

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 clones¹

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:

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.

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 Union⁸ 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.

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 EU¹⁶ 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

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 base¹⁹ 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 laws²⁰ 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.

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.