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COVER NOTE

from:	The House of Commons of the United Kingdom Parliament
date of receipt:	13 February 2014
to:	President of the Council of the European Union
Subject:	Proposal for a Council directive on the placing on the market of food from animal clones [Doc. 18153/13 AGRILEG 181 DENLEG 163 VETER 127 – COM(2013) 893 final] - Opinion [1] on the application of the Principles of Subsidiarity and Proportionality

Delegations will find attached a copy of the abovementioned opinion.

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[1] Translation(s) of the opinion may be available on the Interparliamentary EU Information Exchange site IPEX at the following address: http://www.ipex.eu/IPEXL-WEB/search.do.

HOUSE OF COMMONS

President of the Council of the European Union
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12 February 2014

Dear Mr President

EUROPEAN UNION DOCUMENT NO. 18153/13, A DRAFT COUNCIL DIRECTIVE ON THE PLACING ON THE MARKET OF FOOD FROM ANIMAL CLONES.

On 12 February 2014, the House of Commons of the United Kingdom Parliament resolved as follows:

> That this House considers that the Draft Council Directive on the placing on the market of food from animal clones (European Union Document No. 18153/13) does not comply with the principle of subsidiarity, for the reasons set out in the annex to Chapter One of the Thirty-fifth Report of the European Scrutiny Committee (HC 83-xxxii); and, in accordance with Article 6 of Protocol (No. 2) annexed to the EU Treaties on the application of the principles of subsidiarity and proportionality, instructs the Clerk of the House to forward this reasoned opinion to the Presidents of the European Institutions.

I enclose the relevant extract of the report.

Yours sincerely,

Robert Rogers

Sir Robert Rogers KCB, Clerk of the House of Commons
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Reasoned Opinion of the House of Commons

Submitted to the Presidents of the European Parliament, the Council and the Commission, pursuant to Article 6 of Protocol (No. 2) on the Application of the Principles of Subsidiarity and Proportionality.

concerning

a Draft Directive on the placing on the market of food from animal clones[1]

Treaty framework for appraising compliance with subsidiarity

1. In previous Reasoned Opinions, the House of Commons has set out what it considers to be the correct context in which national parliaments should assess a proposal's compliance with subsidiarity. The House of Commons continues to rely on that context without restating it.

Proposed legislation

Purpose

2. The main objective of the draft Directive, as summarised by the Commission in the explanatory memorandum, is to address consumer perceptions on the use of food from animal clones.[2] This is further explained in Recital (4) to the Directive:

> "The majority of Union citizens disapprove of cloning for food production due to animal welfare and general ethical concerns. They do not want to consume food from animal clones".

3. Recital (6) (but not the explanatory memorandum) to the Directive states how the proposal aims to achieve its main objective (referred to in paragraph 2 above):

> "In order to address consumer perceptions on cloning linked to animal welfare concerns it is necessary to ensure that food from animal clones does not enter the food chain".

4. In addition, Recital (7) states:

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1 COM(13) 893

2 Para 2.1, p.2 of the Commission's explanatory memorandum.

"Animal cloning is allowed in certain third countries. Therefore, measures should be taken to avoid the import into the Union of food obtained from animal clones produced in those third countries".

Legal base

5. The draft Directive is based on Article 352 of the Treaty on the Functioning of the European Union (TFEU) which provides that:

"If action by the Union should prove necessary, within the framework of the policies defined in the Treaties, to attain one of the objectives set out in the Treaties, and the Treaties have not provided the necessary powers, the Council, acting unanimously on a proposal from the Commission and after obtaining the consent of the European Parliament, shall adopt the appropriate measures".

6. In its explanatory memorandum (and Recital (10) to the proposal), the Commission justifies the choice of this Treaty base as follows:

"The Treaty does not provide, for the adoption of this Directive, powers other than those under Article 352. This Directive addresses animal welfare concerns of consumers related to the use of a reproduction technique that has no impact on the safety or quality of the food produced but implies animal suffering. Article 169 TFEU calls the Union to promote the interest of consumers when adopting measures under Article 114 in the context of the completion of the internal market. Under Article 13 TFEU, in formulating and implementing the Union's internal market policy, the Union and the Member States must pay full regard to the welfare requirements of animals since animals are sentient beings. According to an established case-law, the choice of Article 114 TFEU as a legal basis is justified where there are differences between national rules which are such as to hinder the functioning of the internal market. Recourse to that provision is also possible if the aim is to prevent the emergence of such obstacles to trade resulting from the divergent development of national laws. However, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them. In the present case, no current or likely divergence between national legislations was detected. Moreover, during the Conciliation referred to in paragraph 1.1. above, Member States expressed their willingness to see measures on cloning at EU level, but they did not specify which type of national measures they would put in place in the absence of EU initiative."[3]

7. The Commission therefore concludes that reliance on the Article 352 TFEU Treaty base is justified.

8. The House of Commons is aware that there is some academic debate, at least within the UK, as to whether Article 352(2) TFEU, which states that "Using the procedure for monitoring the subsidiarity principle referred to in Article 5(3) of the Treaty on the European Union, the Commission shall draw national Parliaments' attention to proposals based on this Article", provides national Parliaments, within the framework of Protocol (No. 2), with a basis on which

[3] pp.5 and 6 of the explanatory memorandum.

to contest EU competence to adopt the proposal in question rather than simply challenge it on grounds on subsidiarity.[4] Although the House considers that the use of Article 352 TFEU as a legal base for the present proposal is highly doubtful, it does not consider it necessary to rely on this as an extra ground of challenge in this Reasoned Opinion.

Operation

9. In summary, the draft Directive proposes that Member States shall ensure that:

- food from animal clones is not placed on the market;
- that food of animal origin imported from third countries (where it can be legally placed on the market or exported) is only placed on the EU market subject to any specific import conditions (adopted under Regulation (EC) No. 882/2004),[5] thus ensuring no food from animal clones will be exported to the EU from these countries; and
- effective, proportionate and dissuasive penalties are available to enforce these requirements.

Subsidiarity

10. In its explanatory memorandum, the Commission asserts the proposal's compliance with subsidiarity as follows:

> "Isolated Member States measures on food from clones, if adopted, could lead to distortions of the markets concerned. Moreover, the measure concerns import controls. It is thus necessary to ensure that the same conditions apply and thus to address the matter at Union level."[6]

11. In its impact assessment, the Commission justifies EU action as follows:

> "Issues linked to animal cloning relate to the identification and traceability of life animals and of their reproductive material. As live animals, their reproductive materials and derived foods can be freely traded in the Internal Market the issue needs to be addressed at Union level. Isolated national approaches could lead to market distortion."[7]

12. The Commission therefore concludes that the proposal complies with the subsidiarity principle.

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4 See: *The limits of legislative harmonisation ten years after Tobacco Advertising: how the Court's case law has become a drafting guide* (2011) 12 German Law Journal 827 Stephen Wetherill. See also p.92, *Craig and de Burca EU Law*, Fifth Edition, Oxford University Press.

5 Regulation (EC) No. 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

6 Para 3.2, p.6 of the explanatory memorandum.

7 p.24 of the impact assessment.

Aspects of the Directive which do not comply with the principle of subsidiarity

i) Failure to comply with essential procedural requirements

13. By virtue of Article 5 of Protocol (No. 2) "any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality". The requirement for the detailed statement to be within the draft legislative act implies that it should be contained in the Commission's explanatory memorandum, which forms part of the draft legislative act and which, importantly, is translated into all official languages of the EU. The fact that it is translated into all official languages of the EU allows the detailed statement to be appraised for compliance with subsidiarity (and proportionality) in all the national parliaments of Member States of the EU, in conformity with Article 5 of Protocol (No. 2). This is to be contrasted with the Commission's impact assessment, which is not contained within a draft legislative act, and which is not translated into all the official languages of the EU.

14. The presumption in the Treaty on European Union[8] is that decisions should be taken as closely as possible to the EU citizen. A departure from this presumption should not be taken for granted but justified with sufficient detail and clarity that EU citizens and their elected representatives can understand the qualitative and quantitative reasons leading to a conclusion that "a Union objective can be better achieved at union level", as required by Article 5 of Protocol (No. 2). The onus rests on the EU institution which proposes the legislation to satisfy these requirements.

15. For the reasons given below, the House of Commons does not consider that the Commission has provided sufficient qualitative and quantitative substantiation in the explanatory memorandum of the necessity for action at EU level. This omission, the House of Commons submits, is a failure on behalf of the Commission to comply with essential procedural requirements in Article 5 of Protocol (No. 2).

16. The House of Commons further considers that the Commission has failed to comply with Article 5 of Protocol (No. 2) in providing an impact assessment which does not address the present Directive in isolation but also covers the proposed Directive on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes,[9] and conflates them in its statement of their objectives: "to address concerns raised as regards cloning for farm purposes and ensure uniform conditions for farmers in the EU and to protect consumers interests as regard food from cloned animals".[10] Combining its assessment of the two proposals, particularly where the present Directive is based on Article 352 TFEU and requires very careful analysis as to its own compliance with the subsidiarity principle, means that it is difficult for national parliaments to discern which of the qualitative and quantitative factors advanced by the Commission as supporting subsidiarity compliance relates to the present Directive.

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8 Article 5.

9 COM (2013) 892 final.

10 Para 3.1, p.24 of the impact assessment.

ii) Failure to comply with the principle of subsidiarity — necessity

17. The first limb of the subsidiarity test provides that the EU may only act "if and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level".[11]

18. For the following reasons the House of Commons submits that the Commission has not established as part of this test that legislative action at EU level is necessary at all:

(a) The Commission says that food derived from animal clones falls under the scope of the Novel Food Regulation and under "this Regulation food produced by new techniques can only be marketed after specific authorisation. Such pre-market approval must be based on a favourable assessment of the risk for food safety which is to be undertaken by EFSA. No application has ever been submitted for an authorisation to market food produced by means of the cloning technique". [12] This suggests not only that there is the means to tackle the issue of the marketing of food derived from clones, including that imported from third countries, but to date there has been no need to;

(b) The Commission states that "the European Food Safety Authority (EFSA) has concluded that there is no indication of any difference for food safety for meat and milk of clones and their progeny compared with conventionally bred animals".[13] This suggests that there are no risks to human health posed by products derived from clones entering the food chain;

(c) Although the EFSA has identified some risk to animal welfare relating to deaths at birth of clones and to the health of surrogate mothers (the risk of miscarriage and difficult births),[14] these concerns can already be addressed by existing national and EU animal welfare legislation. The Commission says in its impact assessment that Member States may ban explicitly the use of the cloning technique on their territory in accordance with Directive 98/58/EC,[15] since it amounts to a "breeding procedure" which causes "unnecessary pain";

(d) By the Commission's admission there is no cloning for food production taking place within the EU[16] and there is little prospect of commercial cloning activity in the period to 2020, or at least to any significant scale;

(e) The extent to which imports of live animals or animal products from one or more of the five countries where commercial cloning for food production is taking place (the USA, Canada, Argentina, Brazil and Argentina) are derived from or related to clones is unknown because those countries could not confirm the extent to which cloning takes place, there is no requirement (under EU law nor in third countries) to identify them as

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11 See Article 5(3) TEU.

12 Para 1.3, p.3 of the explanatory memorandum.

13 p.2 and para 1.1 of the explanatory memorandum; p.12 of the impact assessment.

14 See footnote 9.

15 Para 2.3, p.13 of the impact assessment.

16 Para 2.1.2, p.4 of the explanatory memorandum and p.20 of the impact assessment.

such and in any event, those imports represent a low percentage compared with EU production; there is therefore no evidence of such food being imported into the EU;[17] and

(f) The Commission says that it is expected that the knowledge on the impact of cloning technique on animal welfare will increase and the cloning technique may improve over time and become more acceptable to consumers.

iii) Failure to comply with the principle of subsidiarity — insufficiency of Member State action

19. The first limb of the test also requires the Commission to prove that the action proposed "cannot be sufficiently achieved by the Member States". The statements of the Commission to the effect that Member State action "could" lead to market distortion are set out in paragraphs 6 and 7 above. Additionally, the Commission says:

> "The growing concern of public opinion in particular about the animal health and welfare issues associated with the use of cloning for food production could push Member States to take measures unilaterally on issues linked to the use of the cloning technique, the use of clones (reproductive material and/or food) and to the labelling of food to inform consumers".[18]

20. The House of Commons considers that the Commission has not satisfied the first limb of the subsidiarity test because its assertions concerning the possibility of divergent national legislation are:

(a) pre-emptive, since, as the Commission concedes, in the absence of current Member State divergent action, there is insufficient likelihood of that to justify the use of Article 114 TFEU as a legal base[19] and that since the 2011 March Conciliation, only Austria has highlighted in writing the need to address cloning at EU level to avoid adoption of diverging national laws[20] and so far only Denmark has adopted legislation prohibiting the practice of animal cloning under Directive 98/58/EC relating to its own national territory (and not the EU);[21] and

(b) speculative as they are based on surveys indicating adverse EU consumer and general public perception of food products derived from clones — such a subjective measure is not a sound basis for regulating and moreover, consumer perception surveys seem to have been accorded precedence over the outcome of other consultation exercises carried out with Member States, third country partners and other stakeholders as the Commission only supplies statistical evidence in respect of the former in its explanatory memorandum.

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17 p.22 of the impact assessment.
18 p.13 of the impact assessment.
19 p.6 of the explanatory memorandum.
20 p.14 of the impact assessment.
21 p.13 of the impact assessment.

iv) Failure to comply with the principle of subsidiarity — action is better achieved at EU level

21. The second limb of the subsidiarity test requires evidence that the objective of the draft Directive would be better achieved, by reason of its scale or effects, by action at EU level. According to the Commission, the benefit of EU-level action would appear to be that of uniformity of approach across the EU to the question of the marketing of food from animal clones, particularly as regards imports to the EU (see paragraphs 10 and 11 above).

22. The House of Commons is not convinced by the Commission's assertion of this benefit of EU-level action, because it relies on weak qualitative and quantitative substantiation as indicated in paragraphs 18–20 above. The House of Commons is also concerned about the potential disadvantages of EU-level action. These include:

(a) the impossibility of enforcing the requirement to trace consignments of cloned animals or material since no records are kept of individual cloning activity and, even if there were, this would not address the issue of such products, if any, already in circulation in the EU;

(b) the imposition of significant regulatory and financial burdens on farmers, food producers and taxpayers arising from any traceability requirement;

(c) jeopardising current bilateral trade negotiations between the EU and both the US and Mercosur since these third countries trade animal products freely without record of whether they derive from clones or not and the current Directive could amount to a trade ban, provoking retaliatory action against the EU and Member States; and

(d) the potential for challenge within the World Trade Organisation should principles set out in the sanitary and phytosanitary agreement be breached.

Conclusion

For these reasons the House of Commons considers this proposal does not comply with the principle of subsidiarity.

1 Animal cloning

(a) (35688) 18152/13 + ADDs 1–2 COM(13) 892	Draft Directive on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes
(b) (35689) 18153/13 COM(13) 893	Draft Council Directive on the placing on the market of food from animal clones

Legal base	(a) Article 43(2) TFEU; co-decision; QMV (b) Article 352(1) TFEU; consent; unanimity
Department	Environment, Food and Rural Affairs
Basis of consideration	Minister's letter of 27 January 2014
Previous Committee Report	HC 83-xxviii (2013-14), chapter 3 (22 January 2014)
Discussion in Council	No date set
Committee's assessment	Legally and politically important
Committee's decision	(a) Not cleared; further information requested (b) Not cleared; recommended debate on the floor of the House on a Reasoned Opinion; further information requested

Background and previous scrutiny

1.1 We set out in full the background to these proposals, a summary of their provisions and the Government's initial view on them in our Thirty-first Report.[1] To recap, the two draft Directives would respectively:

- prohibit the commercial cloning of traditionally farmed species (cattle, sheep, pigs, goats and horses), and the placing on the market of animal clones and embryo clones (document (a)); and
- require Member States to prevent food from animal clones from being placed on the market, and to ensure that food of animal origin imported from third countries where food from clones can be legally placed on the market is only placed on the EU market where it can be established that it does not derive from animal clones (document (b)).

1.2 However, the proposals will allow the continuation of the use of reproductive material from clones for livestock breeding purposes; for scientific research into cloning and its use

1 See headnote.

for the preservation of rare breeds or endangered species; and for sporting or cultural events.

1.3 In summary, the Parliamentary Under Secretary of State at the Department for Environment, Food and Rural Affairs (George Eustice) told us that:

- the absence of any commercial cloning activity in the UK (or EU) at present, means that a ban on the practice will have no direct consequences for UK business;
- from the point of view of subsidiarity, the Government did not believe that either of the proposals is necessary, given the absence of human health concerns associated with cloning (based on the available science, including the view of the European Food Safety Authority) and the protection already offered by the existing EU animal welfare and novel foods regime, but nevertheless considers that if there have to be controls put in place, these must be done consistently at EU level;
- although the proposals aim to address animal welfare concerns related to cloning, the Government believes — and the Commission acknowledges — that the wellbeing of the animals concerned is already generally protected by existing national and EU rules;
- the proposals could affect bilateral trade negotiations between the EU and both the US and Mercosur countries[2] (which already trade animal products freely without traceability) as they could amount to a trade ban;
- the proposals could lead to a challenge within the World Trade Organisation (WTO) should the principles enshrined in the sanitary and phytosanitary agreement be breached;
- the requirement to trace consignments of cloned animals or cloned material would currently be impossible to enforce, place significant regulatory and financial burdens on UK farmers, food producers and taxpayers, and would not address the issue of products already present in the EU;
- he hopes that an EU impact checklist can be made available by the beginning of July; and
- discussions at Council Working Group level are not expected to begin until the end of February with limited progress expected before September 2014 given the intervening elections to the European Parliament and sensitivities surrounding cloning.

1.4 The Minister also commented on some legal issues, namely:

- the proposals may interfere with the fundamental freedom to conduct a business (Article 16 of the Charter) but citing the broad discretion afforded to EU institutions in the *Sky Österreich*[3] judgment and other ECJ cases, he recognised that the Court of Justice would be likely to consider the proposals compatible with the Charter; and

2 Argentina, Brazil, Paraguay, Uruguay and Venezuela.

3 Case C-283/11 *Sky Österreich*, Judgment of 22 January 2013, para 46. See also Case C-348/12P *Kala Naft*, Judgment of 28 November 2013, para 123; Case C-390/12 *Pfleger*, Advocate General's Opinion, para 70.

- as the legal base for document (b) is Article 352(1) TFEU, primary legislation would be required before the UK Government can support or approve the proposal pursuant to section 8 of the European Union Act 2011.

1.5 In our conclusions to that Report, we referred to the previous European Committee debate on the report produced by the Commission in 2010, in which a similar Government view on the policy implications to the one expressed in respect of these proposals was discussed. We therefore did not see any immediate need for further debate at that stage. However, we did request the Minister to respond, before 29 January, to the following three questions:

i) noting that the subsidiarity deadline on both proposals is 17 February, the basis on which the Government could conclude that EU level action was justified if it considered legislative action was not necessary in the first place, a pre-requisite for subsidiarity compliance to be met;

ii) whether the Government had satisfied itself that the legal base of Article 352 TFEU proposed by the Commission in respect of document (b) was justified and the reasons for this; and

iii) whether the Government had considered arguments relating to proportionality in concluding that it was likely that the Court of Justice would not find the proposed legislation incompatible with Article 16 of the Charter of Fundamental Rights.

Minister's letter of 27 January

1.6 We received the Minister's letter on 28 January. In response to the first question the Minister says:

> "We do not see the need for the proposed legislation, because we disagree with the policy objectives (that consumers should be safe in the knowledge that they are not eating food from clones; and that the welfare of the animals concerned needs to be further protected). If however the objectives are ultimately accepted, then they can only realistically be achieved at EU level.
>
> "Whilst the UK currently remains firmly opposed to any further controls on cloning, we are likely to have few if any allies amongst the Commission, European Parliament or other Member States. It is therefore relatively safe to assume that at some point in the future, some new legislation will be ultimately approved, with or without the UK's support. In those circumstances, it is important in our view, that a consistent approach is applied, with the lead being taken by the European Commission. This is particularly critical, given that the controls are also intended to apply to imports.
>
> "In the meantime though, it is important that our negotiating position on the controls themselves remains flexible so that we are able to exert some influence over them and avoid being side-lined in the discussions."

1.7 On the second question regarding the use of Article 352 TFEU, the Minister replies:

> "We are satisfied that the Commission has no express powers within the Treaty to enable it to exercise what it sees as the necessary controls over the placing of food products on the Community market to protect animal welfare (rather than consumer safety or product quality)."

1.8 As to the third question concerning compatibility with the Charter, the Minister tells us that the Government had taken proportionality into account:

> "Our conclusion was based on a balanced assessment of the various considerations, including proportionality. Although we disagree with the need for the proposed legislation, the Commission appear to have restricted their ambitions to seek to control only those elements necessary to deliver their desired level of protection of consumers and the animals involved and have helpfully not been persuaded by the European Parliament's call for significantly more draconian controls, which in our view would be entirely unjustified from a proportionality perspective."

Conclusion

1.9 In the light of the Minister's letter, we have carried out our own further examination of:

i) **whether the Commission has established, in its impact assessment and explanatory memorandum, that the proposals comply with the principle of subsidiarity in accordance with Protocol (No. 2) to the EU Treaties and the subsidiarity principle set out in Article 5(3) TEU; and**

ii) **whether the use of the Article 352(1) TFEU as the legal base for document (b) is legally justified and within the competence of the EU.**

1.10 We have come to the conclusion that, in respect of document (b), the answer to both those questions is no.

1.11 In relation to question (i), we do not consider that the Commission has shown that the proposed legislative action in document (b) is necessary in the first place; that Member State action alone would be insufficient to address the prohibition of the marketing of food derived from animal clones; and that the proposed action would be better achieved at EU level. Our reasoning is set out in full in the attached Reasoned Opinion, which we recommend the House sends to the Presidents of the EU institutions before 17 February 2014, following a debate on the floor of the House.

1.12 Addressing question (ii), we do not agree with the Minister's statement that:

> **"We are satisfied that the Commission has no express powers within the Treaty to enable it to exercise what it sees as the necessary controls over the placing of food products on the Community market to protect animal welfare (rather than consumer safety or product quality)."**

Firstly, it is a condition for the use of Article 352 that the action "by the Union [...] should prove necessary". We have set out in the attached Reasoned Opinion why we consider the EU action proposed in document (b) is not necessary. Secondly, the

Commission concedes that the objective of document (b) is not to protect animal welfare (as the facility already exists for this at EU level in existing legislation) but to address adverse consumer perceptions of food derived from animal clones. This objective must be, in the words of Article 352 "one of the objectives set out in the Treaties". We doubt this to be the case.

1.13 Before the debate takes place on the Reasoned Opinion, we would be grateful if the Minister could write to us with a detailed legal analysis setting out why the Government thinks that Article 352 TFEU is a sound legal base for document (b), whereas we, on the other hand, think it amounts to EU competence creep. Nor do we take lightly the use of Parliamentary time to approve such a proposal by primary legislation pursuant to section 8 of the European Union Act 2011. We bear in mind that the Government has a veto over the adoption of document (b). If the Minister does not persuade us that the use of Article 352 TFEU is legitimate, we consider the issue to be of sufficient importance that we will invite him to give oral evidence before us.