EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2013)

Opinion

Title

DG SANCO - Impact Assessment on an EU initiative on a cloning of animals for food production

(draft version of 19 June 2013) *

(A) Context

Cloning is a relatively new breeding technique which allows, without any genetic modification, the asexual reproduction of an individual farm animal that has shown good productivity. Clones' offspring and descendants (produced via traditional breeding techniques) are destined for direct use in the food chain, e.g. for meat or milk production. Clones, instead, are primarily produced to obtain reproductive material. However, they could be used to obtain meat or milk directly. In this case, food from clones is subject to a pre-market approval in the EU under the existing Novel Food Regulation. A revision of this Regulation reached a stalemate in inter-institutional discussions because of wider issues related to cloning. Conciliation ended unsuccessfully in March 2011 leading to request to the Commission to prepare a separate legislative proposal on all aspects of cloning for food production based on a detailed impact assessment. The scope of this impact assessment is limited to species raised for food production and susceptible to be cloned (bovine, porcine, caprine, ovine and equine). Cloning of animals for research purposes, for producing medicinal products, for preserving endangered species or for sport purposes is excluded from this policy initiative.

(B) Overall opinion: POSITIVE

The report needs to be improved in a number of respects. It should better explain the uncertainty in interpreting the existing regulatory framework as regards the use of the cloning technique in the EU and its potential circumvention. It should also provide more insights into the consumer concerns about cloning of animals. In this context, the report should explain why measures to improve consumer awareness or to upgrade the existing voluntary (organic) label schemes have not been considered. The impact analysis should be further enhanced, namely with respect to impacts on third country and EU operators, consumer prices and choice. In particular, the report should clarify why it is assumed that the impact of mandatory 'positive' labelling of food from offspring could be considered to be marginal for the EU, despite the fact that it is likely to result in a de facto ban of such food. Furthermore, it should identify which Member States will be impacted most and clarify why national authorities are not expected to bear any additional costs. Finally, the report should present all the key results (in qualitative as well as quantitative terms) in a clear and comprehensive overview comparison table.

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted.

Commission européenne, B-1049 Bruxelles - Belgium. Office: BERL 6/29. E-mail: impact-assessment-board@ec.europa.eu

(C) Main recommendations for improvements

(1) Strengthen the problem definition and the baseline scenario. The report should better explain the uncertainty related to the interpretation of the Directive 98/58/EC (on animal welfare) as regards the ban on the cloning technique in the EU. It should also explain how this ban could be circumvented and corroborate this with evidence, if any. It should indicate the likelihood (and legal feasibility) of national measures unilaterally regulating the import of cloned animals, their reproductive material or food. The report should better explain why the existing pre-market approval under the Novel Food Regulation can still be considered as fit for purpose, even though there does not seem to be any food safety concern about meat and milk from clones from bovine and porcine (according to the scientific opinion of the European Food Safety Authority). As regards consumer concerns, it should clarify if there is any evidence that consumer confidence in meat or milk and derived products is currently undermined by the lack of information on cloning. In this context, the report should better explain what the most important drivers of consumer concerns are. Furthermore, it should better explain to what extent consumers might be willing to pay for the required information (reflecting the impact of mandatory labelling measures on the EU production prices). Finally, the report should better explain why the food business operators have not developed any voluntary labelling schemes so far, despite the apparent strong consumer concerns and the fact that it would seem to be already feasible (on request) to identify reproductive materials in major importing countries as being derived from a clone.

(2) Better explain the options. The report should clarify the rationale for the options and explain how exactly they differ from the baseline scenario. In particular, it should clarify: (i) the proportionality of option 2 (i.e. extending the current pre-market approval of food from clones to food from offspring and descendants); and (ii) how the "labelling of food from clones" and the "suspension of the cloning technique" differ from the status quo. Furthermore, given that the provisions related to mandatory vs. voluntary labelling differ substantially in their form as well as the level of ambition, the report should present them as separate policy options, with a clear explanation of how they would be implemented in practice. Similarly, measures on offspring vs descendants of clones should be presented and assessed separately. In addition, the report should justify why measures to improve consumer awareness have not been considered, despite the fact that they could address at least some consumer concerns. Finally, it should clarify why it has not considered a revision of the existing voluntary organic scheme which already excludes cloning as a technique but does not, for example, exclude using the reproductive material of a clone (while giving consumers the choice and allowing the business operators to recover the extra costs).

(3) Better assess and present impacts. The report should present a more comprehensive impact analysis for each of the policy options, particularly as regards impacts on third country and EU operators, consumer prices and choice. First of all, it should clarify the readiness of third countries to put in place the identification and traceability systems and, on that basis, justify why the impact of mandatory 'positive' labelling of food from offspring could be considered marginal for the EU (despite the fact that this would result in a de facto ban – with the possible exception of the catering sector or for further processing). Secondly, the report should revisit the assessment of traceability costs for EU operators and better explain under which circumstances and by whom these costs would be borne (for example, the report currently suggests that the cost for segregating the food supply chain would be marginal, which seems to be counterintuitive). Overall, the report should provide a more conclusive assessment of competitiveness impacts, clearly differentiating between

the impact on EU farmers, importers of food and the food chain industry operators (as appropriate). In doing so, it should identify those Member States that will be impacted most (e.g. because of their higher reliance on imports of reproductive material or meat and milk from countries with commercial cloning activity). Thirdly, the report should refer to and explain how exactly the 2% price increase for the beef sector has been calculated (in the underlying study of the Commission's Joint Research Centre). Furthermore, it should better present and assess the impacts on EU imports and consumer choice, duly reflecting the fact that not all imported products (i.e. raw food of animal origin – meat and/or milk) could be substituted by EU farmers/producers. Fourthly, the report should justify why national authorities are not expected to bear any additional costs and indicate the magnitude of additional costs to be borne by the EU budget (i.e. controls in third countries by the Food and Veterinary Office). Finally, the key results (in qualitative as well as quantitative terms) should be presented in a clear and comprehensive overview comparison table. In addition, and given that none of the options would on its own address all of the objectives, the report could also consider identifying possible combinations of individual measures, minimising the trade-offs between the positive and negative impacts.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report

(D) Procedure and presentation

While the views of stakeholders seem to be rather well known, the report should provide further insights into consumers' views as well as the reactions of individual Member States and third countries. It should avoid presenting overall percentages of consultation replies and accompany the results of public consultation with a summary of the targeted consultation. The report should define monitoring indicators that would correspond to the envisaged data collection, relate them to the identified policy objectives and indicate the benchmarks against which progress would be measured. The summary as well as the 'executive summary sheet' should be completed in order to provide the most relevant information (in particular as regards the inherent trade-offs and the key impacts in qualitative as well as quantitative terms).

(E) IAB scrutiny process	
Reference number	2013/SANCO/007
External expertise used	No
Date of IAB meeting	17 July 2013