J.A., op.cit., p. 29, footnote 2.

33 Emphasis added by the author.


35 Emphasis added by the author.

36 Idem.
derived from new plant varieties, or animal breeds produced by traditional breeding techniques, should not be considered as novel foods\textsuperscript{37}.»\textsuperscript{38}

It would appear then that the definition of novel food in relation to cloned animals or vegetables was not sufficiently clarified or simplified and that this, \textit{inter alia}, was the reason the proposal failed…

\section*{IV. Cloning – for or against?}

\subsection*{1. Subject matter, scope and legal basis of the Directive proposed in the \textit{Commission’s 2013 Proposal}}

\subsection*{1.1 Subject matter}

According to the Commission, the objective of it’s 2013 Proposal «… is to ensure uniform conditions of production for farmers while protecting the health and welfare of animals».\textsuperscript{39} Following on from this, article 1 of the proposed text refers to both the proposal’s subject matter and its scope, providing in the briefest of terms that

« This Directive lays down rules on:

(a) the cloning of animals in the Union;

(b) the placing on the market of embryo clones and animal clones.

It shall apply to animals of the bovine, porcine, ovine, caprine and equine species (‘the animals’) kept and reproduced for farming purposes.».

\subsection*{1.2 Scope of application: the definition of “cloning”}

Paragraph 1.1 of the Explanatory Memorandum of the \textit{2013 Proposal} defines cloning in the following terms: « Cloning is a relatively new technique of asexual reproduction of animals producing near exact genetic copies of the animal cloned, i.e. without modification of genes».

Such a short definition of the scope of the Directive is necessarily expanded upon in paragraph 2(b), which defines "cloning" as

\textsuperscript{37} \textit{Idem}.

\textsuperscript{38} It is also worth remembering that recital 24 provides for the possibility of consulting «… the European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997 […] where appropriate, with a view to obtaining advice on ethical issues regarding the placing on the market of novel foods».

\textsuperscript{39} See paragraph 1.2 of the Explanatory Memorandum of the \textit{Commission’s 2013 Proposal}. 
«[the] asexual reproduction of animals with a technique whereby the nucleus of a cell of an individual animal is transferred into an oocyte from which the nucleus has been removed to create genetically identical individual embryos (embryo clones), that can subsequently be implanted into surrogate mothers in order to produce populations of genetically identical animals (animal clone) ».

1.3 Other definitions

Paragraph 3 of the text proposed by the Commission provides two other definitions «for the purposes of this Directive…», namely

♦ animals kept and reproduced for farming purposes: «… animals kept and reproduced for the production of food, wool, skin or fur or for other farming purposes. It shall not include animals kept and reproduced exclusively for other purposes such as research, the production of medicinal products and medical devices, the preservation of rare breeds or endangered species, sporting and cultural events»; and

♦ placing on the market: «… means the first making available of an animal or a product on the internal market».

1.4 Legal basis and choice of instrument

In paragraph 3.1 of the Explanatory Memorandum of its 2013 proposal, the Commission stresses that said proposal is based on Article 43 TFEU (agriculture). It also notes that EU agricultural policy objectives are set out in Article 39 TFEU, and that they include the rational development of agricultural production. It goes on to conclude that «this implies ensuring uniform conditions of production for farmers». 40 The Commission also advises that in choosing how to achieve these objectives, it is important to take Article 13 TFEU into consideration. This article requires «… in formulating and implementing of, amongst others, the Union's agriculture policy that the Union and the Member States pay full regard to the welfare requirements of animals since they are sentient beings»41.

40 See also paragraph 3.1 of the Explanatory Memorandum of the Commission’s 2013 Proposal.

41 Ibidem I have used the term “Agri-food Law” in the title of this paper in acknowledgement of the legal basis chosen by the Commission (correctly in my opinion), which will no doubt please those authors who have argued for the existence of a legal discipline different from or at least more comprehensive than Food Law [see for example my friend and colleague ALBISINNI, F.’s chapter “El Derecho alimentario como acicate de innovación del Derecho europeo” in BOURGES, L., Sociologia y Derecho alimentarios, Aranzadi, 2013, 123-126. See also “La Propuesta de la Comisión Europea para simplificar, racionalizar y uniformizar los controles sobre los alimentos”, Rivista di diritto alimentare, No. 2, 2013, p. 18, available in the following Internet page: http://www.rivistadirittoalimentare.it/riposta/2013-02/VAQUE.pdf; and COLLART DUTILLEUL, F., “Éléments pour une introduction au droit agroalimentaire” en Mélanges en l'honneur d'Yves Serra, Dalloz, 2006, 91-99, available in the following Internet page: http://www.droit-aliments-terre.eu/documents/sources_lascaux/articles/pre_2009/2006_FCD_elements_introduction_droit_agroalimentaire.pdf].
Although in general I support Regulations as the means by which to achieve a full harmonisation\textsuperscript{42}, in this case it does seem wise that in order to temporarily prohibit cloning the Commission has instead proposed a Directive\textsuperscript{43}…

2. The limits of a “provisional” prohibition

The arguments in favour of the prohibition of animal cloning for food production purposes are clearly set out in the Explanatory Memorandum of the Commission’s 2013 Proposal:

\begin{itemize}
\item «This initiative responds to the above-mentioned concerns while avoiding unnecessary burdens for farmers and breeders established in the Union and in third countries.
\end{itemize}

The proposal envisages a suspension on Union territory of:

\begin{itemize}
\item the use of the technique for food production purposes;
\item the marketing of live clones (animal clones).
\end{itemize}

These \textit{provisional prohibitions}\textsuperscript{44} will confine a production technique causing distress to animals to areas where it appears to have particular benefit.

The provisional prohibitions are kept under review given the development of knowledge on the technique and progress in the application of the technique in areas outside farming.

This initiative excludes cloning carried out in research, for the preservation of rare breeds or endangered species and for the production of medicinal products and medical devices.»\textsuperscript{45}

\begin{itemize}
\item «The suspension of the cloning technique and the suspension of imports of \textit{live clones}\textsuperscript{46} are suitable and necessary measures to achieve the
\end{itemize}

\textsuperscript{42} This is a position which I have put forward in numerous articles and speeches kindly listed and discussed by BOURGES, L. in “La discutible elección de un nivel de armonización adecuado y eficaz en el ámbito del Derecho del Consumo de la UE: ¿armonización máxima, total o completa?”, Gaceta del InDeAl, Vol. 8, No. 3-4, 2006, 10-12.

\textsuperscript{43} See paragraph 3.4 of the Explanatory Memorandum of the Commission’s 2013 Proposal.

\textsuperscript{44} Emphasis added by the author.

\textsuperscript{45} See paragraph 1.4 (“Consistency with other policies and objectives of the Union”) of the Explanatory Memorandum of the Commission’s 2013 Proposal.

\textsuperscript{46} Emphasis added by the author.
objectives. They also present the best cost-benefit ratio to resolve the issues at stake\textsuperscript{47}.

At its present state of development it appears that the use of the cloning technique for farming purposes is of limited benefit. For this reason, this proposal addresses only those aspects related to animal production for farming purposes. It does not cover other areas where cloning can be justified due to a positive risk-benefit ratio (such as research or the use of reproductive material of clones).

The suspension of the cloning technique and of imports of animal clones for farming purposes thus strikes a reasonable fair balance between animal welfare, citizens’ concerns and the interests of farmers, breeders and other stakeholders involved\textsuperscript{48,}"\textsuperscript{49}

These arguments provides the rationale behind article 3 ("Provisional prohibition"). This is perhaps the most important article in the proposed text,\textsuperscript{50} and it stipulates that

«Member States shall provisionally\textsuperscript{51} prohibit:

(a) the cloning of animals;

(b) the placing on the market of animal clones and embryo clones».

The provisional nature of the measure is confirmed by article 5 ("Reporting and Review"), which provides that no later than five years after the date of transposition of the future Directive, the Member States shall report to the Commission on the experience gained by them during its period of application. For its part, the Commission must submit a report to the European Parliament and Council on the application of the regulation. Their report must cover three key aspects:

• the reports submitted by Member States;

\textsuperscript{47} SWINDELLS, J.A. argues that this line of argument is based on a sui generis application/interpretation of the precautionary principle (see Swindells J.A. op.cit., footnote 2, p. 29). Nevertheless this principle is not mentioned in the Commission’s 2013 Proposal.

\textsuperscript{48} Emphasis added by the author.

\textsuperscript{49} See paragraph 3.1 ("Proportionality principle") of the Explanatory Memorandum of the Commission’s 2013 Proposal. (brevitatis causae, I shall not be dealing here with paragraph 3.2, which covers the Subsidiarity Principle).


\textsuperscript{51} Emphasis added by the author.
• scientific and technical progress, in particular relating to the animal welfare aspects of cloning\textsuperscript{52}; and

• international developments.

3. Other provisions

Article 4 of the proposed text is devoted to “Penalties” - an issue of widely recognised importance. Most notably it provides that Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to the Directive to be adopted and shall take all measures necessary to ensure that they are implemented. Furthermore «the penalties provided for must be effective, proportionate and dissuasive».

There is no need for me to comment separately on Articles 6 (“Transposition”), 7 (“Entering into force”), etc.

V. Conclusions

1. Is everyone opposed?

The arguments put forward in the Commission’s 2013 Proposal suggest an unprecedented level of agreement in Europe on the need to prohibit animal cloning - at least provisionally. Paragraph 1.1 of the Explanatory Memorandum of the Proposal ends by emphasising that «the European Food Safety Authority (EFSA) views cloning primarily as an animal welfare hazard\textsuperscript{53} related to the low efficiency of the technique». It is worth recalling here that in 2012 EFSA updated its opinion on the cloning of animals, stating that although knowledge of cloning had improved, its efficiency nevertheless remained low compared to other reproduction techniques\textsuperscript{54}.

The EFSA also features in subparagraph 2.1.3 (“External expertise”):

« In 2008 the European Food Safety Authority (EFSA) delivered an opinion on cloning. It focused on animal clones, their progeny and of the products obtained from those animals. This opinion was up-dated by three statements in 2009, 2010 and 2012\textsuperscript{55}. Based on the available data EFSA saw

\textsuperscript{52} According to SWINDELLS, J.A. this obligation confirms the relevance of a hypothetical application of the precautionary principle (op.cit., footnote 2, p. 29 and footnote 47).

\textsuperscript{53} Emphasis added by the author.

\textsuperscript{54} Likewise see paragraph 1.1 of the Explanatory Memorandum of the Commission’s 2013 Proposal.

\textsuperscript{55} «Food safety, animal health and welfare and environmental impact of animals derived from cloning by SCNT and their offspring and products obtained from those animals» (opinion and statements): http://www.efsa.europa.eu/en/efsajournal/doc/767.pdf;
animal welfare problems related to the health of surrogate mothers (carrying the clones) and the clones themselves. Surrogate dams suffer in particular from placenta dysfunctions contributing to increased levels of miscarriages. This contributes, amongst others, to the low efficiency of the technique (6-15 % for bovine and 6 % for porcine species) and the need to implant embryo clones into several dams to obtain one clone. In addition, clone abnormalities and unusually large offspring result in difficult births and neonatal death. A high mortality rate is a characteristic of the cloning technique. On the other hand EFSA repeatedly stated that cloning has no impact on the safety of meat and milk obtained from the clones56.

The EFSA’s opinion is included in the second recital of the proposed text:

« The European Food Safety Authority (EFSA) has confirmed that surrogate dams used in cloning suffer in particular from placenta dysfunctions contributing to increased levels of miscarriages. This contributes, amongst other things, to the low efficiency of the technique, 6 to 15 % for bovine and 6 % for porcine species, and the need to implant embryo clones into several dams to obtain one clone. In addition, clone abnormalities and unusually large offspring result in difficult births and neonatal deaths.»

The Explanatory Memorandum also refers to a specific report on cloning by the European Group on Ethics in Science and New Technologies (EGE) of 200857 which expressed doubts that animal cloning for farming purposes can be justified «considering the current level of suffering and health problems of surrogate dams and animal clones». The EGE also concluded that it did «not see convincing arguments to justify the production of food from clones and their offspring»58.

Finally, the “results of consultations with the interested parties and impact assessments” (section 2 of the Explanatory Memorandum) indicate widespread opposition to cloning:

• Member States confirmed that animals are presently not cloned for farming purposes in the Union59;

56 Emphasis added by the author.
58 See subparagraph 2.1.1 (“Consultation methods and main sectors targeted”) of the Explanatory Memorandum of the Commission’s 2013 Proposal.
59 The Standing Committee for the Food Chain and Animal Health was the main forum for discussions with Member States [see the aforementioned subparagraph 2.1.1 of the Explanatory Memorandum of the
• the economic sectors involved (farming and breeding) indicated that they have, at this time, no interest to produce animals for farm purposes though cloning (farmers and breeders however stressed that to remain competitive they need to have access to high performance genes including the reproductive material of clones); and

• «Union citizens […] held a broadly negative perception of the use of the cloning technique for the production of animals for farming purposes».60

2. Europe - forever lagging behind?

Apparently so according to the following observations made by the European Commission:

• Argentina, Australia, Brazil, Canada, and the United States confirmed that animals are cloned on their territory but could not indicate to what extent;

• in Brazil, Canada and United States clones are registered by private companies; and

• «in Canada the legal situation on cloning is similar to that in the Union, i.e. food produced from animal clones is considered novel and requires pre-market approval».61

I shall not discuss here whether the influence of radical ecologists on European public opinion continues being the reason why the EU is behind the rest of the world in the development of sectors of considerable future importance, such as biotechnology. It is however a very topical discussion which cannot be continually ignored62.

3. And… the novel foods?

3.1 I simplify, he simplifies, we simplify…

Commission’s 2013 Proposal which specifies that «in addition all Member States completed a specific questionnaire on cloning on their territory».

60 See subparagraph 2.1.2 (“Summary of responses and how they have been taken into account”) of the Explanatory Memorandum of the Commission’s 2013 Proposal.

61 See also subparagraph 2.1.2 of the Explanatory Memorandum of the Commission’s 2013 Proposal.

62 See SWINDELLS, J.A. op.cit., p. 28, footnote 2.
As noted in the introduction, on the same day as the Commission presented its 2013 Proposal it also presented a “Proposal for a Regulation of the European Parliament and of the Council on novel foods”\textsuperscript{63}. In general terms, it would appear that this proposal aims to simplify current legislation and administrative procedures for both the public and private sectors\textsuperscript{64}, proposing that

«— There is only one centralised procedure for the assessment and authorisation of novel foods. The wording of the proposal has been up-dated and clarified.

– National administrative procedures and duplication of work are removed.

– The authorisation procedure is streamlined, increasing its efficiency and reducing the administrative burden in particular for private parties.

– A simplified procedure for the placing on the market of the traditional foods from third countries is introduced.»\textsuperscript{65}

It is expected that these proposed measures will reduce administrative burden and the length\textsuperscript{66} and cost of the authorisation procedure for the food industry (18 months instead of 3 years in average currently): generic authorisation will avoid the re-submission of new applications by other companies for the same novel food and are expected to benefit in particular SMEs. However, in order to maintain an incentive for developing really innovative food products, a «data protection» regime with the granting of an applicant linked authorisation for a maximum of 5 years will be introduced.

In addition the future Regulation needs to be harmonised with other Community regulations, because current novel food legislation has been in force for over a decade now, during which time there have seen significant technological (and even legal) developments in the areas it covers. To this end the novel foods proposal shares the objectives of the Communication on Smart Regulation in the European Union\textsuperscript{67} and of the Europe 2020 Strategy\textsuperscript{68}, and both brings together and updates the provisions in those regulations which will be repealed when the new

\begin{footnotes}
\item[63] See footnote 9.
\item[64] For a different opinion see FERNÁNDEZ MARILGERA, E., op.cit., pp.26-27, footnote 10.
\item[65] See the first paragraph of section 6 of the Explanatory Memorandum of the document cited in footnote 9.
\item[66] Sic in the second paragraph of section 6 of the Explanatory Memorandum of the document cited in footnote 9.
\end{footnotes}
legislation comes into force. This should in turn should lead to a Regulation being adopted which is consistent in both its terminology and content with the EU’s legal acquis on food matters.

This leads us to article 4 of the Commission’s proposed text - “Procedure for determination of novel food status.” This article appears reasonably straightforward, contemplating as it does a logical set of steps to follow:\textsuperscript{69}:

« 1. Food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation\textsuperscript{70}.

2. Food business operators shall consult a Member State where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation. In that case, food business operators shall provide the necessary information to the Member State on request to enable it to determine in particular the extent to which the food in question was used for human consumption within the Union before 15 May 1997.

3. The Commission may, by means of implementing acts, specify the procedural steps of the consultation process provided for in paragraph 2.

[...]»

\textbf{3.2 Legal basis of the future Regulation}

The legal basis of the “Proposal for a Regulation of the European Parliament and of the Council on novel foods” is article 114 TFEU

\textbf{3.3 Objectives}

According to section 1 of the Explanatory Memorandum of the aforementioned Proposal (“Context of the Proposal”), the objectives are

- to ensure food safety, to protect public health and secure the functioning of the internal market for food, while supporting innovation for the food sector;

- to streamline the authorisation procedure, to improve its efficiency and transparency;

\textsuperscript{69} \textit{Sic} in FERNÁNDEZ MARILGERA, E., op.cit., footnote 10, p. 27.

\textsuperscript{70} In general jurisprudence has considered it positive that business operators should take this first step (see for example ANTOÑANZAS SERRERES, J., "UE: Diferencias y concordancias entre la legislación relativa a la seguridad de los alimentos y la referente a la seguridad general de los productos", Documento de trabajo CEEUDECO nº 3/2013, 11-12).
• to clarify the definition of a novel food, including new technologies which have an impact on food; and

• to introduce a faster and more proportionate safety assessment for traditional foods from third countries having a history of safe food use.

In any case the Commission recognises that «the general criteria for the Novel Food definition remain unchanged: novel foods are foods and food ingredients which were not consumed in the EU to a significant degree before the entry into force (15 May 1997) of the […] Regulation [No 258/97]»72.

In particular, the first two recitals of the proposed text emphasise that

• «the free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, as well as benefitting their social and economic interests»;73;

• «differences between national laws concerning the safety assessment and authorisation of novel foods may hinder the free movement of such food, thereby creating unfair conditions of competition»;74; and

• «a high level of protection of human health and of consumers' interests and the effective functioning of the internal market should be assured in the pursuit of Union food policies, whilst ensuring transparency»75.

3.4 Scope: the definition of novel food

As already noted, following the failure of the Commission's 2008 Proposal it was agreed that farm animal cloning issues ought to be addressed in a separate proposal.

Hence article 1.1 of the Commission’s “Proposal for a Regulation of the European Parliament and of the Council on novel foods” provides that

«This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumer interests».

71 See footnote 7.

72 See the first paragraph of section 1 of the Explanatory Memorandum of the document cited in footnote 9.

73 See the first recital of the text presented in the document cited in footnote 9.

74 Ibidem.

75 See the second recital of the text presented in the document cited in footnote 9.
Despite being perhaps somewhat obvious, it is also worth highlighting that the scope of this provision does not extend to foods covered by the proposed Directive on animal cloning in its provisions for the placing on the market of foods derived from animal cloning.

Like other Community rules regulating the food sector in recent years, Article 2 of the proposed text first notes that «for the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 shall apply»,77. It then defines novel food as «... all food that was not used for human consumption to a significant degree within the Union before 15 May 1997 irrespective of the date of accession of the various Member States to the Union and includes in particular, and specifically

(i) food to which a new production process not used for food production within the Union before 15 May 1997 is applied, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised or the level of undesirable substances;

(ii) food containing or consisting of engineered nanomaterials as defined in Article 2(2)(t) of Regulation (EU) No 1169/2011;

(iii) vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:

76 Footnote 34.

77 See article 2.1 of the document cited in footnote 9, as well as the fifth recital, which confirms that «the existing categories of novel food laid down in Article 1 of Regulation (EC) No 258/97 should be clarified and updated by replacing the existing categories with a reference to the general definition of food provided for in Article 2 of Regulation (EC) No 178/2002... ».

78 Emphasis added by the author (see the sixth recital of the text presented in the Commission’s 2013 Proposal).

79 Engineered nanomaterial is defined in this article as «any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale» (Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22/11/2011, p. 18)). In FERNÁNDEZ MARILGERA, E.’s opinion it is not right in this case to reuse a definition which appears in a horizontal regulation relating to labelling... and she may well be right. op.cit., p. 27, footnote 10.


– a new production process has been applied as referred to in point (i) of this paragraph; or

– such substances contain or consist of "engineered nanomaterials" as defined in Article 2(2)t of Regulation (EU) No 1169/2011;

(iv) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC.83

[Compared with the non-definition or indefiniton84 in article 1 of Regulation No 258/97, this definition is clearly more coherent and accurate, despite its (inevitable?) complexity…].

The “Proposal for a Regulation of the European Parliament and of the Council on novel foods” also defines other concepts which space prevents me from discussing in this perhaps somewhat lengthy article. For example traditional food from a third country85, history of safe food use in a third country86, etc.

4. Final comments

Both the Commission’s 2013 proposal on animal cloning which has been the main subject of this article, and the “Proposal for a Regulation of the European Parliament and of the Council on novel foods” discussed in the final section are without doubt a considerable improvement upon the status quo. However they may cause difficulties when it comes to negotiating the Transatlantic Trade and Investment Partnership. Come what may, the Commission should ensure that even if these restrictive regulations come into force scientific research is not paralysed as a result in either sphere.


83 See article 2.2(a) of the document cited in footnote 9.

84 Sic in FERNÁNDEZ MARILGERA, E., op.cit., p. 27, footnote 10.

85 See article 2.2(b) of the document cited in footnote 9.

86 Ibidem, article 2.2(c).
Upon finishing this article unofficial and unconfirmed news (rumours?) have suggested that the Commission’s 2008 proposal might be withdrawn. This would be unfortunate, as a compromise solution with harmonising effects would be better than continuing with a bureaucratic system which threatens the integrity of the Internal Market.